



PMI RESEARCH & DEVELOPMENT

THS Additional Safety Data Report

Tobacco Heating System / iQOS

Appendix 5 Pre-marketing Cumulative Line Listings THS Menthol Products

Report Number: PMI_SURV_2016_SSR03

Sponsor: Philip Morris Products S.A.
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**CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016**

Advanced Condition used in this report:

Advanced Condition: Pre-Marketing Studies All THS Menthol (Created by nicole.miller)

Query Set Selection Criteria:

Report From Study/Other Studies INTERSECT

Ingredients All THS Menthol MINUS

Minus Cases PMI000137 & PMI000150

Advanced Conditions used in this query set:

Advanced Condition: Report From Study/Other Studies (Created by nicole.miller)

Selection Criteria:

(Case Report Type equal to Report From Study AND

Observe Study Type equal to Other Studies)

Advanced Condition: Ingredients All THS Menthol (Created by nicole.miller)

Selection Criteria:

Ingredient equal to Mint Veronica OR

Ingredient equal to Vinny/Ron (half white tipping paper) OR

Ingredient equal to D1 Vinny Low Menthol

Advanced Condition: Minus Cases PMI000137 & PMI000150 (Created by nicole.miller)

Selection Criteria:

Case Number equal to PMI000137 OR

Case Number equal to PMI000150

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No (89)							
PMI000005	ITALY Report From Study	45 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK]	Respiratory		the smell sometimes is unpleasant [PRODUCT ODOUR ABNORMAL] N / Y / Y the menthol taste makes me cough [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 04-Dec-2014 Case Narrative: Verbatim: The menthol taste makes me cough. The smell sometimes is unpleasant.</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 45-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the menthol taste makes her cough. The smell sometimes is unpleasant. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000011	ITALY Report From Study	25 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK]	Respiratory		the menthol taste of the tobacco gave me throatache [OROPHARYNGEAL PAIN] N / N / Y Smoking is uncomfortable / the device is not comfortable to keep in hand [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 04-Dec-2014 Case Narrative: Verbatim: The menthol taste of the tobacco gave me throatache; smoking is uncomfortable, the device is not comfortable to keep in hand.</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 25-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p>							

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the menthol taste of the tobacco gave her throat ache. In addition the respondent stated that smoking is uncomfortable. The device is not comfort hand and you cannot smoke indoors. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000019	ITALY Report From Study	45 Years Female	THS 2.2 Menthol (Vinny / Respiratory Ron) / N/A UNK [UNK] Case Initial Receipt Date: 07-Jan-2015 Case Narrative: Verbatim: I prefer my classic cigarettes. They have a better taste and stay lit until the end, and they did not give me throat ache			Throat ache [OROPHARYNGEAL PAIN] N / N / Y	Unknown
<p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 07-JAN-2015 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 45-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she preferred her classic cigarettes, they had a better taste and they stayed lit until the end and they did not give her throat ache. The event considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000021	SWITZERLAND Report From Study	54 Years Female	THS 2.2 Menthol (Vinny / Respiratory Ron) / N/A UNK [UNK] Case Initial Receipt Date: 31-Oct-2014 Case Narrative: Verbatim: In the beginning I had to cough, later better			in the beginning I had to cough, later better [COUGH] N / N / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 31-OCT-2014 and transferred to safety department on 18-MAR-2015:</p>							

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 54-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that in the beginning she had to cough, later it was better. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000023	SWITZERLAND Report From Study	53 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK]				smoky-scratchy taste in the throat [DYSGEUSIA] N / Y / Y I was coughing [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 31-Oct-2014 Case Narrative: Verbatim: I was coughing, smoky-scratchy taste in the throat</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 31-OCT-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 53-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she was coughing and had a smoky-scratchy taste in the throat. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000027	SWITZERLAND Report From Study	23 Years Male	THS 2.2 Menthol (Vinny / Respiratory Ron) / N/A UNK [UNK]			I exercise and have more energy by using the Heat Sticks [ENERGY INCREASED] N / Y / Y	Unknown
Case Initial Receipt Date: 15-Nov-2014 Case Narrative: Verbatim: I exercise and have more energy by using the Heat Sticks Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 23-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date. The respondent stated that he exercises and has more energy by using the Heat Sticks. The event was considered to be non-serious (intensity not provided). In addition, the also mentioned that one gets used to the menthol taste, and it settles not as badly in the lungs. Action taken with the product was not reported. At the time of reporting, the outcome of the event was unknown. No follow-up information is expected ? case closed.							
PMI000030	SWITZERLAND Report From Study	29 Years Female	THS 2.2 Menthol (Vinny / Respiratory Ron) / N/A UNK [UNK]			I got a very strong cough [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 15-Nov-2014 Case Narrative: Verbatim: I got a very strong cough. Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 29-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date. The respondent stated that she got a very strong cough. The event was considered to be non-serious (intensity not provided). Action taken with the product was not reported.							

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
At the time of reporting, the outcome of the event was unknown.								
No follow-up information is expected ? case closed.								
PMI000033	SWITZERLAND Report From Study	26 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK]	Respiratory			I had to cough [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 15-Nov-2014								
Case Narrative: Verbatim: Had to cough.								
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.								
INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:								
This report concerns a 26-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.								
No medical conditions and concomitant medications were reported.								
No information was provided on the use of conventional cigarettes.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.								
The respondent stated that she had to cough. The event was considered to be non-serious (intensity not provided).								
Action taken with the product was not reported.								
At the time of reporting, the outcome of the event was unknown.								
No follow-up information is expected ? case closed.								
PMI000038	SWITZERLAND Report From Study	59 Years Male	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK]	Respiratory			throat-ache [OROPHARYNGEAL PAIN] N / N / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014								
Case Narrative: Verbatim: throat-ache.								
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.								
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:								
This report concerns a 59-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.								
No medical conditions and concomitant medications were reported.								
No information was provided on the use of conventional cigarettes.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.								
The respondent reported throat ache. The event was considered to be non-serious (intensity not provided). In addition, the respondent mentioned a better taste (no further i								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
			provided).					
			Action taken with the product was not reported.					
			At the time of reporting, the outcome of the event was unknown.					
			No follow-up information is expected ? case closed.					
PMI000039	SWITZERLAND Report From Study	49 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: it gives me headache.	Respiratory			it gives me headache [HEADACHE] N / N / Y	Unknown
			Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.					
			INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:					
			This report concerns a 49-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.					
			No medical conditions and concomitant medications were reported.					
			No information was provided on the use of conventional cigarettes.					
			The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.					
			The respondent stated that it gives her headache. The event was considered to be non-serious (intensity not provided). In addition, the respondent mentioned that as she does much, it is not convenient re-charge each time.					
			Action taken with the product was not reported.					
			At the time of reporting, the outcome of the event was unknown.					
			No follow-up information is expected ? case closed.					
PMI000048	SWITZERLAND Report From Study	59 Years Male	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: Coughing with HeatSticks.	Respiratory			coughing with heatsticks [COUGH] N / N / Y	Unknown
			Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.					
			INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:					
			This report concerns a 59-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.					
			No medical conditions and concomitant medications were reported.					

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported coughing with heatsticks. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000054	SWITZERLAND Report From Study	39 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A Respiratory UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: the taste is more enjoyable and I was coughing less.			I was coughing less [COUGH] N / N / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 39-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the taste was more enjoyable and she was coughing less. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000055	SWITZERLAND Report From Study	22 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A Respiratory UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: the taste scratches my throat a bit too strongly			The taste scratches my throat a bit too strongly [THROAT IRRITATION] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 22-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p>							

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the taste scratches her throat a bit too strongly. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000057	SWITZERLAND Report From Study	48 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK]	Respiratory			even headache [HEADACHE] N / N / Y the heat stick tastes too bitter, burned taste [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: the heat stick tastes too bitter, burned taste, even headache.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 48-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the heat stick tastes too bitter, burned taste. The respondent also reported "even headache" . The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								

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Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000062	SWITZERLAND Report From Study	53 Years Male	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: I got sick from the menthol cigarettes.	Respiratory		I got sick from the menthol cigarettes [MALAISE] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 53-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that he got sick from the menthol cigarettes. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000065	SWITZERLAND Report From Study	30 Years Male	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: the menthol taste suits me but not what stays in the throat after.	Respiratory		The menthol taste suits me but not what stays in the throat after [DYSGEUSIA] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 30-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the menthol taste suits him but not what stays in the throat after. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p>							

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information is expected ? case closed.							
PMI000066	SWITZERLAND Report From Study	43 Years Female	THS 2.2 Menthol (Vinny / Respiratory Ron) / N/A UNK [UNK]			caused nausea with me [NAUSEA] N / N / Y smells very unpleasent and bitter [PRODUCT ODOUR ABNORMAL] N / Y / N	Unknown
Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: Smells very unpleasant and bitter. Caused nausea with me. Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 43-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date. The respondent stated that the smell was very unpleasant and bitter and it caused nausea to her. The events were considered to be non-serious (intensity not provided). Action taken with the product was not reported. At the time of reporting, the outcome of the event was unknown. No follow-up information is expected ? case closed.							
PMI000070	SWITZERLAND Report From Study	34 Years Female	THS 2.2 Menthol (Vinny / Respiratory Ron) / N/A UNK [UNK]			was irritating the throat [THROAT IRRITATION] N / Y / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: was irritating the throat. Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 34-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent stated that it was irritating the throat. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000072	SWITZERLAND Report From Study	28 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: stays in the back of the throat even after drinking or eating	Respiratory		stays in the back of the hroat even after drinking or eating [DYSGEUSIA] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 28-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it stays in the back of the throat even after drinking or eating. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000073	SWITZERLAND Report From Study	63 Years Male	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: too dense, and it itches the tongue after some cigarettes smoked.	Respiratory		too dense, it itches the tongue after several cigarettes smoked [TONGUE PRURITUS] N / Y / Y too dense, it itches the tongue after several cigarettes smoked [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 63-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p>							

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it is too dense, and it itches the tongue after some cigarettes smoked. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000078	SWITZERLAND Report From Study	35 Years Male	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK]		13-NOV-2014	<p>The menthol taste made me sick. Too much refreshment. [MALAISE] N / Y / Y It stings [ORAL PAIN] N / Y / Y no more strength in the right leg for a few seconds up to 20 imes a day [MUSCULAR WEAKNESS] N / Y / Y These cigarettes had a bad influence on my head. Head: light. [DIZZINESS] N / N / Y</p>	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: The menthol taste made me sick. Too much refreshment. The cleaning brush is not easy to unpack. These cigarettes had a bad influence on my head. Head: light. It s (around 13. November) and no more strength in the right leg for a few seconds up to 20 times a day.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 35-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the menthol taste made him sick. Too much refreshment. These cigarettes had a bad influence on his head. Head: light. The respondent also mention stings (around 13 November) and no more strength in the right leg for a few seconds up to 20 times a day. The events were considered to be non-serious (intensity not provid addition, the respondent mentioned that the cleaning brush is not easy to unpack.</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p>							

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information is expected ? case closed.							
PMI000079	SWITZERLAND Report From Study	41 Years Female	THS 2.2 Menthol (Vinny / Respiratory Ron) / N/A UNK [UNK]			the smoking feels extremely unhealthy [MALAISE] N / Y / Y the holder is too hot [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: The burnt stick, the balancing of the holder, the holder is too hot, the smoking feels extremely unhealthy. Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 41-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date. The respondent stated that the smoking feels extremely unhealthy and the holder is too hot. The events were considered to be non-serious (intensity not provided). In addition, the respondent mentioned the burnt stick and the balancing of the holder (no additional information provided). Action taken with the product was not reported. At the time of reporting, the outcome of the events was unknown. No follow-up information is expected ? case closed.							
PMI000086	SWITZERLAND Report From Study	59 Years Male	THS 2.2 Menthol (Vinny / Respiratory Ron) / N/A UNK [UNK]			have to cough [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: have to cough, resolves during a break. Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 59-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date. The respondent stated that he had to cough, it resolves during a break. The event was considered to be non-serious (intensity not provided).							

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000087	SWITZERLAND Report From Study	26 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: Pain.	Respiratory		pain [PAIN] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 26-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported pain (not further specified). The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000095	SWITZERLAND Report From Study	59 Years Male	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: problems with throat and coughing too bitter.	Respiratory		problems with throat [THROAT IRRITATION] N / Y / Y Coughing [COUGH] N / N / Y too bitter [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 59-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p>							

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported problems with throat and coughing as well as too bitter. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000097	SWITZERLAND Report From Study	59 Years Male	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK]	Respiratory		have to cough [COUGH] N / N / Y s inks [PRODUCT ODOUR ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: stinks, have to cough.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 59-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it stinks and he has to cough. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000098	SWITZERLAND Report From Study	22 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK]	Respiratory		itches in the throat [THROAT IRRITATION] N / Y / Y makes me cough [COUGH] N / N / Y too strong in mouth [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p>							

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: too strong in the mouth, itches in the throat and makes me cough.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 22-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it is too strong in the mouth, itches in the throat and makes her cough. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000100	KOREA, REPUBLIC OF Report From Study	54 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [1 -UNK]	Respiratory	10-APR-2015 to 12-APR-2015	10-APR-2015 10-APR-2015	I am not sure if it is because of the bitter taste of HeatSticks, but since I started using the product, the dizziness has lingered uncomfortably and is gone after 30 to 40 minutes. [DIZZINESS] N / N / Y I am not sure if it is because of the bitter taste of HeatSticks, but since I started using the product, the dizziness has lingered uncomfortably and is gone after 30 to 40 minutes. [PRODUCT TASTE ABNORMAL] N / Y / N	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 13-Apr-2015</p> <p>Event Intensity: Mild</p> <p>Case Narrative: Verbatim: I am not sure if it is because of the bitter taste of HeatSticks, but since I started using the product, the dizziness has lingered uncomfortably and is gone after</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 13-Apr-2015:</p> <p>This report concerns a 54-year-old male subject (Respondent Study ID: 1220779) who took part in the above mentioned market research study.</p> <p>No medical history was reported. 'Hepatitis drug' (not further specified) was reported as concomitant medication.</p> <p>The respondent was a daily smoker (10-15 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number C9h FW15 RH5 6N4) on 10-Apr-2015 and used the product occasionally.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>On the same day (10-Apr-2015), the respondent experienced dizziness. He reported that he was not sure if it was because of the bitter taste of HeatSticks, but since he started using the product, the dizziness had lingered uncomfortably and was gone after 30 to 40 minutes. The events were considered to be non-serious. Severity criterion was reported as mild.</p> <p>On the day of the event, the respondent used one Heatstick and smoked 10 conventional cigarettes.</p> <p>The use of the product was discontinued on 12-Apr-2015.</p> <p>It was reported that the problem improved when usage of the product was stopped, and that the product was not restarted.</p> <p>However, at the time of reporting, the outcome of the events was reported as not recovered.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000102	KOREA, REPUBLIC OF Report From Study	46 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	16-APR-2015 to Unknown	16-APR-2015 16-APR-2015	After taking it, the throat was unpleasant, dry, not soft, and harsh [DRY THROAT] N / Y / Y After taking it, the throat was unpleasant, dry, not soft, and harsh [THROAT IRRITATION] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 16-Apr-2015 Case Narrative: Verbatim: After taking it, the throat was unpleasant, dry, not soft, and harsh.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 16-Apr-2015: This report concerns a 46-year-old male subject (Respondent Study ID: 1178724) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average, 15 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number provided: TEST) on 16-Apr-2015.</p> <p>The respondent stated that on the same day (16-Apr-2015), after taking it, the throat was unpleasant, dry, not soft, and harsh. The events were considered to be non-serious. Severity criterion was not provided.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000104	KOREA, REPUBLIC OF Report From Study	35 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	10-APR-2015 to Unknown	10-APR-2015	It is because he hasn' t smoked but started smoking all of a sudden [UNEVALUABLE EVENT] N / Y / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 10-Apr-2015 Event Stop Date: 10-APR-2015 Case Narrative: Verbatim: It is because he hasn' t smoked but started smoking all of a sudden.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 10-Apr-2015: This report concerns a 35-year-old male subject (Respondent Study ID: 1101949) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number not provided) on 10-Apr-2015.</p> <p>On the same day (10-Apr-2015), it was reported that it was the respondent's first cigarette usage of the day and 'It is because he hasn' t smoked but started smoking all of The event was considered to be non-serious. Severity criterion not reported.</p> <p>It was reported that the problem improved when usage of the product was stopped.</p> <p>Action taken with the use of he product was not reported.</p> <p>The event resolved on the same day.</p> <p>Additional information is expected.</p>								
PMI000106	KOREA, REPUBLIC OF Report From Study	41 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory			Felt dizzy after smoking HeatStick [DIZZINESS] N / N / Y Headache [HEADACHE] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 20-Apr-2015 Case Narrative: Verbatim: felt dizzy after smoking HeatStick. (headache)</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 20-Apr-2015: This report concerns a 41-year-old male subject (Respondent Study ID: 1157274) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number KXZ CYJ FAX F4Y) on an unspecified date.</p> <p>On an unspecified date, just after taking the product, the respondent experienced dizziness after smoking the HeatStick and headache. The events were considered to be non-s</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
severity of the adverse events was not reported.								
Action taken with use of the product was not reported.								
At the time of reporting, the events were resolved.								
No follow-up information is expected ? case closed.								
PMI000110	KOREA, REPUBLIC OF Report From Study	47 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	25-APR-2015 to Unknown	25-APR-2015	Cough in inhalation [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 25-Apr-2015								
Case Narrative: Verbatim: After taking a testing product, said "cough in inhalation" in the middle of CLT (added) and also said "(the cough) may not result from this product, it' s comm cough in smoking with cig vaporizer pen as its smoke flows in suddenly for the first puff."								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 25-Apr-2015:								
This report concerns a 47-year-old male subject (Respondent Study ID: 2353530) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
No information on smoking habits was provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number TFQF IJQ 53D OMA8) on 25-Apr-2015.								
On the first day of use (25-Apr-2015), the respondent experienced cough in inhalation. The respondent mentioned that the cough might not result from this product. The event considered to be non-serious. The severity of the adverse event was not reported.								
Action taken with use of the product was not reported.								
At the time of reporting, the outcome of the event was not reported.								
No follow-up information is expected ? case closed.								
PMI000117	KOREA, REPUBLIC OF Report From Study	44 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	22-APR-2015 to Unknown	23-APR-2015 23-APR-2015	Throat is hurting [OROPHARYNGEAL PAIN] N / N / Y Has a little cold symptom [NASOPHARYNGITIS] N / N / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 28-Apr-2015								
Case Narrative: Verbatim: throat is hurting (has a little cold symptoms).								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 28-APR-2015:								
This report concerns a 44-year-old male subject (Respondent Study ID: 1467535) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information on smoking habits was provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number 60B-VWQ-6ZQ-8ET) on 22-Apr-2015.</p> <p>On the next day (23-Apr-2015), the respondent experienced hurting throat and had a little cold symptoms. The events were considered to be non-serious. Severity of the adverse events was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000133	KOREA, REPUBLIC OF Report From Study	47 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	04-MAY-2015 to Unknown	04-MAY-2015 04-MAY-2015	Feels stomach ache and headache [ABDOMINAL PAIN UPPER] N / Y / Y Feels stomach ache and headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 06-May-2015</p> <p>Case Narrative: Verbatim: feels stomach ache and headache.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 06-May-2015:</p> <p>This report concerns a 47-year-old male subject (Respondent Study ID: 2365564) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was reported.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number HC5 166 FNO PW5) on 04-May-2015.</p> <p>On the same day (04-May-2015), the respondent felt stomach ache and headache. The events were considered to be non-serious. Severity of the adverse events was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the events was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000138	KOREA, REPUBLIC OF Report From Study	34 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	25-APR-2015 to Unknown	06-MAY-2015	Feels a twinge in inhaling because parts of gums (which had been treated before) become tightened [GINGIVAL PAIN] N / Y / Y	Not Recovered/Not Resolved
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	25-APR-2015 to Unknown			
Case Initial Receipt Date: 11-May-2015 Event Intensity: Moderate Case Narrative: Verbatim: feels a twinge in inhaling because parts of gums (which had been treated before) become tightened. Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 11-May-2015: This report concerns a 34-year-old male subject (Respondent Study ID: 1463540) who took part in the above mentioned market research study. No concurrent medical history and no concomitant medications were reported. The respondent had a dental treatment for tooth decay the previous year. The respondent was a daily smoker (in average 20 cigarettes per day). The respondent started using both products, Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and THS 2.2 Menthol (Dorado I / Vinny low menthol) on 25-Apr-2015 (Kit WTL HUQ NCE PQL, not specified to which product it corresponds). On 06-May-2015, the respondent felt a twinge in inhaling because parts of gums (which had been treated before) became tightened. The respondent clarified that the pain lasted minutes and that he had no symptom when smoking regular cigarettes. The event was considered to be non-serious. Severity of the adverse event was reported as moderate. The product was used on weekdays, not on weekends. The use of the product was not discontinued due to the occurrence of the adverse event. It was reported that the event re when product was restarted. At the time of reporting, the event was not resolved. No follow-up information is expected ? case closed.								
PMI000139	KOREA, REPUBLIC OF Report From Study	31 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory		06-MAY-2015	Pains and uneasy on throat when smoking in connecting with HeatStick; throat gets uncomfortable [LARYNGEAL DISCOMFORT] N / Y / Y	Unknown
						06-MAY-2015	Pains and uneasy on throat when smoking in connecting with HeatStick; throat gets uncomfortable [OROPHARYNGEAL PAIN] N / N / Y	
Case Initial Receipt Date: 12-May-2015 Case Narrative: Verbatim: feels pains and uneasy on throat when smoking in connecting with HeatStick. My throat gets uncomfortable. Market Research Study P1_WOT1_KO: Whole Offer Test – Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 12-May-2015: This report concerns a 31-year-old male subject (Respondent Study ID: 1253432) who took part in the above mentioned market research study.								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number F6M U6R KB1 LAH) on an unspecified date.</p> <p>On 06-May-2015, the respondent experienced pain and uneasy feeling on the throat. The event was also described as throat getting uncomfortable and occurred when smoking "i connecting" with the HeatStick (presumably, when HeatSticks and conventional cigarettes are used together). The event was considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000140	KOREA, REPUBLIC OF Report From Study	37 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	15-APR-2015 to Unknown	25-APR-2015	My throat gets swollen. The phlegm comes out a lot. My throat gets swollen after using HeatStick altogether in the evening. [PHARYNGEAL OEDEMA] N / Y / Y	Not Recovered/Not Resolved
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	15-APR-2015 to Unknown	25-APR-2015	My throat gets swollen. The phlegm comes out a lot. My throat gets swollen after using HeatStick altogether in the evening. [PRODUCTIVE COUGH] N / Y / Y	
<p>Case Initial Receipt Date: 14-May-2015</p> <p>Event Intensity: Mild</p> <p>Case Narrative: Verbatim: My throat gets swollen. The phlegm comes out a lot. My throat gets swollen after using HeatStick altogether in the evening.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 14-May-2015: This report concerns a 37-year-old male subject (Respondent Study ID: 1218229) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using both products, the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number VXF KQM TGO, not specified to which product it corresponds) on 15-Apr-2015.</p> <p>On 25-Apr-2015, the respondent experienced swelling of throat after using HeatSticks altogether in the evening and phlegm coming out a lot. The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>It was reported that the events improved after product use was stopped and that the events returned when product was restarted.</p> <p>Action taken with the use of the product was unknown.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
At the time of reporting, the events were not resolved.								
No follow-up information is expected ? case closed.								
PMI000151	KOREA, REPUBLIC OF Report From Study	45 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	22-APR-2015 to Unknown	22-APR-2015	Dizzy when using the product with an empty stomach [DIZZINESS] N / N / Y	Unknown
Case Initial Receipt Date: 21-May-2015								
Case Narrative: Verbatim: Feels dizzy when using the product with an empty stomach.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 21-May-2015:								
This report concerns a 45-year-old male subject (Respondent Study ID: 2354647) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
Information on smoking habits was not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit B9S EHS VEE KB5) on 22-Apr-2015.								
On the same day (22-Apr-2015), the respondent felt dizzy when using the product with an empty stomach. The event was considered to be non-serious. Severity of the adverse e not reported.								
Action taken with the use of the product was not reported.								
At the time of reporting, the outcome of the event was not reported.								
No follow-up information is expected ? case closed.								
PMI000156	KOREA, REPUBLIC OF Report From Study	42 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	23-APR-2015 to Unknown	23-APR-2015	Feels hot when putting the product (HeatStick) in the mouth to use. [FEELING HOT] N / Y / Y	Unknown
Case Initial Receipt Date: 22-May-2015								
Case Narrative: Verbatim: Feels hot when putting the product (HeatStick) in the mouth to use.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 22-May-2015:								
This report concerns a 42-year-old male subject (Respondent Study ID: 1254392) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
Information on smoking habits was not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number Y6G S4K 4QX HOF) on 23-Apr-2015.								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>On the same day (23-Apr-2015), the respondent felt hot when putting the HeatStick in the mouth to use. The event was considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000158	KOREA, REPUBLIC OF Report From Study	40 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [qd]	Respiratory 25-APR-2015 to 22-MAY-2015	28-APR-2015 28-APR-2015 28-APR-2015	Stomach-ache and diarrhoea after smoking more than usual. [ABDOMINAL PAIN UPPER] N / Y / Y Stomach-ache and diarrhoea after smoking more than usual. [DIARRHOEA] N / Y / Y Hard to hold (the product) because of its heat from its middle part to up part [DEVICE ISSUE] N / Y / N	Recovered/Resolved
<p>Case Initial Receipt Date: 23-May-2015</p> <p>Event Intensity: Mild Mild Mild</p> <p>Event Stop Date: 30-APR-2015 30-APR-2015 30-APR-2015</p> <p>Case Narrative: Verbatim: Has a stomach-ache and diarrhoea after smoking more than usual -> got diarrhoea after smoking regular menthol cigarettes a little bit more than he used to. Hard to hold (the product) because of its heat from its middle part to up part - used (it) by holding its bottom part.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 23-May-2015: This report concerns a 40-year-old male subject (Respondent Study ID: 1385414) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (in average 10 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 (Dorado I / Vinny low Menthol) (Kit number 2VS 30Y HP4 WNT) on 25-Apr-2015.</p> <p>On 28-Apr-2015, the respondent experienced stomach ache and diarrhoea after smoking more than usual. He explained that he got diarrhoea after smoking regular menthol cigarettes a little bit more than he used to. In addition, the respondent reported that the product was hard to hold because of its heat from the middle part to upper part. He indicated that he held the product by holding its bottom part. The events were considered to be non-serious. Severity of the adverse events was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 12 HeatSticks and smoked 1 conventional cigarette. The last Heatsticks were used on 22-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event.</p> <p>The events resolved on 30-Apr-2015. The respondent indicated that the issue was solved by reducing the amount of pieces (HeatSticks) used. It was indicated that the event did not recur when product was restarted.</p>							

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information is expected ? case closed.								
PMI000162	KOREA, REPUBLIC OF Report From Study	28 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	23-APR-2015 to Unknown	26-APR-2015	Throat gets stinging for spicy tastes when smoking HeatStick. [OROPHARYNGEAL PAIN] N / N / Y	Unknown
Case Initial Receipt Date: 23-May-2015								
Case Narrative: Verbatim: Throat gets stinging for spicy tastes when smoking HeatStick.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 23-May-2015:								
This report concerns a 28-year-old male subject (Respondent Study ID: 1323266) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
Information on smoking habits was not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number ACM Q1M CAD 3QF) on 23-Apr-2015.								
On 26-Apr-2015, the respondent experienced that his throat got stinging for spicy tastes when he was smoking HeatSticks. The event was considered to be non-serious. Severe adverse event was not reported.								
Action taken with the use of the product was not reported.								
At the time of reporting, the outcome of the event was not reported.								
No follow-up information is expected ? case closed.								
PMI000163	KOREA, REPUBLIC OF Report From Study	49 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	25-APR-2015 to Unknown	25-APR-2015	Feels heat and seems to irritate throat. [FEELING HOT] N / Y / Y	Unknown
Case Initial Receipt Date: 23-May-2015								
Case Narrative: Verbatim: Feels heat and seems to irritate throat.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 23-May-2015:								
This report concerns a 49-year-old male subject (Respondent Study ID: 1348800) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
Information on smoking habits was not provided.								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and Menthol (Dorado I / Vinny low menthol) (Kit numbers not provided) on 25-Apr-2015.</p> <p>On the same day (25-Apr-2015), the respondent experienced feeling heat (location not specified) and reported that it seems to irritate the throat. The events were considered non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000166	KOREA, REPUBLIC OF Report From Study	25 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	28-APR-2015 to Unknown	28-APR-2015	Feels hot on throat by sucking the product deeply, because don't know how strongly it needs to be sucked, as this is the first time to use it (when testing) [THROAT IRRITATION] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 26-May-2015</p> <p>Case Narrative: Verbatim: Feels hot on throat by sucking the product deeply, because don't know how strongly it needs to be sucked, as this is the first time to use it (when testing)</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 26-May-2015:</p> <p>This report concerns a 25-year-old male subject (Respondent Study ID: 1466625) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number not provided) on 28-Apr-2015.</p> <p>On the same day (28-Apr-2015), the respondent experienced that he felt hot on throat by sucking the product deeply, because he didn't know how strongly it needed to be sucked, as this was the first time to use it (when testing). The event was considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000170	KOREA, REPUBLIC OF Report From Study	49 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	28-APR-2015 to 18-MAY-2015	11-MAY-2015	Has coughs every time when using HeatStick because of being in a hurry to smoke. [COUGH] N / N / Y	Not Recovered/Not Resolved
<p>THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]</p> <p>Case Initial Receipt Date: 20-May-2015</p> <p>Event Intensity: Mild</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: Never have coughed when using general cigarettes, but has coughs every time when using HeatStick because of being in a hurry to smoke.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 20-May-2015 and transferred to Safety department on 28-May-2015: This report concerns a 49-year-old male subject (Respondent Study ID: 2108635) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 14 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and Menthol (Dorado I / Vinny low menthol) (Kit number TNY JGW LWS 3KZ, not speci for which one of the two products) on 28-Apr-2015.</p> <p>On 11-May-2015 (about two weeks after using the products), the respondent experienced coughing. He indicated that he never had coughed when using regular cigarettes, but ha cough every time when using HeatStick because of being in a hurry to smoke. The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used for 4 days (out of 7 days). On the day of the event, the respondent used 2 HeatSticks and smoked 2 conventional cigarettes. The last Heatsticks were us 18-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event. It was reported that the event returned when use of the product was restarted.</p> <p>At the time of reporting, the event was not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000172	KOREA, REPUBLIC OF Report From Study	32 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [qd]	Respiratory	24-APR-2015 to 26-MAY-2015	24-APR-2015 24-APR-2015	Felt heavy and pain on throat after using this product (HeatStick), which was not similar to smoking general cigarettes. Felt like smoking 4 pieces of general cigarettes in a row. [DISCOMFORT] N / Y / Y Felt heavy and pain on throat after using this product (HeatStick), which was not similar to smoking general cigarettes. Felt like smoking 4 pieces of general cigarettes in a row. [OROPHARYNGEAL PAIN] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 26-May-2015 Event Intensity: Mild Mild</p> <p>Case Narrative: Verbatim: Felt heavy and pain on throat after using this product (HeatStick), which was not similar to smoking general cigarettes. Felt like smoking 4 pieces of general cig</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 26-May-2015: This report concerns a 32-year-old male subject (Respondent Study ID: 2358803) who took part in the above mentioned market research study.</p> <p>No concurrent medical history and no concomitant medications were reported. The respondent had a past history of asthma on bronchus at the age of 20, but it never relapsed moment.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent was a daily smoker (in average 20 cigarettes per day). He also used extra e-cigarettes about 10 times.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular Menthol (Dorado I / Vinny low menthol) (Kit number E1W C6N W6F Y8Y) on 24-Apr-2015.</p> <p>On the same day (24-Apr-2015), the respondent felt heavy and pain on throat after using the HeatStick, which was not similar to smoking general cigarettes. The respondent e it felt like smoking 4 pieces of conventional cigarettes in a row. The events were considered to be non-serious. Severity of the adverse events was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 20 HeatSticks and smoked no conventional cigarettes. The last Heatsticks were used on 26-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event. It was reported that the problem returned when use of the product was restarted.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000175	KOREA, REPUBLIC OF Report From Study	36 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown	29-APR-2015	Becomes dry on mouth, feels nauseous, and has a lot of saliva in mouth, when using both products, Y and Z, at their ends. [DRY MOUTH] N / Y / Y	Unknown
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown	29-APR-2015	Becomes dry on mouth, feels nauseous, and has a lot of saliva in mouth, when using both products, Y and Z, at their ends. [SALIVARY HYPERSECRETION] N / Y / Y	
						29-APR-2015	Becomes dry on mouth, feels nauseous, and has a lot of saliva in mouth, when using both products, Y and Z, at their ends. [NAUSEA] N / N / Y	
<p>Case Initial Receipt Date: 28-May-2015</p> <p>Case Narrative: Verbatim: Becomes dry on mouth, feels nauseous, and has a lot of saliva in mouth, when using both products, Y and Z, at their ends. Didn' t comment (on that) because it happens usually when using regular cigarettes, and it was not a big deal, like testing (the products).</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 28-May-2015:</p> <p>This report concerns a 36-year-old male subject (Respondent Study ID: 2354864) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and Menthol (Dorado I / Vinny low menthol) (Kit number KUI MAM 29Y ONC, not specifying which one of the two products it corresponds) on 29-Apr-2015.</p> <p>Starting on the same day (29-Apr-2015), the respondent experienced dryness in mouth, feeling nauseous and having a lot of saliva in mouth by using both types of HeatSticks. The respondent explained that it happened in testing, and did happen in using as well. In addition, he explained that he didn' t comment on that because it happened usually when using regular cigarettes, and it was not a big deal. The events were considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
At the time of reporting, the outcome of the events was not reported.								
No follow-up information is expected ? case closed.								
PMI000177	KOREA, REPUBLIC OF Report From Study	40 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown	09-MAY-2015	Felt parched on throat from its aftertaste when using both Y and Z. [DRY THROAT] N / Y / Y	Unknown
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown	09-MAY-2015	Felt parched on throat from its aftertaste when using both Y and Z. [DYSGEUSIA] N / Y / Y	
Case Initial Receipt Date: 28-May-2015								
Case Narrative: Verbatim: Used the product on Saturday after two weeks of not taking it. Felt parched on throat from its aftertaste when using both Y and Z.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 28-May-2015:								
This report concerns a 40-year-old male subject (Respondent Study ID: 2359522) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
Information on smoking habits was not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) and Menthol (Dorado I / Vinny low menthol) (Kit number DRS 6EK MQK, not specifying which one of the two products it corresponds) on 29-Apr-2015.								
On 09-May-2015 (after 2 weeks of not using the product), the respondent felt parched on throat from the product's aftertaste when using both types of HeatSticks. The event was considered to be non-serious. Severity of the adverse event was not reported.								
Action taken with the use of the product was not reported.								
At the time of reporting, the outcome of the events was not reported.								
No follow-up information is expected ? case closed.								
PMI000178	KOREA, REPUBLIC OF Report From Study	34 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [qd]	Respiratory	29-APR-2015 to 26-MAY-2015	11-MAY-2015	I felt nauseous when using many pieces in a row because it tastes fishy in the aftertaste. [DYSGEUSIA] N / Y / Y	Not Recovered/Not Resolved
						11-MAY-2015	I felt nauseous when using many pieces in a row because it tastes fishy in the aftertaste. [NAUSEA] N / N / Y	
						11-MAY-2015	I felt nauseous when using many pieces in a row because it tastes fishy in the aftertaste. [PRODUCT TASTE ABNORMAL] N / Y / N	
Case Initial Receipt Date: 30-May-2015								
Event Intensity: Mild								
Mild								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: I felt OK at the first time of using it, but then I felt nauseous when using many pieces in a row because it tastes fishy in the aftertaste.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 30-May-2015: This report concerns a 34-year-old male subject (Respondent Study ID: 2359944) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 30 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number 86T 94V QP9 4AD) on 29-Apr-2015.</p> <p>On 11-May-2015, the respondent felt nauseous when using many pieces in a row because "it tastes fishy in the aftertaste". The respondent clarified that he felt OK at the using the product. The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 20 HeatSticks and smoked 25 conventional cigarettes. The last Heatsticks were used on 26-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000188	ITALY Report From Study	60 Years Female	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]	Respiratory	15-MAY-2014 to 16-MAY-2014	15-MAY-2014 15-MAY-2014 15-MAY-2014 15-MAY-2014	Nausea [NAUSEA] N / N / Y Headache [HEADACHE] N / N / Y Dizziness [DIZZINESS] N / N / Y Too strong menthol smell [PRODUCT ODOUR ABNORMAL] N / Y / Y	
<p>Case Initial Receipt Date: 16-May-2014 Event Intensity: Moderate Moderate Moderate Moderate</p> <p>Case Narrative: Verbatim: Nausea, headache, dizziness, too strong menthol smell.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest, the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 16-MAY-2014: This report concerns a 60-year-old female subject (Respondent Study ID: MIF0101101L) who took part in the above mentioned study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The respondent was a smoker who smoked on average 7 cigarettes per day and was not using any other tobacco products/nicotine products.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number CU005515) on 15-May-2014. She reported that the product had a too strong menthol smell. On 15-May-2014, she experienced nausea, headache and dizziness. The events were considered to be non-serious and moderate in intensity. The respondent stopped using the product on 16-May-2014. At the time of reporting, the event of nausea was still ongoing. On the day of the occurrence of the events, the respondent smoked 8 cigarettes and used 3 sticks.								
No follow-up information has been requested ? case closed.								
PMI000196	KOREA, REPUBLIC OF Report From Study	29 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	29-APR-2015 to 29-APR-2015	29-APR-2015 29-APR-2015	Feels dry on throat, which is drier than when smoking general cigarettes. Feels parched in mouth. [DRY THROAT] N / Y / Y Feels dry on throat, which is drier than when smoking general cigarettes. Feels parched in mouth. [DRY MOUTH] N / Y / Y	Recovered/Resolved
Case Initial Receipt Date: 29-May-2015 Event Intensity: Mild Mild Event Stop Date: 29-APR-2015 29-APR-2015 Case Narrative: Verbatim: Feels dry on throat, which is drier than when smoking general cigarettes. Feels parched in mouth								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 29-May-2015: This report concerns a 29-year-old male subject (Respondent Study ID: 2354471) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
The respondent was a daily smoker.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number not provided) on 29-Apr-2015.								
On the same day (29-Apr-2015), the respondent felt dry on throat and parched in mouth. He explained that it was drier than when smoking conventional cigarettes. The events considered to be non-serious. Severity of the adverse event was reported as mild.								
The product was used only once. It was mentioned that the event improved after usage of the product was stopped and that it did not return when use of the product was restarted (conflicting information).								
The events resolved on the same day (29-Apr-2015).								
No follow-up information is expected ? case closed.								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000200	ITALY Report From Study	67 Years Female	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]	Respiratory	15-MAY-2014 to 15-MAY-2014	15-MAY-2014	Dizzy [DIZZINESS] N / N / Y	Recovered/Resolved
Case Initial Receipt Date: 26-May-2014 Event Intensity: Moderate Event Stop Date: 15-MAY-2014 Case Narrative: Verbatim: Dizzy								
Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.								
INITIAL INFORMATION RECEIVED ON 26-MAY-2014: This report concerns a 67-year-old female subject (Respondent Study ID: BUS0414102L) who took part in the above mentioned market research study.								
The respondent had no medical conditions and was not taking any concomitant medications.								
The respondent was a smoker who smoked on average 20 cigarettes per day.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number CU004778) on 15-May-2014. On 15-May-2014, she felt dizzy. The event was considered to be non-serious and moderate in intensity. The respondent stopped using the product on 15-May-2014 and the event resolved on the same day. On the day of the occurrence of the event, the respondent used 2 sticks and smoked 15 cigarettes.								
No follow-up information has been requested ? case closed.								
PMI000202	ITALY Report From Study	51 Years Female	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]	Respiratory	20-MAY-2014 to 28-MAY-2014	20-MAY-2014 20-MAY-2014 20-MAY-2014	Influenza [INFLUENZA] N / Y / Y Fever [PYREXIA] N / Y / Y Cough [COUGH] N / N / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 29-May-2014 Event Intensity: Mild Mild Mild Case Narrative: Verbatim: Influenza, fever, cough								
Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.								
INITIAL INFORMATION RECEIVED ON 29-MAY-2014: This report concerns a 51-year-old female subject (Respondent Study ID: MIB0729101L) who took part in the above mentioned market research study.								
The respondent's medical conditions included anaemia. The respondent was not taking any concomitant medications.								
The respondent was a smoker who smoked on average 5 cigarettes per day.								

**CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016**

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number CU005021) on 20-May-2014. On 20-May-2014, she experienced cough, influenza and fever. However, she added that these symptoms were already present prior to using the THS. The events were considered to be non-serious and mild in intensity. respondent was treated with unspecified antibiotics. The respondent stopped using the product on 28-May-2014 evening and at the time of this report, the events were ongoing day of the occurrence of the events, the respondent used 3 sticks and smoked 2 cigarettes.								
No follow-up information has been requested ? case closed.								
PMI000212	ITALY Report From Study	19 Years Male	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK] Case Initial Receipt Date: 24-May-2014 Case Narrative: Verbatim: Light feeling of nausea	Respiratory	24-MAY-2014 to Unknown	24-MAY-2014	Light feeling of nausea [NAUSEA] N / N / Y	Unknown
Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and interview, also at central location, after two weeks.								
INITIAL INFORMATION RECEIVED ON 24-MAY-2014: This report concerns a 19-year-old male subject who took part in the above mentioned market research study.								
The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number not provided) on 24-May-2014. On the same day, the respondent stated that he was used to his cigarettes and preferred the taste of tobacco. He reported that, after smoking for a while, he experienced a light feeling of nausea. The event was considered non-serious. The outcome was unknown.								
No follow-up information has been requested ? case closed.								
PMI000215	ITALY Report From Study	64 Years Female	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK] Case Initial Receipt Date: 15-May-2014 Case Narrative: Verbatim: Makes me cough. Menthol taste too strong.			15-MAY-2014 15-MAY-2014	Makes me cough [COUGH] N / N / Y Menthol taste too strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and interview, also at central location, after two weeks.								
INITIAL INFORMATION RECEIVED ON 15-MAY-2014: This report concerns a 64-year-old female subject who took part in the above mentioned market research study.								
The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number not provided) on 15-May-2014. On the same day, the respondent reported								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
the product made her cough and that the product menthol taste was too strong. The events were considered to be non-serious. The outcome was unknown.								
No follow-up information has been requested ? case closed.								
PMI000224	KOREA, REPUBLIC OF Report From Study	38 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [qd]	Respiratory	28-APR-2015 to 27-MAY-2015	07-MAY-2015 07-MAY-2015	Within five minutes of using the HeatStick, my head felt heavy and I got a little dizzy. [HEAD DISCOMFORT] N / Y / Y Within five minutes of using the HeatStick, my head felt heavy and I got a little dizzy. [DIZZINESS] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 28-May-2015 Event Intensity: Mild Mild Event Stop Date: 21-MAY-2015 21-MAY-2015 Case Narrative: Verbatim: Within five minutes of using the HeatStick, my head felt heavy and I got a little dizzy.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 28-May-2015 and received by the safety department on 05-JUN-2015: This report concerns a 38-year-old male subject (Respondent Study ID: 1467153) who took part in the above mentioned market research study.</p> <p>No medical history was reported. Omega 3 and vitamins for the eyes were reported as concomitant medications (not specified).</p> <p>The respondent was a daily smoker (on average, 12 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number 56V H06 J6L LPP) on 28-Apr-2015.</p> <p>On 07-May-2015, within five minutes of using the HeatStick, the respondent' s head felt heavy and he got a little dizzy. The events were considered to be non-serious. Several adverse events was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 7 HeatSticks and smoked 5 conventional cigarettes. The last Heatsticks were used on 27-May-2015.</p> <p>It was reported that the events improved after product was stopped and returned when use of the product was restarted (about 2-3 times).</p> <p>The events resolved on 21-May-2015.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000225	KOREA, REPUBLIC OF Report From Study	37 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [qd]	Respiratory	01-MAY-2015 to 28-MAY-2015	05-MAY-2015	I didn' t feel it when testing, but starting about 5th May, which was around four days after having used the product, I felt phlegm in my throat after use [PRODUCTIVE COUGH] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 01-Jun-2015 Event Intensity: Mild Case Narrative: Verbatim: didn' t feel it when testing, but starting about 5th May, which was around four days after having used the product, I felt phlegm in my throat after use. I could from time to time throughout the four weeks that I was using the product.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 01-JUN-2015 AND TRANSFERRED TO SAFETY DEPARTMENT ON 05-JUN-2015: This report concerns a 37-year-old male subject (Respondent Study ID: 2365125) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 10 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number MY3 RCL QOC P2D) on 01-May-2015.</p> <p>On 05-May-2015, the respondent felt phlegm in his throat after use. He could feel the phlegm from time to time throughout the four weeks that he was using the product. The considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 14 HeatSticks and smoked 8 conventional cigarettes. The last Heatsticks were used on 28-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event. It was reported that the event returned when product was restarted.</p> <p>At the time of reporting, the event was not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000234	ITALY Report From Study	59 Years Male	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]	Respiratory			It irritates the throat [THROAT IRRITATION] N / N / Y Causes a bit of cough [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 23-May-2014 Case Narrative: Verbatim: It irritates the throat, causes a bit of cough.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 59-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent' s medical history and concomitant medications were not provided.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number not provided) on an unspecified date. The respondent reported that the irritated his throat, caused a bit of cough and that it did not satisfy him completely as he smoked a lot. The events were considered to be non-serious. The outcome was unknown.								
No follow-up information has been requested ? case closed.								
PMI000241	ITALY Report From Study	37 Years Female	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]	Respiratory			Gives me headache [HEADACHE] N / N / Y Gives me nausea [NAUSEA] N / N / Y	Unknown
Case Initial Receipt Date: 29-May-2014 Case Narrative: Verbatim: Gives me headache and nausea.								
Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.								
INITIAL INFORMATION RECEIVED ON 29-MAY-2014: This report concerns a 37-year-old female subject who took part in the above mentioned market research study.								
The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number not provided) on an unspecified date. The respondent reported that the respondent gave her headache and nausea. The events were considered to be non-serious. The outcome was unknown.								
No follow-up information has been requested ? case closed.								
PMI000243	ITALY Report From Study	49 Years Male	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]	Respiratory			It gave me nausea [NAUSEA] N / N / Y	Unknown
Case Initial Receipt Date: 03-Jun-2014 Case Narrative: Verbatim: It gave me nausea.								
Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.								
INITIAL INFORMATION RECEIVED ON 03-JUN-2014: This report concerns a 49-year-old male subject who took part in the above mentioned market research study.								
The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number not provided) on an unspecified date. The respondent reported that the respondent gave him nausea. The event was considered to be non-serious. The outcome was unknown.								
No follow-up information has been requested ? case closed.								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000259	ITALY Report From Study	21 Years Female	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]	Respiratory			Gave me a feeling of nausea [NAUSEA] N / N / Y Mint is too strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 06-Jun-2014 Case Narrative: Verbatim: Mint is too strong, gave me a feeling of nausea.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 06-JUN-2014: This report concerns a 21-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number not provided) on an unspecified date. The respondent reported that the product was too strong and the product gave her a feeling of nausea. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000260	ITALY Report From Study	46 Years Male	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]	Respiratory			Something really heavy to breathe [CHEST DISCOMFORT] N / Y / Y Unpleasant taste [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-May-2014 Case Narrative: Verbatim: Unpleasant taste, something really heavy to breathe.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 30-MAY-2014: This report concerns a 46-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number not provided) on an unspecified date. The respondent reported that the product had an unpleasant taste and it was something really heavy to breathe. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000272	SWITZERLAND Report From Study	45 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK]	Respiratory	10-NOV-2014 to 10-NOV-2014	10-NOV-2014 10-NOV-2014 10-NOV-2014 10-NOV-2014	Very tired [FATIGUE] N / Y / Y Headache [HEADACHE] N / N / Y Nausea [NAUSEA] N / N / Y Vertigo [VERTIGO] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 11-Nov-2014 Event Intensity: Severe Severe Severe Severe</p> <p>Case Narrative: Verbatim: Vertigo, Headache, Nausea, Very tired</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 11-NOV-2014: This report concerns a 45-year-old female subject (Respondent Study ID: F184606) who took part in the above mentioned market research study.</p> <p>The respondent had no medical history and was not taking any concomitant medications. It was reported that the respondent took antibiotics for angina (tonsillitis) one month prior to the occurrence of the reported events.</p> <p>The respondent was a daily smoker who smoked on average 12 cigarettes per day (80 cigarettes per month).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number CU003883) on 10-Nov-2014. On the same day, she experienced vertigo, headache, nausea and felt very tired. The events were considered to be non-serious and severe in intensity.</p> <p>On 10-Nov-2014, the respondent used 5 sticks and she smoked 5 cigarettes. She stopped using the sticks on the same day. The reported events did not improve after she stopped the product. At the time of reporting, the events were not resolved.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000273	SWITZERLAND Report From Study	Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK]	Respiratory		10-NOV-2014 10-NOV-2014	Felt sick [MALAISE] N / Y / Y Vomit [VOMITING] N / Y / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 10-Nov-2014 Case Narrative: Verbatim: Felt sick, vomit</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 10-NOV-2014 (Two different sets of information transferred at different dates):</p> <p>This report concerns a female subject (Respondent Study ID: F192769) who took part in the above mentioned market research study.</p> <p>The respondent's medical history and concomitant medications were not reported.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date. She reported she did not like the menthol Heat Sticks and that she was feeling sick. The two last times she used the sticks she had to vomit. According to the respondent, the taste is very strong though she is used to it as she smokes a lot. The events were considered to be non-serious.								
At the time of reporting, the events were not resolved.								
No follow-up information has been requested ? case closed.								
PMI000345	UNITED STATES Report From Study	66 Years Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	12-OCT-2015 to 12-OCT-2015	12-OCT-2015	her stomach was upset [ABDOMINAL DISCOMFORT] N / Y / Y had dry heaves [RETCHING] N / Y / Y also having diarrhea [DIARRHOEA] N / Y / Y they made me sick [MALAISE] N / Y / Y as soon as she finished using the IQOS device she started to get dizzy and tasted a very strong menthol taste [DIZZINESS] N / N / Y She stated that, after using IQOS, she felt icky (described as feeling nauseous) / sick to her stomach [NAUSEA] N / N / Y having a headache [HEADACHE] N / N / Y was not able to get the device to work [DEVICE ISSUE] N / Y / N tasted a very strong menthol taste [PRODUCT TASTE ABNORMAL] N / Y / N	Recovered/Resolved
Case Initial Receipt Date: 15-Oct-2015								
Case Followup Receipt Date: 26-Oct-2015 00:00								
Event Intensity: Severe								
Severe								
Severe								
Severe								
Severe								
Severe								
Event Stop Date: 15-OCT-2015								
15-OCT-2015								
15-OCT-2015								
15-OCT-2015								
15-OCT-2015								
15-OCT-2015								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: She stated that, as soon as she finished using the IQOS device, she started to get dizzy and tasted a very strong menthol taste. She stated that, after using IQOS, she felt icky (described as feeling nauseous), having a headache, and her stomach was upset. She then tried a third heatstick and reported she was not able to get the device to work. She was unable to finish the cigarette because she still felt dizzy, sick to her stomach and had dry heaves. She was also having diarrhea.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 15-Oct-2015 and forwarded to Safety department on 16-Oct-2015.</p> <p>This report concerns a 66-year-old female subject (Respondent Study ID: 538801) who took part in the above mentioned market research study.</p> <p>Medical history of high blood pressure, breast cancer, hypothyroid and high cholesterol was reported. The following concomitant medications were reported: Synthroid (levo thyroxine sodium), Cadeut (presumably Caduet, amlodipine besilate, atorvastatin calcium), Advil (ibuprofen), doses, treatment dates and indications not provided.</p> <p>The consumer was a daily smoker (approximately 10 conventional menthol cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol Dorado I / Vinny Low Menthol (kit numbers (01)-5410706815337 (21) 2T4TNK9RU6SR (240) DK000024.01 on 12-Oct-2015. The consumer smoked 3 Heatsticks and 2 conventional cigarettes on the day of the event.</p> <p>On 12-Oct-2015, the participant smoked regular, conventional, menthol cigarette, and then tried IQOS device, using 1 full menthol heatstick. She then indicated she tried to use a second heatstick and was only able to take 1 puff. She then tried a third heatstick and reported she was not able to get the device to work. She stated that, as soon as she finished using the IQOS device, she started to get dizzy and tasted a very strong menthol taste. She stated that, after using IQOS she felt icky (described as feeling nauseous), having a headache, and her stomach was upset. Later that evening, she tried to smoke a regular, conventional menthol cigarette, but reported she was unable to finish the cigarette because she still felt dizzy, sick to her stomach and had dry heaves. She stated she spent all day in bed on 13-Oct-2015 because she kept feeling dizzy during the day and was also having diarrhea.</p> <p>The intensity of the events was reported as severe. The events were considered to be non-serious. Participant did not seek medical advice.</p> <p>It was reported that the events improved when the usage of the product was discontinued. Product was not restarted.</p> <p>Consumer stated that she felt fine on 15-Oct-2015. The events were resolved.</p> <p>No follow-up information is expected. Case closed.</p> <p>FOLLOW-UP INFORMATION was received on 26-Oct-2015 and forwarded to the Safety department on 2-Nov-2015.</p> <p>Verbatim: they made me sick</p> <p>In addition to the previous reported events, the respondent stated that "They made me sick".</p> <p>The event severity was not reported. The event was considered to be non-serious. The outcome of the event was not reported.</p> <p>No further information was provided.</p> <p>No follow-up information is expected. Case closed.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000361	UNITED STATES Report From Study	22 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	25-OCT-2015 to 27-OCT-2015	27-OCT-2015	his chest was hurting real bad [CHEST PAIN] N / Y / Y	Not Recovered/Not Resolved
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	25-OCT-2015 to 27-OCT-2015	26-OCT-2015 25-OCT-2015 25-OCT-2015	he started coughing up green stuff [SPUTUM DISCOLOURED] N / Y / Y As he smoked more of the product, it was like it was pulling air out of his lungs [CHEST DISCOMFORT] N / N / Y each time he smoked, he would cough [COUGH] N / N / Y	
<p>Case Initial Receipt Date: 27-Oct-2015</p> <p>Event Intensity: Moderate Moderate Moderate Moderate</p> <p>Case Narrative: Verbatim: He stated that at first the smoking experience wasn't so bad, but then as he smoked more of the product, it was like it was pulling air out of his lungs. He stated that he then found that each time he smoked, he would cough. On 26-Oct-2015, he started coughing up green stuff. On the morning of 27-Oct-2015, when he woke up, his chest was hurting real bad, but the coughing had slowed down.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 27-Oct-2015 and forwarded to Safety department on the same day.</p> <p>This report concerns a 22-year-old male subject (Respondent Study ID: 751825) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The respondent was a daily smoker (approximately 15-20 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit numbers (01)5410706815337, (21)MHZKNOLUZYR, (240)DK000024.01) on 25-Oct-2015.</p> <p>On 25-Oct-2015, the study respondent started using the product. He stated that, at first, the smoking experience wasn't so bad, but then, as he smoked more of the product, it was like it was pulling air out of his lungs. He stated that he then found that, each time he smoked, he would cough. On 26-Oct-2015, he started coughing up green stuff. On the morning of 27-Oct-2015, when he woke up, his chest was hurting real bad, but the coughing had slowed down. The participant stated the menthol caused the problem more than the regular flavor.</p> <p>The events severity was reported as moderate. The events were considered to be non-serious.</p> <p>The consumer used the Heatsticks every day. He used 10 Heatsticks and 10 cigarettes on the day of the events.</p> <p>The respondent stopped using the product on 27-Oct-2015. The events improved when usage of the products was stopped. The products were not restarted.</p> <p>At time of reporting, the events were not resolved.</p> <p>No follow-up information is expected. Case closed.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000364	UNITED STATES Report From Study	28 Years Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	09-OCT-2015 to Unknown	09-OCT-2015 09-OCT-2015	inhaled for 2 seconds, and experienced a really warm sensation on her lips [FEELING HOT] N / Y / Y it felt too close to her lips and she was being burned / burning sensation on the lips [ORAL DISCOMFORT] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 30-Oct-2015 Case Followup Receipt Date: 30-Oct-2015 00:00 Event Intensity: Mild Mild Case Narrative: Verbatim: Inhaled for 2 seconds, and experienced a really warm sensation on her lips. Participant stated it felt too close to her lips and she was being burned. Burning sensation on the lips.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 30-Oct-2015 and forwarded to Safety department on the same day. Additional information with same initial date was forwarded to Safety department on 02-Nov-2015.</p> <p>This report concerns a 28-year-old female subject (Respondent Study ID: 535255) who took part in the above mentioned market research study.</p> <p>Medical history included gallbladder removal ten years ago. No concomitant medication was reported.</p> <p>The consumer was a daily smoker (approximately 10 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number 5410706815337) on 09-Oct-2015.</p> <p>Participant started using the product on 09-Oct-2015. She stated that, with her regular Newport conventional cigarettes, she inhaled for about 2 seconds. When she did the same with the IQOS device, she experienced a really warm sensation on her lips. She tried to keep smoking but it was just too much heat. Participant stated it felt too close to her lips and she was being burned. She reported that she experienced the same symptoms with each use.</p> <p>The events severity was reported as mild. The events were considered to be non-serious.</p> <p>The participant used the Heatstick occasionally, once per week. The study respondent used 1 Heatstick and 1 cigarette on the day of the event. She mentioned that the event improved when product was stopped and returned when product was restarted.</p> <p>Participant last used the device on 23-Oct-2015 but stated she planned to continue using the device.</p> <p>At time of reporting, the events were not resolved.</p> <p>No follow-up information is expected. Case closed.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000366	UNITED STATES Report From Study	20 Years Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	15-OCT-2015 to 21-OCT-2015	15-OCT-2015	Heatsticks giving me headaches/ gave me headaches [HEADACHE] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 29-Oct-2015 Case Followup Receipt Date: 01-Nov-2015 00:00 Event Intensity: Moderate Case Narrative: Verbatim: Heatsticks giving me headaches; gave me headaches</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 29-Oct-2015 and 1-Nov-2015 and forwarded to Safety department on 2-Nov-2015.</p> <p>This report concerns a 20-year-old female subject (Respondent Study ID: 201662) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The respondent was a daily smoker (approximately 10 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number 72QGCB189GV) on 15-Oct-2015.</p> <p>The respondent stated that she experienced headaches after using the Heatsticks from 15-Oct-2015.</p> <p>The event severity was reported as moderate.</p> <p>The respondent used the Heatsticks occasionally. She used 1 Heatstick and 15 cigarettes on the day of the event.</p> <p>It was reported that the event improved when usage of the product was stopped and returned when usage of the product was restarted. The product permanently stopped on 21-Oct-2015.</p> <p>At time of reporting, the event was not resolved.</p> <p>No follow-up information is expected. Case closed.</p>								
PMI000372	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory			gave me headaches [HEADACHE] N / N / Y didn't like the taste [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]</p> <p>Case Initial Receipt Date: 26-Oct-2015 Event Intensity: Unknown Case Narrative: Verbatim: gave me headaches; didn't like the taste.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 26-Oct-2015 and forwarded to Safety department on 2-Nov-2015.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a female subject born in 1959 (Respondent Study ID: 181262) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The respondent was a daily smoker (number of conventional cigarettes per day not provided).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) and THS 2.2 Regular (Dorado II / Ron) on an unspecified date (kit number).</p> <p>The respondent stated that the use of the device gave her headaches and that she didn't like its taste.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The frequency of use of the Heatstick was not provided. No information was provided regarding the number of Heatsticks and conventionnal cigarettes used by the respondent on the day of the event.</p> <p>No information regarding the action taken with the drug was provided.</p> <p>At time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected. Case closed.</p>								
PMI000373	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015 2015 2015	made my chest hurt [CHEST PAIN] N / Y / Y burning my throat [THROAT IRRITATION] N / Y / Y coughing [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 22-Oct-2015 Case Followup Receipt Date: 09-Nov-2015 00:00 Event Intensity: Unknown Unknown Unknown Case Narrative: Verbatim: burning my throat, coughing, made my chest hurt.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 22-Oct-2015 and forwarded to Safety department on 02-Nov-2015.</p> <p>This report concerns a female subject born in 1963 (Respondent Study ID: 187828) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The respondent was a daily smoker (number of conventional cigarettes per day not provided).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number and start date not provided).</p> <p>On an unspecified date, the respondent experienced burning of her throat and coughing.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The severity of the events was not reported. The events were assessed as non-serious.</p> <p>The frequency of use of the Heatstick was not provided. No information was provided regarding the number of Heatsticks and cigarettes used by the respondent on the day of the event.</p> <p>No information regarding the action taken with the product was provided.</p> <p>At time of reporting, the outcome of the event was not reported.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 09-NOV-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>The study respondent reported that the product made his chest hurt.</p> <p>No follow-up information is expected. Case closed.</p>								
PMI000374	UNITED STATES Report From Study	Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory			Makes me feel nauseated / makes me nauseous [NAUSEA] N / N / Y smell is awful [PRODUCT ODOUR ABNORMAL] N / Y / N it feels cumbersome / it's an inconvenience to clean it and to carry it all / not convenient [DEVICE DIFFICULT TO USE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 20-Oct-2015 Case Followup Receipt Date: 09-Nov-2015 00:00 Event Intensity: Unknown Case Narrative: Verbatim: Makes me feel nauseated, and it feels cumbersome. It's an inconvenience to clean it and to carry it all. Smell is awful.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 20-Oct-2015 and forwarded to Safety department on 2-Nov-2015.</p> <p>This report concerns a male subject born in 1980 (Respondent Study ID: 829559) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The respondent was a daily smoker (number of conventional cigarettes per day not provided).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number and start date not provided).</p> <p>The respondent stated that he was feeling nauseated after using the Heats icks. He also reported that the device was cumbersome and that it was an inconvenience to clean it and to carry it.</p> <p>The severity of the events were not reported. The events were assessed as non-serious.</p> <p>The frequency of use of the Heatstick was not provided. No information was provided regarding the number of Heatsticks and cigarettes used by the respondent on the day of the event.</p> <p>No information regarding the action taken with the product was provided.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
At time of reporting, the outcome of the events was not reported.								
FOLLOW-UP INFORMATION RECEIVED ON 09-NOV-2015 and forwarded to Safety department on 05-Apr-2016.								
The study respondent reported that the product smells awful, it made him nauseous and it was not convenient.								
No further information on the events or their outcome was provided.								
No follow-up information is expected. Case closed.								
PMI000382	UNITED STATES Report From Study	51 Years Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	01-OCT-2015 to 07-NOV-2015	06-NOV-2015 06-NOV-2015 01-OCT-2015	HeatSticks usage causes burning/hot lips [ORAL DISCOMFORT] N / Y / Y the problem severely impacts her because it affects her mental state if she cannot continue the study (she needs the money) [MENTAL STATUS CHANGES] N / Y / N She has developed a cough since beginning the study, which she attributes to the IQOS vapor-based system [COUGH] N / N / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 09-Nov-2015								
Event Intensity: Severe								
Severe								
Severe								
Case Narrative: Verbatim: HeatSticks usage causes burning/hot lips / The problem severely impacts her because it affects her mental state if she cannot continue the study (she needs the money) / She has developed a cough since beginning the study, which she attributes to the IQOS vapor-based system								
Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.								
INITIAL INFORMATION RECEIVED on 09-Nov-2015 and forwarded to Safety department on 10-Nov-2015.								
This report concerns a 51-year-old female subject (Respondent Study ID: 757225) who took part in the above mentioned market research study.								
No medical history was reported. No concomitant medication was reported.								
The respondent was a daily smoker (approximately 20 conventional cigarettes per day).								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Vinny Low Menthol) (kit number QFW75841PM15) on 01-Oct-2015.								
The respondent stated that heatsticks usage caused burning/hot lips with the current pack of C3 Menthol; burning sensation started slowly with usage on 06-Nov-2015. She has developed a cough since beginning the study, which she attributes to the IQOS vapor-based system. She stated that the problem severely impacts her because it affects her mental state if she cannot continue the study; that she needs the money. Respondent stated that she has not used any HeatSticks the last 2 days due to the burning/hot lips.								
The events severity was reported as severe (of note, it was specified that it was because it affects her mental state if she cannot continue the study; needs the money) . The events were assessed as non-serious.								
The respondent used the Heatsticks every day. She used 2 Heatsticks and 20 cigarettes on the day of the event.								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The events improved when usage of the product was stopped, the product was not restarted. The last day of product use was on 07-Nov-2015.								
At time of reporting, the events were not resolved.								
No further information is expected. Case closed.								
PMI000407	UNITED STATES Report From Study	27 Years Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK] UNK [UNK]	Respiratory	17-OCT-2015 to (b) (6)	10-NOV-2015 10-NOV-2015	strep hroat [PHARYNGITIS STREPTOCOCCAL] N / Y / Y respiratory infection [RESPIRATORY TRACT INFECTION] N / Y / Y	Recovered/Resolved
			THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK] UNK [UNK]	Respiratory	2015 to 11-NOV-2015 17-NOV-2015 to Unknown			
Case Initial Receipt Date: 24-Nov-2015								
Event Intensity: Severe								
Event Stop Date: 17-NOV-2015								
17-NOV-2015								
Case Narrative: Verbatim: strep throat / respiratory infection								
Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.								
INITIAL INFORMATION RECEIVED ON 24-Nov-2015 and forwarded to Safety department on the same day.								
This report concerns a 27-year-old female subject (Respondent Study ID: 185638) who took part in the above mentioned market research study.								
No medical history and no concomitant medicationw were reported.								
The respondent was a daily smoker (approximately 10 conventional cigarettes per day).								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) and Regular (Dorado II / Ron) (kit number 6USB5XGJ3YD1) on 17-Oct-2015. She started with men hol and then switched to regular (date not provided).								
The respondent stated that she had strep throat and a respiratory infection which began on 10-Nov-2015. Or (b) (6), she saw a doctor at the hospital who did a test for strep throat which was positive. The doctor also told her she had a respiratory infection (NOS). The doctor told her she could not smoke. The doctor gave her amoxicillin and a shot (NOS) in her buttock, as treatment for the events.								
The events severity was reported as severe and required medical advice on 11-Nov-2015 and treatment (dates unspecified). The events were assessed as non-serious.								
The respondent used the heatsticks every day, except for when prohibited by doctor. The respondent used 1 Heatstick and 0 cigarette on the day of the event.								
The events improved when usage of the product was stopped, and did not returned when use of the prodct was restarted. The last day of product use was on 24-Nov-2015 (day of reporting). No further information was reported regarding the final action taken with the product.								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The events resolved on 17-Nov-2015, when the respondent was told she could return to work and smoking.								
No further information is expected. Case closed.								
PMI000411	UNITED STATES Report From Study	35 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory			he had a cold [NASOPHARYNGITIS] N / N / Y he sounded "ridiculous" [DYSPHONIA] N / Y / Y	Unknown
Case Initial Receipt Date: 04-Oct-2015								
Event Intensity: Unknown								
Case Narrative: Verbatim: he had a cold; he sounded "ridiculous"								
Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.								
INITIAL INFORMATION RECEIVED ON 04-Oct-2015 and forwarded to Safety department on 02-Dec-2015.								
This report concerns a 35-year-old male subject (Respondent Study ID: 453172) who took part in the above mentioned market research study.								
No medical history and no concomitant medication were reported.								
The smoking status of the respondent was not reported.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number J343KDKLYC0) on an unknown date.								
The respondent stated that he had a cold which was why he sounded "ridiculous" during a call on 04-Oct-2015. The start date of the event was unknown.								
The event severity was not reported. The event was assessed as non-serious.								
The respondent's smoking habits with heatstick was not reported. The number of heatsticks and cigarettes used on the day of the event was not reported.								
No information was provided about the action taken with the product.								
No information was provided about the outcome of the event.								
No further information is expected. Case closed.								
PMI000483	UNITED STATES Report From Study	30 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	SEP-2015 to DEC-2015	10-JAN-2016	Pregnancy [MATERNAL EXPOSURE T MING UNSPECIFIED] N / Y / N	Unknown
Case Initial Receipt Date: 03-Feb-2016								
Case Followup Receipt Date: 16-Feb-2016 00:00								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Comment Text: Maternal exposure timing unspecified was assessed as non-serious.</p> <p>Expectedness and causality assessments are not applicable for Maternal exposure timing unspecified. However, expectedness for Maternal exposure timing unspecified has been captured as unlisted, by default, in the safety database.</p> <p>No adverse events were reported in association with Maternal exposure timing unspecified.</p> <p>This pregnancy report shall be followed-up until an outcome is reached, as per protocol.</p> <p>Case Narrative: Verbatim: Pregnancy</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 03-FEB-2016 and forwarded to Safety department on 05-FEB-2016.</p> <p>This report concerns a 30-year-old female subject (Respondent Study ID: 751296) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medication were reported.</p> <p>The respondent was a daily smoker (approximately 2 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) and Regular (Dorado II / Ron) (kit numbers not provided) on an unknown date in Sep-2015.</p> <p>The respondent reported a pregnancy. Date of awareness of pregnancy was 10-Jan-2016. Last menstrual period was in Dec-2015 (not further specified). The pregnancy was confirmed by a HCP. Delivery date was uncertain. It was reported that the respondent was not using any contraception at time of report.</p> <p>The respondent had one previous pregnancy and one delivery (no therapeutic or planned abortion).</p> <p>The study respondent used the THS products up to an unspecified date in Dec-2015 (prior to awareness of pregnancy).</p> <p>Further information is expected.</p> <p>FOLLOW-UP INFORMATION received on 16-Feb-2016 and forwarded to Safety Department on 17-Feb-2016.</p> <p>The following kit number was provided: V4P4S3WB2REL (not specified if it corresponds to THS 2.2 Regular or Menthol. Start date of product use was reported as Sep-2015, with a comment that the study participant was unsure of exact date and stated it took place at end the month. The respondent's eDiary entries showed initial recorded use of IQOS device on 26-Oct-2015 (Enrollment center issued kit on 26-Oct-2015).</p> <p>The product stop date was reported as Dec-2015, with a comment that the study participant was unsure of exact date, and stated it took place at beginning of month. The respondent's eDiary entries showed that the last date of recorded use was 08-Dec-2015.</p> <p>First day of last menstrual period was reported as Dec-2015, with a comment that the study participant was unsure of exact date, and stated it took place in middle of month.</p> <p>Estimated delivery date was reported as 28-Aug-2016.</p> <p>Participant denied history of any ongoing medical conditions, for which she was seeing a healthcare professional, for which she was taking medications, or for which she was previously assessed.</p> <p>Participant reported that initial doctor visit on 10-Jan-2016 resulted in a blood test which confirmed pregnancy (follow-up appointment with her doctor was scheduled on 18-Feb-2016).</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Further information is expected.								
PMI000589	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	The smell of the Heatsticks makes me feel sick [MALAISE] N / Y / Y The smell of the Heatsticks makes me feel sick [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 09-Nov-2015 Case Narrative: Verbatim: The smell of the Heatsticks makes me feel sick.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 09-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 43-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 184275) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that the smell of the heatstick made her feel sick.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000590	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	Gave me a headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 09-Nov-2015 Case Narrative: Verbatim: gave me a headache</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 09-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 29-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 351426) who took part in the above mentioned market research study.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that the product gave her a headache.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000592	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	Got sick [MALAISE] N / Y / Y	Unknown
<p>THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]</p> <p>Case Initial Receipt Date: 09-Nov-2015 Case Narrative: Verbatim: got sick</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 09-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 21-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 458445) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unreported date.</p> <p>The respondent stated that she got sick.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No further information is expected. Case closed.								
PMI000593	UNITED STATES Report From Study	Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015 2015	too much work and gives headache [HEADACHE] N / N / Y too much work and gives headache [DEVICE DIFFICULT TO USE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 16-Nov-2015 Case Narrative: Verbatim: too much work and gives headache</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 16-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 45-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 536655) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that the product was too much work and gave him headache.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p>								
No further information is expected. Case closed.								
PMI000595	UNITED STATES Report From Study	Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015 2015	made me feel kinda groggy, dragged me [SOMNOLENCE] N / Y / Y I wasn't comfortable with them [DEVICE DIFFICULT TO USE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 16-Nov-2015 Case Narrative: Verbatim: made me feel kinda groggy, dragged me, I wasn't comfortable with them.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 16-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 47-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 351842) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unreported date.</p> <p>The respondent stated that the heatsticks made him feel kind of groggy, dragged him, and hat he wasn't comfortable with them.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000596	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015 2015	gives me a headache and it's a hassle [HEADACHE] N / N / Y gives me a headache and it's a hassle [DEVICE DIFFICULT TO USE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 16-Nov-2015</p> <p>Case Narrative: Verbatim: gives me a headache and it's a hassle</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 16-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 72-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 358759) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that the heatsticks gave her a headache and that it was a hassle.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000597	UNITED STATES Report From Study	Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015 2015	irritates my throat [THROAT IRRITATION] N / Y / Y too much menthol [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
Case Initial Receipt Date: 16-Nov-2015 Case Narrative: Verbatim: irritates my throat, too much menthol Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2. INITIAL INFORMATION RECEIVED ON 16-Nov-2015 and forwarded to Safety department on 05-Apr-2016. This report concerns a 56-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 185025) who took part in the above mentioned market research study. No medical history was reported. No concomitant medication was reported. No information on smoking habits was reported (conventional cigarettes and heatsticks). The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unreported date. The respondent stated that the product irritated his throat, and that there was too much menthol. The severity of the event was not reported. The event was assessed as non-serious. The outcome of the event was not reported. Action taken with the THS product was not reported. No further information is expected. Case closed.								
PMI000599	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	Sick [MALAISE] N / Y / Y	Unknown
Case Initial Receipt Date: 23-Nov-2015 Case Narrative: Verbatim: sick Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2. INITIAL INFORMATION RECEIVED ON 23-Nov-2015 and forwarded to Safety department on 05-Apr-2016. This report concerns a 23-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 757519) who took part in the above mentioned market research study. No medical history was reported. No concomitant medication was reported.								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent reported: "sick".</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000600	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015 2015	breathing trouble [DYSпноEA] N / Y / Y Sore throat [OROPHARYNGEAL PAIN] N / N / Y	Unknown
<p>THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]</p> <p>Case Initial Receipt Date: 23-Nov-2015 Case Narrative: Verbatim: sore throat, breathing trouble</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 23-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 55-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 181832) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent reported sore hroat and breathing trouble.</p> <p>The severity of the events was not reported. The events were assessed as non-serious.</p> <p>The outcome of the events was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000601	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015 2015	Taste and smell gave her headaches [HEADACHE] N / N / Y Taste and smell gave her headaches [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 30-Nov-2015 Case Narrative: Verbatim: Taste and smell gave her headaches.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 30-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 55-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 182351) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that the taste and smell of the heatstick gave her headaches.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000602	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	Problem with my throat [PHARYNGEAL DISORDER] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-Nov-2015 Case Narrative: Verbatim: Problem with my throat</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 30-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 55-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 533787) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent reported a problem with her throat.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000603	UNITED STATES Report From Study	Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	I think they were giving me an upset stomach [ABDOMINAL DISCOMFORT] N / Y / Y	Unknown
<p>THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]</p> <p>Case Initial Receipt Date: 07-Dec-2015 Case Narrative: Verbatim: I think they were giving me an upset stomach</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 07-Dec-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 58-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 650514) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) and THS 2.2 Regular (Dorado II / Ron) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that she thought the heatsticks were giving her an upset stomach.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000604	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK] Case Initial Receipt Date: 07-Dec-2015 Case Narrative: Verbatim: it too strong for my throat	Respiratory	2015 to Unknown	2015	it too strong for my throat [LARYNGEAL DISCOMFORT] N / Y / Y	Unknown
<p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 07-DEC-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 48-year-old female (approximate age, at the time of reporting) subject (Respondent Study ID: 533722) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that the product was too strong for her throat.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000605	UNITED STATES Report From Study	Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK] Case Initial Receipt Date: 07-Dec-2015 Case Narrative: Verbatim: chewed it	Buccal	2015 to Unknown	2015	chewed it [WRONG TECHNIQUE IN PRODUCT USAGE PROCESS] N / Y / N	Unknown
<p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 07-DEC-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 22-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 820149) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unreported date.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The respondent mentioned that he chewed the product. No associated adverse event was reported.								
The case was considered to be non-serious.								
Action taken with the THS product was not reported.								
No further information is expected. Case closed.								
PMI000606	UNITED STATES Report From Study	Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK] Case Initial Receipt Date: 21-Dec-2015 Case Narrative: Verbatim: heart burn	Respiratory	2015 to Unknown	2015	heart burn [DYSPEPSIA] N / Y / Y	Unknown
Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.								
INITIAL INFORMATION RECEIVED ON 21-DEC-2015 and forwarded to Safety department on 05-Apr-2016.								
This report concerns a 22-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 759773) who took part in the above mentioned market research study.								
No medical history was reported. No concomitant medication was reported.								
No information on smoking habits was reported (conventional cigarettes and heatsticks).								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.								
The respondent reported heartburn.								
The severity of the event was not reported. The event was assessed as non-serious.								
The outcome of the event was not reported.								
Action taken with the THS product was not reported.								
No further information is expected. Case closed.								
Yes (7)								
³ PMI000128	KOREA, REPUBLIC OF Report From Study	40 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK] THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory Respiratory	24-APR-2015 to Unknown 24-APR-2015 to Unknown	03-MAY-2015 03-MAY-2015 03-MAY-2015	Fire breaks out on the charger: gets injured / was hurt Recovered/Resolved by debris [INJURY ASSOCIATED WITH DEVICE] Y / Y / Y get something stuck in to his hand / his hand was smeared with ash / burned issue [THERMAL BURN] Y / Y / Y Fire breaks out on the charger: gets injured [DEVICE BATTERY ISSUE] N / Y / N	

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
							the device pieces were physically damaged due to external causes, including dismantling of the charger and of the battery [DEVICE DAMAGE] N / Y / N the device pieces were physically damaged due to external causes, including dismantling of the charger and of the battery [DEVICE USE ERROR] N / Y / N	
			Case Initial Receipt Date: 03-May-2015 Case Followup Receipt Date: 14-May-2015 00:00 21-May-2015 00:00 18-Apr-2016 00:00 Event Stop Date: 04-MAY-2015 04-MAY-2015 04-MAY-2015 Case Comment Text: The Injury associated with device and Thermal burn were assessed as serious (medically significant). The Device battery issue was assessed as non-serious.					
			Injury associated with device and Thermal burn are unlisted for THS 2.2 Regular or THS 2.2 Menthol, according to the Investigator Brochure.					
			The causality and listedness assessments are not applicable for Device battery issue.					
			There is limited information in this case. However, considering the temporal relationship and the knowledge about the product in question, the Company assesses the reported adverse events as related to the use of the THS 2.2 Regular and THS 2.2 Menthol.					
			Case Narrative: Verbatim: fire breaks out on the charger: gets injured					
			Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).					
			INITIAL INFORMATION RECEIVED ON 03-May-2015: This report concerns a 40-year-old male subject (Respondent Study ID: 1410947) who took part in the above mentioned market research study.					
			No medical history and no concomitant medications were reported.					
			No information on smoking habits was provided.					
			The respondent started using the Tobacco Heating System (THS) 2.2 on an unspecified date (reported as 24-May-2015 which is subsequent to report date, therefore, most likely, 24-Apr-2015). According to the information received, the respondent used both products, THS 2.2 Regular (Genebra / Fitz) and THS 2.2 Men hol (Dorado I / Vinny low menthol) (Kit numbers not provided).					
			On 03-May-2015, the respondent experienced fire breaking out of the charger and got injured (not further specified). The events were considered to be non-serious. Severity of the adverse events was not reported.					
			Action taken with the use of the product was not reported.					
			At the time of reporting, the outcome of the events was not reported.					
			Follow-up information is expected.					
			FOLLOW-UP INFORMATION RECEIVED ON 14-MAY-2015:					

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Clarification was received that the respondent used two study products (THS 2.2 Regular (Genebra / Fitz) and THS 2.2 Menthol (Dorado I / Vinny low menthol)) with a start date of 24-Apr-2015. It was not specified with which one of the products the event occurred.</p> <p>No further information on the type of injury was received.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 21-MAY-2015:</p> <p>The device kit number WL9 L4K MN7 RSY was provided (not specified if it is for Menthol or Regular).</p> <p>The respondent mentioned that "he was hurt by debris of something", that "he got something stuck into his hand" (not further explained) and that he went to the emergency room due to his problem. He further clarified that "what he described as something stuck into his hand was because his hand was smeared with ash (but didn't explain more about the burned issue)".</p> <p>Regarding the charger, it was reported that the charger caught fire, and possibly exploded. It was also mentioned that "He dropped charger (the holder was in it) on the floor during they were charging. He also told that the holder was too hot because he dropped holder on the floor." It was not clearly explained if the charger was dropped before or after the injury occurred.</p> <p>The event improved when use of the product was stopped, and the product was not restarted.</p> <p>The outcome of the events was indicated as resolved on 04-May-2015.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 18-APR-2016:</p> <p>A technical investigation had been conducted. It appeared that the device pieces were physically damaged due to external causes, including dismantling of the charger and of the battery.</p> <p>No further information is expected. Case closed.</p>								
PMI000365	UNITED STATES Report From Study	43 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [qd]	Respiratory	15-OCT-2015 to (b) (6)	(b) (6)	Health related problem requiring hospitalization / in hospital [HOSPITALISATION] Y / Y / N	Recovered/Resolved
<p>Case Initial Receipt Date: 30-Oct-2015</p> <p>Case Followup Receipt Date: 12-Nov-2015 00:00</p> <p>Event Stop Date: 29-OCT-2015</p> <p>Case Comment Text: Hospitalization was assessed as serious.</p> <p>Hospitalization is unlisted for THS 2.2 Menthol, as per Reference Safety Information (i.e. IB).</p> <p>Hospitalisation is not an adverse event per se. In this case, the reason for hospitalisation, which would potentially be the actual adverse event, was vaguely provided as health problems, which were assessed by the reporter as being not related to the product in question. The information provided in this report with regard to the medical history, relevant investigations, and treatment received during hospitalisation, is also limited. Based on reporter's causality assessment, the Hospitalisation is assessed as not related to the use of THS 2.2 Menthol, in this patient, who had been a smoker of conventional cigarettes.</p> <p>Case Narrative: Verbatim: Health related problem requiring hospitalization; in hospital.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 30-Oct-2015 and forwarded to Safety department on the same day.</p> <p>This report concerns a 43-year-old male subject (Respondent Study ID: 209653) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent was a daily smoker (approximately 8 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number W834WAQ1LAN4) on 15-Oct-2015.</p> <p>On (b) (6), the study respondent was hospitalized for health-related reasons. As per reporter, the hospitalization was not related to the product.</p> <p>On 29-Oct-2015, the event resolved (hospital discharge date not provided).</p> <p>The hospitalization (underlying reason not reported) was considered as serious.</p> <p>The consumer used the Heatstick every day. The use of the IQOS device was stopped on 22-Oct-2015. The study respondent used 4 Heatsticks and 7 conventional cigarettes on the day of the event. It was reported that the event did not improve when usage of the product was stopped, and that the event did not return when usage of the product was restarted. A re-start date was indicated for usage of the product.</p> <p>Further information is expected.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 12-Nov-2015 and forwarded to Safety department on 13-Nov-2015.</p> <p>Three follow-up attempts were performed, unsuccessfully. No additional information was provided.</p> <p>No further information is expected. Case Closed.</p>							
PMI000367	UNITED STATES	51 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	09-SEP-2015 to 28-OCT-2015	(b) (6)	was in an accident; a 400 lb table slid down her leg pushing her into a garden bed where there were some rocks and she fell [ACCIDENT] Y / Y / Y	Unknown
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	09-SEP-2015 to 28-OCT-2015	(b) (6)	injured her left leg and foot, the bone had been smashed (in an accident); received intravenous antibiotics, a tetanus shot, and leg staples [LIMB INJURY] Y / Y / Y	
					16-SEP-2015	injured her left leg and foot, the bone had been smashed (in an accident) [SKELETAL INJURY] Y / Y / Y Participant stated her foot is infected and that the infection had gotten into the bone [OSTEOMYELITIS] Y / Y / Y the nerves are dead and there is no flow (NOS) [NERVE INJURY] Y / Y / Y	
<p>Case Initial Receipt Date: 02-Nov-2015</p> <p>Case Followup Receipt Date: 10-Nov-2015 00:00</p> <p>Event Intensity: Severe Severe Severe Severe Severe</p> <p>Event Stop Date: (b) (6)</p>							

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Case Comment Text: The Accident, Limb injury, Lower limb fracture, Osteomyelitis, and Nerve injury were assessed as serious, due to requiring hospitalization.								
Accident, Limb injury, Lower limb fracture, Osteomyelitis, and Nerve injury are unlisted for THS 2.2 Menthol and THS 2.2 Regular, as per the Reference Safety Information (i.e. the IB).								
Considering the circumstances provided in this report, the Accident and the ensuing adverse events (i.e. Limb injury, Lower limb fracture, Osteomyelitis, Nerve injury) are assessed as not related to the use of the products, in this patient, who had been a smoker of conventional cigarettes.								
Case Narrative: Verbatim: was in an accident; a 400 lb table slid down her leg pushing her into a garden bed where there were some rocks and she fell / injured her left leg and foot, the bone had been smashed (in an accident); received intravenous antibiotics, a tetanus shot, and leg staples / Participant stated her foot is infected and that the infection had gotten into the bone / the nerves are dead and there is no flow (NOS)								
Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.								
INITIAL INFORMATION RECEIVED ON 2-Nov-2015 and forwarded to Safety department on the same day.								
This report concerns a 51-year-old female subject (Respondent Study ID: 654390) who took part in the above mentioned market research study.								
No medical history was reported. No concomitant medications were reported.								
The respondent was a daily smoker (approximately 10 - 20 conventional cigarettes per day).								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) and THS 2.2 Regular (Dorado II / Ron) (kit number JXT0TVB1ZHS6) on an unknown date.								
The respondent stated that she was in an accident on (b) (6). Her left leg and foot were injured and the bone had been smashed. She was hospitalized on an unknown date. On an unknown date, she had been released from the hospital, had been bed-ridden for 3 weeks, and had gone back to work on 8-Oct-2015. On (b) (6) she was hospitalized for the second time. She stated her foot was infected and that the infection had gotten into the bone, further stating that it was probably infected from the beginning. She also stated the nerves were dead, there was no flow and they will be doing who-knows how many surgeries. She stated that she would be in the hospital at least 4 months and that she was on a lot of medications. The study respondent requested to be withdrawn from the study.								
The events severity was reported as severe. The events were assessed as serious due to hospitalization.								
The respondent used the Heatsticks every day. No information was provided regarding the number of Heatsticks and cigarettes used by the respondent on the day of the event. Last day of product usage was indicated as 28-Oct-2015.								
At time of reporting, the outcome of the events was unknown; however, the respondent was in hospital at time of reporting.								
Further information is expected.								
FOLLOW-UP INFORMATION was received on 10-Nov-2015 and forwarded to the Safety department on 13-Nov-2015.								
The recipient stated that she was unsure of when she started to use the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) and THS 2.2 Regular (Dorado II / Ron) (kit number JXT0TVB1ZHS6) but she felt that it may have been around 09-SEP-2015.								
She stated that it was a wonderful morning (70 degrees), she was at work, when a 400 lb table slid down her leg pushing her into a garden bed where there were some rocks and she fell. She mentioned that she was unsure of what exactly happened.								
The respondent stated that, after the accident, one of her supervisors or somebody at her work that was in a position of responsibility drove her to the hospital on (b) (6). Once at the hospital, the respondent stated that she was not formally admitted, but spent a few hours in the emergency room (ER) where she received intravenous antibiotics, a tetanus shot, and								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>leg staples. On the same day, after being released from the ER, she was able to walk around and went to the mall site to explain her situation. The respondent stated that, since her release from the ER, her condition worsened and she was admitted to the hospital; she was unsure of the date, but that she believed it was about two Wednesdays prior to reporting date. She was currently still in the hospital.</p> <p>The respondent stated that the events were still ongoing as of 10-Nov-2015.</p> <p>No additional information was provided. The respondent refused to provide any more information. She wanted to know why these questions were asked stating that they sound like questions that a lawyer may ask. She stated that she was unwilling to provide these answers until she gets her explanation. The respondent stated that she is willing to be called back.</p> <p>Further information is expected.</p>								
PMI000381	UNITED STATES Report From Study	57 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	01-OCT-2015 to Unknown	(b) (6) 5 OCT-2015 (b) (6) (b) (6) 2015	<p>he was in a fight during which he was hit over the head with a baseball bat and a 2x4 [HEAD INJURY] Y / Y / Y</p> <p>Since that incident occurred, he has been having dizzy spells and blacking out due to low blood pressure [HYPOTENSION] N / Y / Y</p> <p>Since that incident occurred, he has been having dizzy spells and blacking out due to low blood pressure [LOSS OF CONSCIOUSNESS] N / Y / Y</p> <p>Since that incident occurred, he has been having dizzy spells and blacking out due to low blood pressure [DIZZINESS] N / N / Y</p> <p>device had broken [DEVICE DEFECTIVE] N / Y / N</p>	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 09-Nov-2015 Case Followup Receipt Date: 23-Nov-2015 00:00 Event Intensity: Moderate Moderate Moderate Moderate</p> <p>Case Comment Text: The Head injury was assessed as serious, due to requiring hospitalization. The Hypotension, Loss of consciousness, Dizziness, and Device defective were assessed as non-serious, based on the provided information.</p> <p>Head injury, Hypotension, and Loss of consciousness (described as blackout) are considered unlisted, as per the Reference Safety Information (i.e. the IB). Dizziness is listed, as per the IB.</p> <p>Listedness and causality assessments are not applicable for Device defective.</p> <p>The information provided in this non-medically confirmed report is limited. It was reported that the Head injury was the results of a blow to the head sustained during a fight. Therefore, the Head injury is assessed as not related to the use of Tobacco Heating System (THS) 2.2. Although Hypotension, Loss of consciousness, and Dizziness were reportedly following the Head injury, and despite their persistence even after stopping the use of product (due to Device defective), considering the current knowledge on the product in question, the causality relationship between the use of THS 2.2 and Hypotension, Loss of consciousness, and Dizziness cannot be excluded and, therefore, is assessed as related.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: he was in a fight during which he was hit over the head with a baseball bat and a 2x4 and ended up in the hospital / since hat incident occurred he has been having dizzy spells and blacking out due to low blood pressure / device had broken</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 09-Nov-2015 and forwarded to Safety department on he same day.</p> <p>This report concerns a 57-year-old male subject (Respondent Study ID: 821416) who took part in the above mentioned market research study.</p> <p>The following medical history was reported: back broken, low blood platelets, glaucoma, degenerative rheumatoid arthritis, fractured right knee cap, broken teeth, eye problems (additional information not provided).</p> <p>The respondent was a daily smoker (approximately 15 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number 5U85BNX8J7JR) on 01-Oct-2015.</p> <p>The respondent stated that, (b) (6), he was in a fight during which he was hit over the head with a baseball bat and a 2x4 and ended up in the hospital on the same day. The respondent stated he was in the hospital for 4 days. Following that incident, he went to the enrolment center to pick up a replacement device. While waiting for the replacement he reported he felt asleep and attributed the fact that he felt asleep to having low blood pressure and the recent hospitalization/fight, date unknown. Since hat incident occurred, he has been having dizzy spells and blacking out due to low blood pressure (as per reporter).</p> <p>The events severity was reported as moderate. The events were assessed as serious due to hospitalization.</p> <p>He used 15 cigarettes on the day of the event however the respondent did not remember about the number of Heatsticks used.</p> <p>The event improved when usage of the product was stopped and product was not restarted. Respondent stated he liked the device but that his device had broken. Due to device being broken he has not resumed use.</p> <p>At time of reporting, the events were not resolved.</p> <p>Further information is expected.</p> <p>NOTE:</p> <p>New information received on 23-Nov-2015. 3 unsuccessful follow-up attempts were made on 19-Nov-2015, 20-Nov-2015, 23-Nov-2015 respectively. No further information is expected. Case closed.</p>								
PMI000404	UNITED STATES Report From Study	48 Years Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK] 1 DF [1 DF-qd]	Respiratory	OCT-2015 to OCT-2015	2015	she was diagnosed with both Acute Bronchitis and a double ear infection [BRONCHITIS] Y / Y / Y	Recovered/Resolved
				Respiratory	2015 Ongoing	2015	she was diagnosed with both Acute Bronchitis and a double ear infection [EAR INFECTION] Y / Y / Y	
						OCT-2015	nerve damage pain in her hands [NERVE INJURY] N / Y / N	
						OCT-2015	nerve damage pain in her hands [NEURALGIA] N / Y / N	

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
						OCT-2015	She stated that after the neck surgery, her hand and arm pain was so severe it hurt to touch anything, making it difficult and painful to use the IQOS holder/arm and hand pain when using the holder [HYPERAESTHESIA] N / Y / N	
						2015	inhaling smoke from a fire that occurred when a cement truck caught on fire near her house; inhaling metal and chemicals from the fire [RESPIRATORY FUME INHALATION DISORDER] N / Y / N	
						2015	She stated that after the neck surgery, her hand and arm pain was so severe it hurt to touch anything, making it difficult and painful to use the IQOS holder/arm and hand pain when using the holder [DEVICE DIFFICULT TO USE] N / Y / N	
<p>Case Initial Receipt Date: 21-Nov-2015 Case Followup Receipt Date: 23-Dec-2015 00:00 Event Intensity: Severe Severe Unknown Severe Moderate Moderate Event Stop Date: OCT-2015 OCT-2015 OCT-2015 21-NOV-2015 21-NOV-2015 Case Comment Text: The Bronchitis and Ear infection were conservatively assessed as serious, due to the reported visit to hospital and required antibiotic treatment (i.e. medically important intervention).</p> <p>Nerve injury, Neuralgia, Hyperaesthesia, Respiratory fume inhalation disorder, and Device difficult to use were assessed as non-serious.</p> <p>Bronchitis, Ear infection, Nerve injury, Neuralgia, Hyperaesthesia, Respiratory fume inhalation disorder, and Device difficult to use are unlisted, as per the Reference Safety Information for THS 2.2 Regular (i.e. the IB).</p> <p>The information provided in this non-medically confirmed report is limited and unclear, particularly regarding the relevant medical history, respective adverse events' onset and resolution dates.</p> <p>Although the Bronchitis and Ear infection were diagnosed after reportedly inhaling smoke with chemicals from a fire occurred near her house, the causal relationship between the use of THS 2.2 and these two adverse events cannot be completely ruled out and, therefore, is assessed as possible. Of note, the subject, who had been a smoker of conventional cigarettes, used the product in question only occasionally. Although she continued to use the product during her acute bronchitis and ear infection, these adverse events resolved.</p> <p>The Nerve injury, Neuralgia, and Hyperaesthesia associated with Device difficult to use were reported as consequences of a traffic accident and its treatment (neck surgery). Therefore, these events are assessed as not related to the use of THS 2.2. Of note, these events have also resolved, despite the continued usage of the product.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: she was diagnosed with both acute bronchitis and a double ear infection; hand and arm pain was so severe it hurt to touch anything; nerve damage pain in her hands; inhaling smoke from a fire; difficult and painful to use the IQOS holder/arm and hand pain when using the holder</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 21-Nov-2015 and forwarded to Safety department on 21-Nov-2015.</p> <p>This report concerns a 48-year-old female subject (Respondent Study ID: 656993) who took part in the above mentioned market research study.</p> <p>Medical history of hepatitis C was reported. It was also reported that in Oct-2015 he respondent had neck surgery related to injuries resulting from being hit by a drunk driver in 2014. The following concomitant medications were reported: Erythromycin, Celexa (citalopram hydrobromide) 10mg, low dosage of Aspirin (acetylsalicylic acid), Topamirate, Xanax (alprazolam) 0.25mg and a hair/skin/nails vitamin.</p> <p>The respondent was a daily smoker (approximately 1 to 7 conventional cigarettes per week).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number 4YDU57Q4UMSB) in early Oct-2015.</p> <p>The respondent stated that in October 2015 she had neck surgery related to injuries resulting from being hit by a drunk driver in 2014 which caused her to experience nerve damage pain in her hands. She stated that after the neck surgery, her hand and arm pain was so severe it hurt to touch anything, making it difficult and painful to use the IQOS holder. At that time, she stopped using the IQOS holder and she could not give an exact date as to when she stopped but stated it was sometime in October, before Halloween.</p> <p>After receiving a call from the enrollment center sometime after stopping use of the heatsticks, she resumed use of the device, so she could remain a participant in the study. At that time, she stated she was no longer experiencing the hand and arm pain (exact date not reported).</p> <p>The respondent stated that approximately two or three weeks prior to the date of this report, she went to the hospital after inhaling smoke from a fire that occurred when a cement truck caught on fire near her house. She stated she began coughing up phlegm and mucus after inhaling metal and chemicals from the fire and she stated she ended up going to the hospital. She stated she was diagnosed with both acute bronchitis and a double ear infection which required antibiotics. She said she was trying not to smoke because of the infections but continued to use her IQOS device and to use approximately one heatstick per day. Respondent stated that on the day of the report, it was the first day she felt better.</p> <p>The severity was reported as moderate for the events of acute bronchitis and double ear infection and as severe for hand and arm pain (not reported for the other events). The events acute bronchitis and double ear infection were assessed as serious. The remaining events were assessed as non-serious.</p> <p>The respondent used the heatsticks occasionally. She mentioned that she used HeatSticks every day until arm/hand pain began when using the holder, then she began using 0-1 Heatsticks a day after starting use of the product again. Numbers of Heatsticks and cigarette used on the day of the events are unknown.</p> <p>It was reported that the events of hand/arm pain improved when usage of the product was stopped and did not return when usage of the product was restarted (not specified for the other events). She continued to use Heatsticks during her acute bronchitis/double ear infection. The last day of product use was reported as unknown.</p> <p>The event of hand and arm pain resolved in Oct-2015. The events of ear infection and acute bronchitis resolved on 21-Nov-2015. The outcome of the other events was not reported.</p> <p>No further information is expected.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000409	UNITED STATES Report From Study	36 Years Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	Unknown to (b) (6)	(b) (6) OCT-2015	developed cyst on throat / cyst at tonsils / cyst at palatine tonsils / surgery on tonsils [TONSILLAR CYST] Y / Y / Y seasonal sore hroat [OROPHARYNGEAL PAIN] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 25-Nov-2015 Case Followup Receipt Date: 09-Nov-2015 00:00 23-Dec-2015 00:00 Event Intensity: Unknown Case Comment Text: The Tonsillar cyst was assessed as serious (medically important, requiring drainage). The Oropharyngeal pain was assessed as non-serious.</p> <p>Tonsillar cyst is unlisted, whereas Oropharyngeal pain is listed, as per the Reference Safety Information (i.e. he IB).</p> <p>The information provided in this non-medically confirmed report is limited. The temporal relationship cannot be accurately assessed, as the product usage start date was not provided. Judging by the pharmacological treatment (i.e. unspecified antibiotics) administered for the Tonsillar cyst, one may deduce that it was infectious cyst, which may had been associated with the reported seasonal sore throat. Considering the current knowledge on the product in question, the causality relationship between the use of THS 2.2 and Tonsillar cyst and Oropharyngeal pain cannot be excluded and, therefore, is assessed as related. Of note, the subject had been a smoker of conventional cigarettes.</p> <p>Case Narrative: Verbatim: developed cyst on throat / cyst at tonsils / cyst at palatine tonsils/ surgery on tonsils; seasonal sore throat</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 25-Nov-2015 and forwarded to Safety department on the same day.</p> <p>This report concerns a 36-year-old female subject (Respondent Study ID: 184377) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medication were reported. The respondent denied any other medical conditions within the last year.</p> <p>The respondent was a daily smoker (approximately 8 conventional cigarettes per day, 2.5-3 packs per week).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) on an unknown date. The respondent did not remember when she started using the product.</p> <p>The respondent stated that, 2-3 days before the 23-Oct-2015 or the 24-Oct-2015, the onset of symptoms began (also reported as 23-Oct-2015). These symptoms were described as what the respondent thought was seasonal sore throat. She went to the hospital on the (b) (6) or (b) (6) the respondent is unsure (call was disconnected before it was confirmed if she was hospitalized or if she went to emergency room). On the 23-Oct-2015 or 24-Oct-2015, at the hospital, a cyst at palatine tonsils was found. Follow-up appointment with personal physician 3-4 days after the hospitalization confirmed the diagnosis.</p> <p>At hospital, drainage of cyst at tonsils and a biopsy were performed. Percocet (acetaminophen, oxycodone) treatment for pain and unknown antibiotic medication were administered to the respondent. At personal doctor, Percocet (acetaminophen, oxycodone) treatment for pain and unknown antibiotic medication (that was different than the one used at the hospital) were administered to the respondent (call disconnected before able to confirm route of antibiotics, dosage of medications).</p> <p>The event severity was not reported. The event required medical advice and treatment. The event was assessed as non-serious.</p> <p>The smoking status of the respondent with the heatstick was not reported. The number of Heatstick and cigarette used by the respondent on the day of the event was unknown.</p> <p>The use of the product was stopped on 24-Oct-2015.</p>								

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>At time of the report, the event was not recovered. Condition was ongoing with upcoming follow-up to drain remaining fluid.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 09-NOV-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>Surgery on tonsils was reported (no further information provided).</p> <p>No further information is expected. Case closed.</p>							
PMI000410	UNITED STATES Report From Study	46 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	19-OCT-2015 to Unknown	(b) (6) had been hospitalized during the observation period (health problem) [ADVERSE EVENT] Y / Y / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 30-Nov-2015 Case Followup Receipt Date: 11-Dec-2015 00:00 Event Stop Date: 06-NOV-2015 Case Comment Text: The unspecified Adverse event was assessed as serious (due to hospitalization).</p> <p>Adverse event (not further unspecified, in this report) is considered unlisted for THS 2.2 Menthol, as per the Reference Safety Information (i.e. Investigator's Brochure).</p> <p>The information provided in this report is limited, particularly regarding to the patient's unspecified health problem, the reason and dates of hospitalisation, and the action taken with the product. However, considering the plausible temporal relationship, a causal relationship between the use of THS 2.2 Menthol and the reported event cannot be excluded and, therefore, is assessed as possible.</p> <p>Case Narrative: Verbatim: had been hospitalized during the observation period (health problem)</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 30-Nov-2015 and forwarded to Safety department on 02-Dec-2015.</p> <p>This report concerns a 46-year-old male subject (Respondent Study ID: 759911) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medication were reported.</p> <p>The respondent was a daily smoker (approximately 8 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) kit number 7JUFE86NJOKL) on 19-Oct-2015.</p> <p>The respondent stated that he had been hospitalised during the observation period. The respondent experienced a health problem (not further specified) from (b) (6) to 06-Nov-2015. No further information was provided.</p> <p>The event severity of the adverse event was not reported. The case was assessed as serious due to the hospitalisation.</p> <p>The smoking habits related to the heatstick was not reported. The respondent used 2 Heatsticks and 8 cigarettes on the day of the event (presumably, the unknown event which caused the hospitalisation, occurring on (b) (6)).</p> <p>No information was provided about the action taken with the product.</p> <p>The unspecified health problem resolved on 06-Nov-2015.</p>							

CUM LL All Cases Pre-Marketing All THS Menthol
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
			Daily Dose [Dose Frequency]	Route				
Follow-up information was expected, however, all attempts to obtain additional information from the respondent were unsuccessful. Case closed.								

Total number of case entries printed: 96

Total number of cases printed: 96

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Advanced Condition used in this report:

Advanced Condition: THS Menthol D1 Vinny Low Menthol and Vinny / Ron (Created by nicole.miller)

Query Set Selection Criteria:

Report From Study/Other Studies INTERSECT

Ingredient Vinny/Ron and D1 Vinny Low Menthol MINUS

Minus Cases PMI000137 & PMI000150

Advanced Conditions used in this query set:

Advanced Condition: Report From Study/Other Studies (Created by nicole.miller)

Selection Criteria:

(Case Report Type equal to Report From Study AND

Observe Study Type equal to Other Studies)

Advanced Condition: Ingredient Vinny/Ron and D1 Vinny Low Menthol (Created by nicole.miller)

Selection Criteria:

Ingredient equal to Vinny/Ron (half white tipping paper) OR

Ingredient equal to D1 Vinny Low Menthol

Advanced Condition: Minus Cases PMI000137 & PMI000150 (Created by nicole.miller)

Selection Criteria:

Case Number equal to PMI000137 OR

Case Number equal to PMI000150

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No (79)							
PMI000005	ITALY Report From Study	45 Years Female	THS 2.2 Menthol (Vinny / Respiratory Ron) / N/A UNK [UNK]			the smell sometimes is unpleasant [PRODUCT ODOUR ABNORMAL] N / Y / Y the menthol taste makes me cough [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 04-Dec-2014</p> <p>Case Narrative: Verbatim: The menthol taste makes me cough. The smell sometimes is unpleasant.</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 45-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the menthol taste makes her cough. The smell sometimes is unpleasant. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000011	ITALY Report From Study	25 Years Female	THS 2.2 Menthol (Vinny / Respiratory Ron) / N/A UNK [UNK]			the menthol taste of the tobacco gave me throatache [OROPHARYNGEAL PAIN] N / N / Y Smoking is uncomfortable / the device is not comfortable to keep in hand [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 04-Dec-2014</p> <p>Case Narrative: Verbatim: The menthol taste of the tobacco gave me throatache; smoking is uncomfortable, the device is not comfortable to keep in hand.</p> <p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 04-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 25-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p>							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the menthol taste of the tobacco gave her throat ache. In addition the respondent stated that smoking is uncomfortable. The device is not comfort hand and you cannot smoke indoors. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000019	ITALY Report From Study	45 Years Female	THS 2.2 Menthol (Vinny / Respiratory Ron) / N/A UNK [UNK] Case Initial Receipt Date: 07-Jan-2015 Case Narrative: Verbatim: I prefer my classic cigarettes. They have a better taste and stay lit until the end, and they did not give me throat ache			Throat ache [OROPHARYNGEAL PAIN] N / N / Y	Unknown
<p>Market Research Study P1_WOT2_IT: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 07-JAN-2015 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 45-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she preferred her classic cigarettes, they had a better taste and they stayed lit until the end and they did not give her throat ache. The event considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000021	SWITZERLAND Report From Study	54 Years Female	THS 2.2 Menthol (Vinny / Respiratory Ron) / N/A UNK [UNK] Case Initial Receipt Date: 31-Oct-2014 Case Narrative: Verbatim: In the beginning I had to cough, later better			in the beginning I had to cough, later better [COUGH] N / N / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 31-OCT-2014 and transferred to safety department on 18-MAR-2015:</p>							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 54-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that in the beginning she had to cough, later it was better. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000023	SWITZERLAND Report From Study	53 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK]	Respiratory			smoky-scratchy taste in the throat [DYSGEUSIA] N / Y / Y I was coughing [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 31-Oct-2014 Case Narrative: Verbatim: I was coughing, smoky-scratchy taste in the throat</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 31-OCT-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 53-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she was coughing and had a smoky-scratchy taste in the throat. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000027	SWITZERLAND Report From Study	23 Years Male	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 15-Nov-2014 Case Narrative: Verbatim: I exercise and have more energy by using the Heat Sticks	Respiratory		I exercise and have more energy by using the Heat Sticks [ENERGY INCREASED] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 23-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that he exercises and has more energy by using the Heat Sticks. The event was considered to be non-serious (intensity not provided). In addition, the also mentioned that one gets used to the menthol taste, and it settles not as badly in the lungs.</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000030	SWITZERLAND Report From Study	29 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 15-Nov-2014 Case Narrative: Verbatim: I got a very strong cough.	Respiratory		I got a very strong cough [COUGH] N / N / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 29-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that she got a very strong cough. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p>							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000033	SWITZERLAND Report From Study	26 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 15-Nov-2014 Case Narrative: Verbatim: Had to cough.	Respiratory		I had to cough [COUGH] N / N / Y	Unknown
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 15-NOV-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 26-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent stated that she had to cough. The event was considered to be non-serious (intensity not provided).							
Action taken with the product was not reported.							
At the time of reporting, the outcome of the event was unknown.							
No follow-up information is expected ? case closed.							
PMI000038	SWITZERLAND Report From Study	59 Years Male	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: throat-ache.	Respiratory		throat-ache [OROPHARYNGEAL PAIN] N / N / Y	Unknown
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.							
INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:							
This report concerns a 59-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.							
No medical conditions and concomitant medications were reported.							
No information was provided on the use of conventional cigarettes.							
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							
The respondent reported throat ache. The event was considered to be non-serious (intensity not provided). In addition, the respondent mentioned a better taste (no further i							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
			provided).				
			Action taken with the product was not reported.				
			At the time of reporting, the outcome of the event was unknown.				
			No follow-up information is expected ? case closed.				
PMI000039	SWITZERLAND Report From Study	49 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: it gives me headache.	Respiratory		it gives me headache [HEADACHE] N / N / Y	Unknown
			Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.				
			INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:				
			This report concerns a 49-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.				
			No medical conditions and concomitant medications were reported.				
			No information was provided on the use of conventional cigarettes.				
			The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.				
			The respondent stated that it gives her headache. The event was considered to be non-serious (intensity not provided). In addition, the respondent mentioned that as she does much, it is not convenient re-charge each time.				
			Action taken with the product was not reported.				
			At the time of reporting, the outcome of the event was unknown.				
			No follow-up information is expected ? case closed.				
PMI000048	SWITZERLAND Report From Study	59 Years Male	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: Coughing with HeatSticks.	Respiratory		coughing with heatsticks [COUGH] N / N / Y	Unknown
			Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.				
			INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:				
			This report concerns a 59-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.				
			No medical conditions and concomitant medications were reported.				

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported coughing with heatsticks. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000054	SWITZERLAND Report From Study	39 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A Respiratory UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: the taste is more enjoyable and I was coughing less.			I was coughing less [COUGH] N / N / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 39-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the taste was more enjoyable and she was coughing less. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000055	SWITZERLAND Report From Study	22 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A Respiratory UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: the taste scratches my throat a bit too strongly			The taste scratches my throat a bit too strongly [THROAT IRRITATION] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 22-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p>							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the taste scratches her throat a bit too strongly. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000057	SWITZERLAND Report From Study	48 Years Female	THS 2.2 Menthol (Vinny / Respiratory Ron) / N/A UNK [UNK]			even headache [HEADACHE] N / N / Y the heat stick tastes too bitter, burned taste [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: the heat stick tastes too bitter, burned taste, even headache.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 48-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the heat stick tastes too bitter, burned taste. The respondent also reported "even headache" . The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000062	SWITZERLAND Report From Study	53 Years Male	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: I got sick from the menthol cigarettes.	Respiratory		I got sick from he menthol cigarettes [MALAISE] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 53-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that he got sick from the menthol cigarettes. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000065	SWITZERLAND Report From Study	30 Years Male	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: the menthol taste suits me but not what stays in the throat after.	Respiratory		The menthol taste suits me but not what stays in the throat after [DYSGEUSIA] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 30-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the menthol taste suits him but not what stays in the throat after. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p>							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information is expected ? case closed.							
PMI000066	SWITZERLAND Report From Study	43 Years Female	THS 2.2 Menthol (Vinny / Respiratory Ron) / N/A UNK [UNK]			caused nausea with me [NAUSEA] N / N / Y smells very unpleasent and bitter [PRODUCT ODOUR ABNORMAL] N / Y / N	Unknown
Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: Smells very unpleasant and bitter. Caused nausea with me. Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 43-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date. The respondent stated that the smell was very unpleasant and bitter and it caused nausea to her. The events were considered to be non-serious (intensity not provided). Action taken with the product was not reported. At the time of reporting, the outcome of the event was unknown. No follow-up information is expected ? case closed.							
PMI000070	SWITZERLAND Report From Study	34 Years Female	THS 2.2 Menthol (Vinny / Respiratory Ron) / N/A UNK [UNK]			was irritating the throat [THROAT IRRITATION] N / Y / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: was irritating the throat. Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 34-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent stated that it was irritating the throat. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000072	SWITZERLAND Report From Study	28 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: stays in the back of the throat even after drinking or eating			stays in the back of the hroat even after drinking or eating [DYSGEUSIA] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 28-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it stays in the back of the throat even after drinking or eating. The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000073	SWITZERLAND Report From Study	63 Years Male	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: too dense, and it itches the tongue after some cigarettes smoked.			too dense, it itches the tongue after several cigarettes smoked [TONGUE PRURITUS] N / Y / Y too dense, it itches the tongue after several cigarettes smoked [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 63-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p>							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it is too dense, and it itches the tongue after some cigarettes smoked. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000078	SWITZERLAND Report From Study	35 Years Male	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK]		13-NOV-2014	<p>The menthol taste made me sick. Too much refreshment. [MALAISE] N / Y / Y It stings [ORAL PAIN] N / Y / Y no more strength in the right leg for a few seconds up to 20 times a day [MUSCULAR WEAKNESS] N / Y / Y These cigarettes had a bad influence on my head. Head: light. [DIZZINESS] N / N / Y</p>	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: The menthol taste made me sick. Too much refreshment. The cleaning brush is not easy to unpack. These cigarettes had a bad influence on my head. Head: light. It stings (around 13. November) and no more strength in the right leg for a few seconds up to 20 times a day.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 35-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that the menthol taste made him sick. Too much refreshment. These cigarettes had a bad influence on his head. Head: light. The respondent also mentioned stings (around 13 November) and no more strength in the right leg for a few seconds up to 20 times a day. The events were considered to be non-serious (intensity not provided). In addition, the respondent mentioned that the cleaning brush is not easy to unpack.</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p>							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information is expected ? case closed.							
PMI000079	SWITZERLAND Report From Study	41 Years Female	THS 2.2 Menthol (Vinny / Respiratory Ron) / N/A UNK [UNK]			the smoking feels extremely unhealthy [MALAISE] N / Y / Y the holder is too hot [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: The burnt stick, the balancing of the holder, the holder is too hot, the smoking feels extremely unhealthy. Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 41-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date. The respondent stated that the smoking feels extremely unhealthy and the holder is too hot. The events were considered to be non-serious (intensity not provided). In addition, the respondent mentioned the burnt stick and the balancing of the holder (no additional information provided). Action taken with the product was not reported. At the time of reporting, the outcome of the events was unknown. No follow-up information is expected ? case closed.							
PMI000086	SWITZERLAND Report From Study	59 Years Male	THS 2.2 Menthol (Vinny / Respiratory Ron) / N/A UNK [UNK]			have to cough [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: have to cough, resolves during a break. Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1. INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015: This report concerns a 59-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study. No medical conditions and concomitant medications were reported. No information was provided on the use of conventional cigarettes. The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date. The respondent stated that he had to cough, it resolves during a break. The event was considered to be non-serious (intensity not provided).							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000087	SWITZERLAND Report From Study	26 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: Pain.	Respiratory		pain [PAIN] N / Y / Y	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 26-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported pain (not further specified). The event was considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the event was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000095	SWITZERLAND Report From Study	59 Years Male	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK] Case Initial Receipt Date: 01-Dec-2014 Case Narrative: Verbatim: problems with throat and coughing too bitter.	Respiratory		problems with throat [THROAT IRRITATION] N / Y / Y Coughing [COUGH] N / N / Y too bitter [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 59-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p>							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent reported problems with throat and coughing as well as too bitter. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000097	SWITZERLAND Report From Study	59 Years Male	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK]	Respiratory		have to cough [COUGH] N / N / Y s inks [PRODUCT ODOUR ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p> <p>Case Narrative: Verbatim: stinks, have to cough.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 59-year-old male subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it stinks and he has to cough. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>							
PMI000098	SWITZERLAND Report From Study	22 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK]	Respiratory		itches in the throat [THROAT IRRITATION] N / Y / Y makes me cough [COUGH] N / N / Y too strong in mouth [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>Case Initial Receipt Date: 01-Dec-2014</p>							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: too strong in the mouth, itches in the throat and makes me cough.</p> <p>Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.</p> <p>INITIAL INFORMATION RECEIVED ON 01-DEC-2014 and transferred to safety department on 18-MAR-2015:</p> <p>This report concerns a 22-year-old female subject (Respondent Study ID not reported) who took part in the above mentioned market research study.</p> <p>No medical conditions and concomitant medications were reported.</p> <p>No information was provided on the use of conventional cigarettes.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date.</p> <p>The respondent stated that it is too strong in the mouth, itches in the throat and makes her cough. The events were considered to be non-serious (intensity not provided).</p> <p>Action taken with the product was not reported.</p> <p>At the time of reporting, the outcome of the events was unknown.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000100	KOREA, REPUBLIC OF Report From Study	54 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [1 -UNK]	Respiratory	10-APR-2015 to 12-APR-2015	10-APR-2015 10-APR-2015	I am not sure if it is because of the bitter taste of HeatSticks, but since I started using the product, the dizziness has lingered uncomfortably and is gone after 30 to 40 minutes. [DIZZINESS] N / N / Y I am not sure if it is because of the bitter taste of HeatSticks, but since I started using the product, the dizziness has lingered uncomfortably and is gone after 30 to 40 minutes. [PRODUCT TASTE ABNORMAL] N / Y / N	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 13-Apr-2015</p> <p>Event Intensity: Mild Mild</p> <p>Case Narrative: Verbatim: I am not sure if it is because of the bitter taste of HeatSticks, but since I started using the product, the dizziness has lingered uncomfortably and is gone after</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 13-Apr-2015:</p> <p>This report concerns a 54-year-old male subject (Respondent Study ID: 1220779) who took part in the above mentioned market research study.</p> <p>No medical history was reported. 'Hepatitis drug' (not further specified) was reported as concomitant medication.</p> <p>The respondent was a daily smoker (10-15 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number C9h FW15 RH5 6N4) on 10-Apr-2015 and used the product occasionally.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>On the same day (10-Apr-2015), the respondent experienced dizziness. He reported that he was not sure if it was because of the bitter taste of HeatSticks, but since he started using the product, the dizziness had lingered uncomfortably and was gone after 30 to 40 minutes. The events were considered to be non-serious. Severity criterion was reported as mild.</p> <p>On the day of the event, the respondent used one Heatstick and smoked 10 conventional cigarettes.</p> <p>The use of the product was discontinued on 12-Apr-2015.</p> <p>It was reported that the problem improved when usage of the product was stopped, and that the product was not restarted.</p> <p>However, at the time of reporting, the outcome of the events was reported as not recovered.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000102	KOREA, REPUBLIC OF Report From Study	46 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	16-APR-2015 to Unknown	16-APR-2015 16-APR-2015	After taking it, the throat was unpleasant, dry, not soft, and harsh [DRY THROAT] N / Y / Y After taking it, the throat was unpleasant, dry, not soft, and harsh [THROAT IRRITATION] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 16-Apr-2015 Case Narrative: Verbatim: After taking it, the throat was unpleasant, dry, not soft, and harsh.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 16-Apr-2015: This report concerns a 46-year-old male subject (Respondent Study ID: 1178724) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average, 15 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number provided: TEST) on 16-Apr-2015.</p> <p>The respondent stated that on the same day (16-Apr-2015), after taking it, the throat was unpleasant, dry, not soft, and harsh. The events were considered to be non-serious. Severity criterion was not provided.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000104	KOREA, REPUBLIC OF Report From Study	35 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	10-APR-2015 to Unknown	10-APR-2015	It is because he hasn' t smoked but started smoking all of a sudden [UNEVALUABLE EVENT] N / Y / Y	Recovered/Resolved
Case Initial Receipt Date: 10-Apr-2015 Event Stop Date: 10-APR-2015 Case Narrative: Verbatim: It is because he hasn' t smoked but started smoking all of a sudden. Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 10-Apr-2015: This report concerns a 35-year-old male subject (Respondent Study ID: 1101949) who took part in the above mentioned market research study. No medical history and no concomitant medications were reported. Information on smoking habits was not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number not provided) on 10-Apr-2015. On the same day (10-Apr-2015), it was reported that it was the respondent's first cigarette usage of the day and 'It is because he hasn' t smoked but started smoking all of The event was considered to be non-serious. Severity criterion not reported. It was reported that the problem improved when usage of the product was stopped. Action taken with the use of he product was not reported. The event resolved on the same day. Additional information is expected.								
PMI000106	KOREA, REPUBLIC OF Report From Study	41 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory			Felt dizzy after smoking HeatStick [DIZZINESS] N / N / Y Headache [HEADACHE] N / N / Y	Recovered/Resolved
Case Initial Receipt Date: 20-Apr-2015 Case Narrative: Verbatim: felt dizzy after smoking HeatStick. (headache) Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 20-Apr-2015: This report concerns a 41-year-old male subject (Respondent Study ID: 1157274) who took part in the above mentioned market research study. No medical history and no concomitant medications were reported. No information on smoking habits was provided. The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number KXZ CYJ FAX F4Y) on an unspecified date. On an unspecified date, just after taking the product, the respondent experienced dizziness after smoking the HeatStick and headache. The events were considered to be non-s								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
severity of the adverse events was not reported.								
Action taken with use of the product was not reported.								
At the time of reporting, the events were resolved.								
No follow-up information is expected ? case closed.								
PMI000110	KOREA, REPUBLIC OF Report From Study	47 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	25-APR-2015 to Unknown	25-APR-2015	Cough in inhalation [COUGH] N / N / Y	Unknown
Case Initial Receipt Date: 25-Apr-2015								
Case Narrative: Verbatim: After taking a testing product, said "cough in inhalation" in the middle of CLT (added) and also said "(the cough) may not result from this product, it's comm cough in smoking with cig vaporizer pen as its smoke flows in suddenly for the first puff."								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 25-Apr-2015:								
This report concerns a 47-year-old male subject (Respondent Study ID: 2353530) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
No information on smoking habits was provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number TFQF IJQ 53D OMA8) on 25-Apr-2015.								
On the first day of use (25-Apr-2015), the respondent experienced cough in inhalation. The respondent mentioned that the cough might not result from this product. The event considered to be non-serious. The severity of the adverse event was not reported.								
Action taken with use of the product was not reported.								
At the time of reporting, the outcome of the event was not reported.								
No follow-up information is expected ? case closed.								
PMI000117	KOREA, REPUBLIC OF Report From Study	44 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	22-APR-2015 to Unknown	23-APR-2015 23-APR-2015	Throat is hurting [OROPHARYNGEAL PAIN] N / N / Y Has a little cold symptom [NASOPHARYNGITIS] N / N / Y	Not Recovered/Not Resolved
Case Initial Receipt Date: 28-Apr-2015								
Case Narrative: Verbatim: throat is hurting (has a little cold symptoms).								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 28-APR-2015:								
This report concerns a 44-year-old male subject (Respondent Study ID: 1467535) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information on smoking habits was provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number 60B-VWQ-6ZQ-8ET) on 22-Apr-2015.</p> <p>On the next day (23-Apr-2015), the respondent experienced hurting throat and had a little cold symptoms. The events were considered to be non-serious. Severity of the adverse events was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000133	KOREA, REPUBLIC OF Report From Study	47 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	04-MAY-2015 to Unknown	04-MAY-2015 04-MAY-2015	Feels stomach ache and headache [ABDOMINAL PAIN UPPER] N / Y / Y Feels stomach ache and headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 06-May-2015</p> <p>Case Narrative: Verbatim: feels stomach ache and headache.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 06-May-2015:</p> <p>This report concerns a 47-year-old male subject (Respondent Study ID: 2365564) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>No information on smoking habits was reported.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number HC5 166 FNO PW5) on 04-May-2015.</p> <p>On the same day (04-May-2015), the respondent felt stomach ache and headache. The events were considered to be non-serious. Severity of the adverse events was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the events was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000138	KOREA, REPUBLIC OF Report From Study	34 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	25-APR-2015 to Unknown	06-MAY-2015	Feels a twinge in inhaling because parts of gums (which had been treated before) become tightened [GINGIVAL PAIN] N / Y / Y	Not Recovered/Not Resolved
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	25-APR-2015 to Unknown			
			Case Initial Receipt Date: 11-May-2015 Event Intensity: Moderate Case Narrative: Verbatim: feels a twinge in inhaling because parts of gums (which had been treated before) become tightened. Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 11-May-2015: This report concerns a 34-year-old male subject (Respondent Study ID: 1463540) who took part in the above mentioned market research study. No concurrent medical history and no concomitant medications were reported. The respondent had a dental treatment for tooth decay the previous year. The respondent was a daily smoker (in average 20 cigarettes per day). The respondent started using both products, Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and THS 2.2 Menthol (Dorado I / Vinny low menthol) on 25-Apr-2015 (Kit WTL HUQ NCE PQL, not specified to which product it corresponds). On 06-May-2015, the respondent felt a twinge in inhaling because parts of gums (which had been treated before) became tightened. The respondent clarified that the pain last minutes and that he had no symptom when smoking regular cigarettes. The event was considered to be non-serious. Severity of the adverse event was reported as moderate. The product was used on weekdays, not on weekends. The use of the product was not discontinued due to the occurrence of the adverse event. It was reported that the event re when product was restarted. At the time of reporting, the event was not resolved. No follow-up information is expected ? case closed.					
PMI000139	KOREA, REPUBLIC OF Report From Study	31 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory		06-MAY-2015 06-MAY-2015	Pains and uneasy on throat when smoking in connecting with HeatStick; throat gets uncomfortable [LARYNGEAL DISCOMFORT] N / Y / Y Pains and uneasy on throat when smoking in connecting with HeatStick; throat gets uncomfortable [OROPHARYNGEAL PAIN] N / N / Y	Unknown
			Case Initial Receipt Date: 12-May-2015 Case Narrative: Verbatim: feels pains and uneasy on throat when smoking in connecting with HeatStick. My throat gets uncomfortable. Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1). INITIAL INFORMATION RECEIVED ON 12-May-2015: This report concerns a 31-year-old male subject (Respondent Study ID: 1253432) who took part in the above mentioned market research study.					

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number F6M U6R KB1 LAH) on an unspecified date.</p> <p>On 06-May-2015, the respondent experienced pain and uneasy feeling on the throat. The event was also described as throat getting uncomfortable and occurred when smoking "i connecting" with the HeatStick (presumably, when HeatSticks and conventional cigarettes are used together). The event was considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000140	KOREA, REPUBLIC OF Report From Study	37 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	15-APR-2015 to Unknown	25-APR-2015	My throat gets swollen. The phlegm comes out a lot. My throat gets swollen after using HeatStick altogether in the evening. [PHARYNGEAL OEDEMA] N / Y / Y	Not Recovered/Not Resolved
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	15-APR-2015 to Unknown	25-APR-2015	My throat gets swollen. The phlegm comes out a lot. My throat gets swollen after using HeatStick altogether in the evening. [PRODUCTIVE COUGH] N / Y / Y	
<p>Case Initial Receipt Date: 14-May-2015</p> <p>Event Intensity: Mild</p> <p>Case Narrative: Verbatim: My throat gets swollen. The phlegm comes out a lot. My throat gets swollen after using HeatStick altogether in the evening.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 14-May-2015: This report concerns a 37-year-old male subject (Respondent Study ID: 1218229) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using both products, the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number VXF KQM TGO, not specified to which product it corresponds) on 15-Apr-2015.</p> <p>On 25-Apr-2015, the respondent experienced swelling of throat after using HeatSticks altogether in the evening and phlegm coming out a lot. The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>It was reported that the events improved after product use was stopped and that the events returned when product was restarted.</p> <p>Action taken with the use of the product was unknown.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
At the time of reporting, the events were not resolved.								
No follow-up information is expected ? case closed.								
PMI000151	KOREA, REPUBLIC OF Report From Study	45 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	22-APR-2015 to Unknown	22-APR-2015	Dizzy when using the product with an empty stomach [DIZZINESS] N / N / Y	Unknown
Case Initial Receipt Date: 21-May-2015								
Case Narrative: Verbatim: Feels dizzy when using the product with an empty stomach.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 21-May-2015:								
This report concerns a 45-year-old male subject (Respondent Study ID: 2354647) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
Information on smoking habits was not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit B9S EHS VEE KB5) on 22-Apr-2015.								
On the same day (22-Apr-2015), the respondent felt dizzy when using the product with an empty stomach. The event was considered to be non-serious. Severity of the adverse e not reported.								
Action taken with the use of the product was not reported.								
At the time of reporting, the outcome of the event was not reported.								
No follow-up information is expected ? case closed.								
PMI000156	KOREA, REPUBLIC OF Report From Study	42 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	23-APR-2015 to Unknown	23-APR-2015	Feels hot when putting the product (HeatStick) in the mouth to use. [FEELING HOT] N / Y / Y	Unknown
Case Initial Receipt Date: 22-May-2015								
Case Narrative: Verbatim: Feels hot when putting the product (HeatStick) in the mouth to use.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 22-May-2015:								
This report concerns a 42-year-old male subject (Respondent Study ID: 1254392) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
Information on smoking habits was not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number Y6G S4K 4QX HOF) on 23-Apr-2015.								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>On the same day (23-Apr-2015), the respondent felt hot when putting the HeatStick in the mouth to use. The event was considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000158	KOREA, REPUBLIC OF Report From Study	40 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [qd]	Respiratory	25-APR-2015 to 22-MAY-2015	28-APR-2015 28-APR-2015 28-APR-2015	Stomach-ache and diarrhoea after smoking more than usual. [ABDOMINAL PAIN UPPER] N / Y / Y Stomach-ache and diarrhoea after smoking more than usual. [DIARRHOEA] N / Y / Y Hard to hold (the product) because of its heat from its middle part to up part [DEVICE ISSUE] N / Y / N	Recovered/Resolved
<p>Case Initial Receipt Date: 23-May-2015 Event Intensity: Mild Mild Mild Event Stop Date: 30-APR-2015 30-APR-2015 30-APR-2015 Case Narrative: Verbatim: Has a stomach-ache and diarrhoea after smoking more than usual -> got diarrhoea after smoking regular menthol cigarettes a little bit more than he used to. Hard to hold (the product) because of its heat from its middle part to up part - used (it) by holding its bottom part.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 23-May-2015: This report concerns a 40-year-old male subject (Respondent Study ID: 1385414) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (in average 10 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 (Dorado I / Vinny low Menthol) (Kit number 2VS 30Y HP4 WNT) on 25-Apr-2015.</p> <p>On 28-Apr-2015, the respondent experienced stomach ache and diarrhoea after smoking more than usual. He explained that he got diarrhoea after smoking regular menthol cigarettes a little bit more than he used to. In addition, the respondent reported that the product was hard to hold because of its heat from the middle part to upper part. He indicated that he held the product by holding its bottom part. The events were considered to be non-serious. Severity of the adverse events was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 12 HeatSticks and smoked 1 conventional cigarette. The last Heatsticks were used on 22-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event.</p> <p>The events resolved on 30-Apr-2015. The respondent indicated that the issue was solved by reducing the amount of pieces (HeatSticks) used. It was indicated that the event did not recur when product was restarted.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No follow-up information is expected ? case closed.								
PMI000162	KOREA, REPUBLIC OF Report From Study	28 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	23-APR-2015 to Unknown	26-APR-2015	Throat gets stinging for spicy tastes when smoking HeatStick. [OROPHARYNGEAL PAIN] N / N / Y	Unknown
Case Initial Receipt Date: 23-May-2015								
Case Narrative: Verbatim: Throat gets stinging for spicy tastes when smoking HeatStick.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 23-May-2015:								
This report concerns a 28-year-old male subject (Respondent Study ID: 1323266) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
Information on smoking habits was not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number ACM Q1M CAD 3QF) on 23-Apr-2015.								
On 26-Apr-2015, the respondent experienced that his throat got stinging for spicy tastes when he was smoking HeatSticks. The event was considered to be non-serious. Severe adverse event was not reported.								
Action taken with the use of the product was not reported.								
At the time of reporting, the outcome of the event was not reported.								
No follow-up information is expected ? case closed.								
PMI000163	KOREA, REPUBLIC OF Report From Study	49 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	25-APR-2015 to Unknown	25-APR-2015	Feels heat and seems to irritate throat. [FEELING HOT] N / Y / Y	Unknown
Case Initial Receipt Date: 23-May-2015								
Case Narrative: Verbatim: Feels heat and seems to irritate throat.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 23-May-2015:								
This report concerns a 49-year-old male subject (Respondent Study ID: 1348800) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
Information on smoking habits was not provided.								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and Menthol (Dorado I / Vinny low menthol) (Kit numbers not provided) on 25-Apr-2015.</p> <p>On the same day (25-Apr-2015), the respondent experienced feeling heat (location not specified) and reported that it seems to irritate the throat. The events were considered non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000166	KOREA, REPUBLIC OF Report From Study	25 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	28-APR-2015 to Unknown	28-APR-2015	Feels hot on throat by sucking the product deeply, because don't know how strongly it needs to be sucked, as this is the first time to use it (when testing) [THROAT IRRITATION] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 26-May-2015</p> <p>Case Narrative: Verbatim: Feels hot on throat by sucking the product deeply, because don't know how strongly it needs to be sucked, as this is the first time to use it (when testing)</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 26-May-2015:</p> <p>This report concerns a 25-year-old male subject (Respondent Study ID: 1466625) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number not provided) on 28-Apr-2015.</p> <p>On the same day (28-Apr-2015), the respondent experienced that he felt hot on throat by sucking the product deeply, because he didn't know how strongly it needed to be sucked, as this was the first time to use it (when testing). The event was considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p> <p>At the time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000170	KOREA, REPUBLIC OF Report From Study	49 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	28-APR-2015 to 18-MAY-2015	11-MAY-2015	Has coughs every time when using HeatStick because of being in a hurry to smoke. [COUGH] N / N / Y	Not Recovered/Not Resolved
<p>THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]</p> <p>Case Initial Receipt Date: 20-May-2015</p> <p>Event Intensity: Mild</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: Never have coughed when using general cigarettes, but has coughs every time when using HeatStick because of being in a hurry to smoke.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 20-May-2015 and transferred to Safety department on 28-May-2015: This report concerns a 49-year-old male subject (Respondent Study ID: 2108635) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 14 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and Menthol (Dorado I / Vinny low menthol) (Kit number TNY JGW LWS 3KZ, not speci for which one of the two products) on 28-Apr-2015.</p> <p>On 11-May-2015 (about two weeks after using the products), the respondent experienced coughing. He indicated that he never had coughed when using regular cigarettes, but ha cough every time when using HeatStick because of being in a hurry to smoke. The event was considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used for 4 days (out of 7 days). On the day of the event, the respondent used 2 HeatSticks and smoked 2 conventional cigarettes. The last Heatsticks were us 18-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event. It was reported that the event returned when use of the product was restarted.</p> <p>At the time of reporting, the event was not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000172	KOREA, REPUBLIC OF Report From Study	32 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [qd]	Respiratory	24-APR-2015 to 26-MAY-2015	24-APR-2015 24-APR-2015	Felt heavy and pain on throat after using this product (HeatStick), which was not similar to smoking general cigarettes. Felt like smoking 4 pieces of general cigarettes in a row. [DISCOMFORT] N / Y / Y Felt heavy and pain on throat after using this product (HeatStick), which was not similar to smoking general cigarettes. Felt like smoking 4 pieces of general cigarettes in a row. [OROPHARYNGEAL PAIN] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 26-May-2015 Event Intensity: Mild Mild</p> <p>Case Narrative: Verbatim: Felt heavy and pain on throat after using this product (HeatStick), which was not similar to smoking general cigarettes. Felt like smoking 4 pieces of general cig</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 26-May-2015: This report concerns a 32-year-old male subject (Respondent Study ID: 2358803) who took part in the above mentioned market research study.</p> <p>No concurrent medical history and no concomitant medications were reported. The respondent had a past history of asthma on bronchus at the age of 20, but it never relapsed moment.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent was a daily smoker (in average 20 cigarettes per day). He also used extra e-cigarettes about 10 times.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular Menthol (Dorado I / Vinny low menthol) (Kit number E1W C6N W6F Y8Y) on 24-Apr-2015.</p> <p>On the same day (24-Apr-2015), the respondent felt heavy and pain on throat after using the HeatStick, which was not similar to smoking general cigarettes. The respondent e it felt like smoking 4 pieces of conventional cigarettes in a row. The events were considered to be non-serious. Severity of the adverse events was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 20 HeatSticks and smoked no conventional cigarettes. The last Heatsticks were used on 26-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event. It was reported that the problem returned when use of the product was restarted.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000175	KOREA, REPUBLIC OF Report From Study	36 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown	29-APR-2015	Becomes dry on mouth, feels nauseous, and has a lot of saliva in mouth, when using both products, Y and Z, at their ends. [DRY MOUTH] N / Y / Y	Unknown
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown	29-APR-2015	Becomes dry on mouth, feels nauseous, and has a lot of saliva in mouth, when using both products, Y and Z, at their ends. [SALIVARY HYPERSECRETION] N / Y / Y	
						29-APR-2015	Becomes dry on mouth, feels nauseous, and has a lot of saliva in mouth, when using both products, Y and Z, at their ends. [NAUSEA] N / N / Y	
<p>Case Initial Receipt Date: 28-May-2015</p> <p>Case Narrative: Verbatim: Becomes dry on mouth, feels nauseous, and has a lot of saliva in mouth, when using both products, Y and Z, at their ends. Didn' t comment (on that) because it happens usually when using regular cigarettes, and it was not a big deal, like testing (the products).</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 28-May-2015:</p> <p>This report concerns a 36-year-old male subject (Respondent Study ID: 2354864) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>Information on smoking habits was not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Ginebra / Fitz) and Menthol (Dorado I / Vinny low menthol) (Kit number KUI MAM 29Y ONC, not specifying which one of the two products it corresponds) on 29-Apr-2015.</p> <p>Starting on the same day (29-Apr-2015), the respondent experienced dryness in mouth, feeling nauseous and having a lot of saliva in mouth by using both types of HeatSticks. The respondent explained that it happened in testing, and did happen in using as well. In addition, he explained that he didn' t comment on that because it happened usually when using regular cigarettes, and it was not a big deal. The events were considered to be non-serious. Severity of the adverse event was not reported.</p> <p>Action taken with the use of the product was not reported.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
At the time of reporting, the outcome of the events was not reported.								
No follow-up information is expected ? case closed.								
PMI000177	KOREA, REPUBLIC OF Report From Study	40 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown	09-MAY-2015	Felt parched on throat from its aftertaste when using both Y and Z. [DRY THROAT] N / Y / Y	Unknown
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	29-APR-2015 to Unknown	09-MAY-2015	Felt parched on throat from its aftertaste when using both Y and Z. [DYSGEUSIA] N / Y / Y	
Case Initial Receipt Date: 28-May-2015								
Case Narrative: Verbatim: Used the product on Saturday after two weeks of not taking it. Felt parched on throat from its aftertaste when using both Y and Z.								
Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).								
INITIAL INFORMATION RECEIVED ON 28-May-2015:								
This report concerns a 40-year-old male subject (Respondent Study ID: 2359522) who took part in the above mentioned market research study.								
No medical history and no concomitant medications were reported.								
Information on smoking habits was not provided.								
The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II/ Fitz) and Menthol (Dorado I / Vinny low menthol) (Kit number DRS 6EK MQK, not specifying which one of the two products it corresponds) on 29-Apr-2015.								
On 09-May-2015 (after 2 weeks of not using the product), the respondent felt parched on throat from the product's aftertaste when using both types of HeatSticks. The event was considered to be non-serious. Severity of the adverse event was not reported.								
Action taken with the use of the product was not reported.								
At the time of reporting, the outcome of the events was not reported.								
No follow-up information is expected ? case closed.								
PMI000178	KOREA, REPUBLIC OF Report From Study	34 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [qd]	Respiratory	29-APR-2015 to 26-MAY-2015	11-MAY-2015	I felt nauseous when using many pieces in a row because it tastes fishy in the aftertaste. [DYSGEUSIA] N / Y / Y	Not Recovered/Not Resolved
						11-MAY-2015	I felt nauseous when using many pieces in a row because it tastes fishy in the aftertaste. [NAUSEA] N / N / Y	
						11-MAY-2015	I felt nauseous when using many pieces in a row because it tastes fishy in the aftertaste. [PRODUCT TASTE ABNORMAL] N / Y / N	
Case Initial Receipt Date: 30-May-2015								
Event Intensity: Mild								
Mild								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: I felt OK at the first time of using it, but then I felt nauseous when using many pieces in a row because it tastes fishy in the aftertaste.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 30-May-2015: This report concerns a 34-year-old male subject (Respondent Study ID: 2359944) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 30 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number 86T 94V QP9 4AD) on 29-Apr-2015.</p> <p>On 11-May-2015, the respondent felt nauseous when using many pieces in a row because "it tastes fishy in the aftertaste". The respondent clarified that he felt OK at the using the product. The events were considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 20 HeatSticks and smoked 25 conventional cigarettes. The last Heatsticks were used on 26-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event.</p> <p>At the time of reporting, the events were not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000196	KOREA, REPUBLIC OF Report From Study	29 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	29-APR-2015 to 29-APR-2015	29-APR-2015 29-APR-2015	Feels dry on throat, which is drier than when smoking general cigarettes. Feels parched in mouth. [DRY THROAT] N / Y / Y Feels dry on throat, which is drier than when smoking general cigarettes. Feels parched in mouth. [DRY MOUTH] N / Y / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 29-May-2015 Event Intensity: Mild Mild Event Stop Date: 29-APR-2015 29-APR-2015 Case Narrative: Verbatim: Feels dry on throat, which is drier than when smoking general cigarettes. Feels parched in mouth</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 29-May-2015: This report concerns a 29-year-old male subject (Respondent Study ID: 2354471) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number not provided) on 29-Apr-2015.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>On the same day (29-Apr-2015), the respondent felt dry on throat and parched in mouth. He explained that it was drier than when smoking conventional cigarettes. The events considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used only once. It was mentioned that the event improved after usage of the product was stopped and that it did not return when use of the product was restarted (conflicting information).</p> <p>The events resolved on the same day (29-Apr-2015).</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000224	KOREA, REPUBLIC OF Report From Study	38 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [qd]	Respiratory	28-APR-2015 to 27-MAY-2015	07-MAY-2015 07-MAY-2015	<p>Within five minutes of using the HeatStick, my head felt heavy and I got a little dizzy. [HEAD DISCOMFORT] N / Y / Y</p> <p>Within five minutes of using the HeatStick, my head felt heavy and I got a little dizzy. [DIZZINESS] N / N / Y</p>	Recovered/Resolved
<p>Case Initial Receipt Date: 28-May-2015 Event Intensity: Mild Mild Event Stop Date: 21-MAY-2015 21-MAY-2015 Case Narrative: Verbatim: Within five minutes of using the HeatStick, my head felt heavy and I got a little dizzy.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 28-May-2015 and received by the safety department on 05-JUN-2015: This report concerns a 38-year-old male subject (Respondent Study ID: 1467153) who took part in the above mentioned market research study.</p> <p>No medical history was reported. Omega 3 and vitamins for the eyes were reported as concomitant medications (not specified).</p> <p>The respondent was a daily smoker (on average, 12 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number 56V H06 J6L LPP) on 28-Apr-2015.</p> <p>On 07-May-2015, within five minutes of using the HeatStick, the respondent's head felt heavy and he got a little dizzy. The events were considered to be non-serious. Several adverse events was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 7 HeatSticks and smoked 5 conventional cigarettes. The last Heatsticks were used on 27-May-2015.</p> <p>It was reported that the events improved after product was stopped and returned when use of the product was restarted (about 2-3 times).</p> <p>The events resolved on 21-May-2015.</p> <p>No follow-up information is expected ? case closed.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000225	KOREA, REPUBLIC OF Report From Study	37 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [qd]	Respiratory	01-MAY-2015 to 28-MAY-2015	05-MAY-2015	I didn' t feel it when testing, but starting about 5th May, which was around four days after having used the product, I felt phlegm in my throat after use [PRODUCTIVE COUGH] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 01-Jun-2015 Event Intensity: Mild Case Narrative: Verbatim: didn' t feel it when testing, but starting about 5th May, which was around four days after having used the product, I felt phlegm in my throat after use. I could from time to time throughout the four weeks that I was using the product.</p> <p>Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).</p> <p>INITIAL INFORMATION RECEIVED ON 01-JUN-2015 AND TRANSFERRED TO SAFETY DEPARTMENT ON 05-JUN-2015: This report concerns a 37-year-old male subject (Respondent Study ID: 2365125) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medications were reported.</p> <p>The respondent was a daily smoker (on average 10 cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (Kit number MY3 RCL QOC P2D) on 01-May-2015.</p> <p>On 05-May-2015, the respondent felt phlegm in his throat after use. He could feel the phlegm from time to time throughout the four weeks that he was using the product. The considered to be non-serious. Severity of the adverse event was reported as mild.</p> <p>The product was used every day. On the day of the event, the respondent used 14 HeatSticks and smoked 8 conventional cigarettes. The last Heatsticks were used on 28-May-2015.</p> <p>The use of the product was not discontinued due to the occurrence of the adverse event. It was reported that the event returned when product was restarted.</p> <p>At the time of reporting, the event was not resolved.</p> <p>No follow-up information is expected ? case closed.</p>								
PMI000272	SWITZERLAND Report From Study	45 Years Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK]	Respiratory	10-NOV-2014 to 10-NOV-2014	10-NOV-2014 10-NOV-2014 10-NOV-2014 10-NOV-2014	Very tired [FATIGUE] N / Y / Y Headache [HEADACHE] N / N / Y Nausea [NAUSEA] N / N / Y Vertigo [VERTIGO] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 11-Nov-2014 Event Intensity: Severe Severe Severe Severe</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Case Narrative: Verbatim: Vertigo, Headache, Nausea, Very tired								
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.								
INITIAL INFORMATION RECEIVED ON 11-NOV-2014: This report concerns a 45-year-old female subject (Respondent Study ID: F184606) who took part in the above mentioned market research study.								
The respondent had no medical history and was not taking any concomitant medications. It was reported that the respondent took antibiotics for angina (tonsillitis) one month prior to the occurrence of the reported events.								
The respondent was a daily smoker who smoked on average 12 cigarettes per day (80 cigarettes per month).								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number CU003883) on 10-Nov-2014. On the same day, she experienced vertigo, headache, nausea and felt very tired. The events were considered to be non-serious and severe in intensity.								
On 10-Nov-2014, the respondent used 5 sticks and she smoked 5 cigarettes. She stopped using the sticks on the same day. The reported events did not improve after she stopped using the product. At the time of reporting, the events were not resolved.								
No follow-up information has been requested ? case closed.								
PMI000273	SWITZERLAND Report From Study	Female	THS 2.2 Menthol (Vinny / Ron) / N/A UNK [UNK]	Respiratory		10-NOV-2014 10-NOV-2014	Felt sick [MALAISE] N / Y / Y Vomit [VOMITING] N / Y / Y	Recovered/Resolved
Case Initial Receipt Date: 10-Nov-2014 Case Narrative: Verbatim: Felt sick, vomit								
Market Research Study P1_WOT1_CH: Whole Offer Test and large-scale quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1.								
INITIAL INFORMATION RECEIVED ON 10-NOV-2014 (Two different sets of information transferred at different dates):								
This report concerns a female subject (Respondent Study ID: F192769) who took part in the above mentioned market research study.								
The respondent's medical history and concomitant medications were not reported.								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Vinny / Ron) half white tipping paper (Kit number not provided) on an unspecified date. She reported that she did not like the menthol Heat Sticks and that she was feeling sick. The two last times she used the sticks she had to vomit. According to the respondent, the taste is very unpleasant though she is used to it as she smokes a lot. The events were considered to be non-serious.								
At the time of reporting, the events were not resolved.								
No follow-up information has been requested ? case closed.								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000345	UNITED STATES Report From Study	66 Years Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	12-OCT-2015 to 12-OCT-2015	12-OCT-2015 12-OCT-2015 13-OCT-2015 12-OCT-2015 12-OCT-2015 12-OCT-2015 12-OCT-2015 12-OCT-2015	her stomach was upset [ABDOMINAL DISCOMFORT] N / Y / Y had dry heaves [RETCHING] N / Y / Y also having diarrhea [DIARRHOEA] N / Y / Y they made me sick [MALAISE] N / Y / Y as soon as she finished using the IQOS device she started to get dizzy and tasted a very strong menthol taste [DIZZINESS] N / N / Y She stated that, after using IQOS, she felt icky (described as feeling nauseous) / sick to her stomach [NAUSEA] N / N / Y having a headache [HEADACHE] N / N / Y was not able to get the device to work [DEVICE ISSUE] N / Y / N tasted a very strong menthol taste [PRODUCT TASTE ABNORMAL] N / Y / N	Recovered/Resolved
<p>Case Initial Receipt Date: 15-Oct-2015 Case Followup Receipt Date: 26-Oct-2015 00:00 Event Intensity: Severe Severe Severe Severe Severe Severe Event Stop Date: 15-OCT-2015 15-OCT-2015 15-OCT-2015 15-OCT-2015 15-OCT-2015 15-OCT-2015 Case Narrative: Verbatim: She stated that, as soon as she finished using the IQOS device, she started to get dizzy and tasted a very strong menthol taste. She stated that, after using IQOS, she felt icky (described as feeling nauseous), having a headache, and her stomach was upset. She then tried a third heatstick and reported she was not able to get the device to work. She was unable to finish the cigarette because she still felt dizzy, sick to her stomach and had dry heaves. She was also having diarrhea.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 15-Oct-2015 and forwarded to Safety department on 16-Oct-2015.</p> <p>This report concerns a 66-year-old female subject (Respondent Study ID: 538801) who took part in the above mentioned market research study.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Medical history of high blood pressure, breast cancer, hypothyroid and high cholesterol was reported. The following concomitant medications were reported: Synthroid (levo hyroxine sodium), Cadeut (presumably Caduet, amlodipine besilate, atorvastatin calcium), Advil (ibuprofen), doses, treatment dates and indications not provided.</p> <p>The consumer was a daily smoker (approximately 10 conventional menthol cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol Dorado I / Vinny Low Menthol (kit numbers (01)-5410706815337 (21) 2T4TNK9RU6SR (240) DK000024.01 on 12-Oct-2015. The consumer smoked 3 Heatsticks and 2 conventional cigarettes on the day of the event.</p> <p>On 12-Oct-2015, the participant smoked regular, conventional, menthol cigarette, and hen tried IQOS device, using 1 full menthol heatstick. She then indicated she tried to use a second heatstick and was only able to take 1 puff. She then tried a third heatstick and reported she was not able to get the device to work. She stated that, as soon as she finished using the IQOS device, she started to get dizzy and tasted a very strong menthol taste. She stated that, after using IQOS she felt icky (described as feeling nauseous), having a headache, and her stomach was upset. Later that evening, she tried to smoke a regular, conventional menthol cigarette, but reported she was unable to finish he cigarette because she still felt dizzy, sick to her stomach and had dry heaves. She stated she spent all day in bed on 13-Oct-2015 because she kept feeling dizzy during the day and was also having diarrhea.</p> <p>The intensity of the events was reported as severe. The events were considered to be non-serious. Participant did not seek medical advice.</p> <p>It was reported that the events improved when he usage of the product was discontinued. Product was not restarted.</p> <p>Consumer stated that she felt fine on 15-Oct-2015. The events were resolved.</p> <p>No follow-up information is expected. Case closed.</p> <p>FOLLOW-UP INFORMATION was received on 26-Oct-2015 and forwarded to the Safety department on 2-Nov-2015.</p> <p>Verbatim: they made me sick</p> <p>In addition to the previous reported events, the respondent stated that "They made me sick".</p> <p>The event severity was not reported. The event was considered to be non-serious. The outcome of the event was not reported.</p> <p>No further information was provided.</p> <p>No follow-up information is expected. Case closed.</p>								
PMI000361	UNITED STATES Report From Study	22 Years Male	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	25-OCT-2015 to 27-OCT-2015	27-OCT-2015	his chest was hurting real bad [CHEST PAIN] N / Y / Y	Not Recovered/Not Resolved
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	25-OCT-2015 to 27-OCT-2015	26-OCT-2015	he started coughing up green stuff [SPUTUM DISCOLOURED] N / Y / Y	
						25-OCT-2015	As he smoked more of the product, it was like it was pulling air out of his lungs [CHEST DISCOMFORT] N / N / Y	
						25-OCT-2015	each time he smoked, he would cough [COUGH] N / N / Y	
	Case Initial Receipt Date: 27-Oct-2015 Event Intensity: Moderate Moderate Moderate							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
			Moderate					
			Case Narrative: Verbatim: He stated that at first the smoking experience wasn't so bad, but then as he smoked more of the product, it was like it was pulling air out of his lungs. He stated that he then found that each time he smoked, he would cough. On 26-Oct-2015, he started coughing up green stuff. On the morning of 27-Oct-2015, when he woke up, his chest was hurting real bad, but the coughing had slowed down.					
			Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.					
			INITIAL INFORMATION RECEIVED ON 27-Oct-2015 and forwarded to Safety department on the same day.					
			This report concerns a 22-year-old male subject (Respondent Study ID: 751825) who took part in the above mentioned market research study.					
			No medical history was reported. No concomitant medication was reported.					
			The respondent was a daily smoker (approximately 15-20 conventional cigarettes per day).					
			The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit numbers (01)5410706815337, (21)MHZKNOLUZYR, (240)DK000024.01) on 25-Oct-2015.					
			On 25-Oct-2015, the study respondent started using the product. He stated that, at first, the smoking experience wasn't so bad, but then, as he smoked more of the product, it was like it was pulling air out of his lungs. He stated that he then found that, each time he smoked, he would cough. On 26-Oct-2015, he started coughing up green stuff. On the morning of 27-Oct-2015, when he woke up, his chest was hurting real bad, but the coughing had slowed down. The participant stated the menthol caused the problem more than the regular flavor.					
			The events severity was reported as moderate. The events were considered to be non-serious.					
			The consumer used the Heatsticks every day. He used 10 Heatsticks and 10 cigarettes on the day of the events.					
			The respondent stopped using the product on 27-Oct-2015. The events improved when usage of the products was stopped. The products were not restarted.					
			At time of reporting, the events were not resolved.					
			No follow-up information is expected. Case closed.					
PMI000364	UNITED STATES Report From Study	28 Years Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	09-OCT-2015 to Unknown	09-OCT-2015 09-OCT-2015	inhaled for 2 seconds, and experienced a really warm sensation on her lips [FEELING HOT] N / Y / Y it felt too close to her lips and she was being burned / burning sensation on the lips [ORAL DISCOMFORT] N / Y / Y	Not Recovered/Not Resolved
			Case Initial Receipt Date: 30-Oct-2015 Case Followup Receipt Date: 30-Oct-2015 00:00 Event Intensity: Mild Mild					
			Case Narrative: Verbatim: Inhaled for 2 seconds, and experienced a really warm sensation on her lips. Participant stated it felt too close to her lips and she was being burned. Burning sensation on the lips.					
			Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.					
			INITIAL INFORMATION RECEIVED ON 30-Oct-2015 and forwarded to Safety department on the same day. Additional information with same initial date was forwarded to Safety department on 02-Nov-2015.					

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This report concerns a 28-year-old female subject (Respondent Study ID: 535255) who took part in the above mentioned market research study.</p> <p>Medical history included gallbladder removal ten years ago. No concomitant medication was reported.</p> <p>The consumer was a daily smoker (approximately 10 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number 5410706815337) on 09-Oct-2015.</p> <p>Participant started using the product on 09-Oct-2015. She stated that, with her regular Newport conventional cigarettes, she inhaled for about 2 seconds. When she did the same with the IQOS device, she experienced a really warm sensation on her lips. She tried to keep smoking but it was just too much heat. Participant stated it felt too close to her lips and she was being burned. She reported that she experienced the same symptoms with each use.</p> <p>The events severity was reported as mild. The events were considered to be non-serious.</p> <p>The participant used the Heatstick occasionally, once per week. The study respondent used 1 Heatstick and 1 cigarette on the day of the event. She mentioned that the event improved when product was stopped and returned when product was restarted.</p> <p>Participant last used the device on 23-Oct-2015 but stated she planned to continue using the device.</p> <p>At time of reporting, the events were not resolved.</p> <p>No follow-up information is expected. Case closed.</p>							
PMI000366	UNITED STATES Report From Study	20 Years Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	15-OCT-2015 to 21-OCT-2015	15-OCT-2015 Heatsticks giving me headaches/ gave me headaches [HEADACHE] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 29-Oct-2015 Case Followup Receipt Date: 01-Nov-2015 00:00 Event Intensity: Moderate Case Narrative: Verbatim: Heatsticks giving me headaches; gave me headaches</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 29-Oct-2015 and 1-Nov-2015 and forwarded to Safety department on 2-Nov-2015.</p> <p>This report concerns a 20-year-old female subject (Respondent Study ID: 201662) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The respondent was a daily smoker (approximately 10 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number 72QGCB189GV) on 15-Oct-2015.</p> <p>The respondent stated that she experienced headaches after using the Heatsticks from 15-Oct-2015.</p> <p>The event severity was reported as moderate.</p>							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent used the Heatsticks occasionally. She used 1 Heatstick and 15 cigarettes on the day of the event.</p> <p>It was reported that the event improved when usage of the product was stopped and returned when usage of the product was restarted. The product permanently stopped on 21-Oct-2015.</p> <p>At time of reporting, the event was not resolved.</p> <p>No follow-up information is expected. Case closed.</p>							
PMI000372	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory		gave me headaches [HEADACHE] N / N / Y didn't like the taste [PRODUCT TASTE ABNORMAL] N / Y / N	Unknown
<p>THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]</p> <p>Case Initial Receipt Date: 26-Oct-2015 Event Intensity: Unknown Case Narrative: Verbatim: gave me headaches; didn't like the taste.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 26-Oct-2015 and forwarded to Safety department on 2-Nov-2015.</p> <p>This report concerns a female subject born in 1959 (Respondent Study ID: 181262) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The respondent was a daily smoker (number of conventional cigarettes per day not provided).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) and THS 2.2 Regular (Dorado II / Ron) on an unspecified date (kit number).</p> <p>The respondent stated that the use of the device gave her headaches and that she didn't like its taste.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The frequency of use of the Heatstick was not provided. No information was provided regarding the number of Heatsticks and conventionnal cigarettes used by the respondent on the day of the event.</p> <p>No information regarding the action taken with the drug was provided.</p> <p>At time of reporting, the outcome of the event was not reported.</p> <p>No follow-up information is expected. Case closed.</p>							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000373	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015 2015 2015	made my chest hurt [CHEST PAIN] N / Y / Y burning my throat [THROAT IRRITATION] N / Y / Y coughing [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 22-Oct-2015 Case Followup Receipt Date: 09-Nov-2015 00:00 Event Intensity: Unknown Unknown Unknown Case Narrative: Verbatim: burning my throat, coughing, made my chest hurt.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 22-Oct-2015 and forwarded to Safety department on 02-Nov-2015.</p> <p>This report concerns a female subject born in 1963 (Respondent Study ID: 187828) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The respondent was a daily smoker (number of conventional cigarettes per day not provided).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number and start date not provided).</p> <p>On an unspecified date, the respondent experienced burning of her throat and coughing.</p> <p>The severity of the events was not reported. The events were assessed as non-serious.</p> <p>The frequency of use of the Heatstick was not provided. No information was provided regarding the number of Heatsticks and cigarettes used by the respondent on the day of the event.</p> <p>No information regarding the action taken with the product was provided.</p> <p>At time of reporting, the outcome of the event was not reported.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 09-NOV-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>The study respondent reported that the product made his chest hurt.</p> <p>No follow-up information is expected. Case closed.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000374	UNITED STATES Report From Study	Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory			Makes me feel nauseated / makes me nauseous [NAUSEA] N / N / Y smell is awful [PRODUCT ODOUR ABNORMAL] N / Y / N it feels cumbersome / it's an inconvenience to clean it and to carry it all / not convenient [DEVICE DIFFICULT TO USE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 20-Oct-2015 Case Followup Receipt Date: 09-Nov-2015 00:00 Event Intensity: Unknown Case Narrative: Verbatim: Makes me feel nauseated, and it feels cumbersome. It's an inconvenience to clean it and to carry it all. Smell is awful.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 20-Oct-2015 and forwarded to Safety department on 2-Nov-2015.</p> <p>This report concerns a male subject born in 1980 (Respondent Study ID: 829559) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The respondent was a daily smoker (number of conventional cigarettes per day not provided).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number and start date not provided).</p> <p>The respondent stated that he was feeling nauseated after using the Heats icks. He also reported that the device was cumbersome and that it was an inconvenience to clean it and to carry it.</p> <p>The severity of the events were not reported. The events were assessed as non-serious.</p> <p>The frequency of use of the Heatstick was not provided. No information was provided regarding the number of Heatsticks and cigarettes used by the respondent on the day of the event.</p> <p>No information regarding the action taken with the product was provided.</p> <p>At time of reporting, the outcome of the events was not reported.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 09-NOV-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>The study respondent reported that the product smells awful, it made him nauseous and it was not convenient.</p> <p>No further information on the events or their outcome was provided.</p> <p>No follow-up information is expected. Case closed.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000382	UNITED STATES Report From Study	51 Years Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	01-OCT-2015 to 07-NOV-2015	06-NOV-2015 06-NOV-2015 01-OCT-2015	HeatSticks usage causes burning/hot lips [ORAL DISCOMFORT] N / Y / Y the problem severely impacts her because it affects her mental state if she cannot continue the study (she needs the money) [MENTAL STATUS CHANGES] N / Y / N She has developed a cough since beginning the study, which she attributes to the IQOS vapor-based system [COUGH] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 09-Nov-2015 Event Intensity: Severe Severe Severe Case Narrative: Verbatim: HeatSticks usage causes burning/hot lips / The problem severely impacts her because it affects her mental state if she cannot continue the study (she needs the money) / She has developed a cough since beginning the study, which she attributes to the IQOS vapor-based system</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED on 09-Nov-2015 and forwarded to Safety department on 10-Nov-2015.</p> <p>This report concerns a 51-year-old female subject (Respondent Study ID: 757225) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>The respondent was a daily smoker (approximately 20 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado I / Vinny Low Menthol) (kit number QFW75841PM15) on 01-Oct-2015.</p> <p>The respondent stated that heatsticks usage caused burning/hot lips with the current pack of C3 Menthol; burning sensation started slowly with usage on 06-Nov-2015. She has developed a cough since beginning the study, which she attributes to the IQOS vapor-based system. She stated that the problem severely impacts her because it affects her mental state if she cannot continue the study; that she needs the money. Respondent stated that she has not used any HeatSticks the last 2 days due to the burning/hot lips.</p> <p>The events severity was reported as severe (of note, it was specified that it was because it affects her mental state if she cannot continue the study; needs the money) . The events were assessed as non-serious.</p> <p>The respondent used the Heatsticks every day. She used 2 Heatsticks and 20 cigarettes on the day of the event.</p> <p>The events improved when usage of the product was stopped, the product was not restarted. The last day of product use was on 07-Nov-2015.</p> <p>At time of reporting, the events were not resolved.</p> <p>No further information is expected. Case closed.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000407	UNITED STATES Report From Study	27 Years Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK] UNK [UNK]	Respiratory	17-OCT-2015 to (b) (6)	10-NOV-2015 10-NOV-2015	strep hroat [PHARYNGITIS STREPTOCOCCAL] N / Y / Y respiratory infection [RESPIRATORY TRACT INFECTION] N / Y / Y	Recovered/Resolved
			THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK] UNK [UNK]	Respiratory	2015 to (b) (6) 5 17-NOV-2015 to Unknown			
<p>Case Initial Receipt Date: 24-Nov-2015 Event Intensity: Severe Severe Event Stop Date: 17-NOV-2015 17-NOV-2015 Case Narrative: Verbatim: strep throat / respiratory infection</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 24-Nov-2015 and forwarded to Safety department on the same day.</p> <p>This report concerns a 27-year-old female subject (Respondent Study ID: 185638) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medication were reported.</p> <p>The respondent was a daily smoker (approximately 10 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) and Regular (Dorado II / Ron) (kit number 6USB5XGJ3YD1) on 17-Oct-2015. She started with menthol and then switched to regular (date not provided).</p> <p>The respondent stated that she had strep throat and a respiratory infection which began on 10-Nov-2015. On (b) (6), she saw a doctor at the hospital who did a test for strep throat which was positive. The doctor also told her she had a respiratory infection (NOS). The doctor told her she could not smoke. The doctor gave her amoxicillin and a shot (NOS) in her buttock, as treatment for the events.</p> <p>The events severity was reported as severe and required medical advice on 11-Nov-2015 and treatment (dates unspecified). The events were assessed as non-serious.</p> <p>The respondent used the heatsticks every day, except for when prohibited by doctor. The respondent used 1 Heatstick and 0 cigarette on the day of the event.</p> <p>The events improved when usage of the product was stopped, and did not return when use of the product was restarted. The last day of product use was on 24-Nov-2015 (day of reporting). No further information was reported regarding the final action taken with the product.</p> <p>The events resolved on 17-Nov-2015, when the respondent was told she could return to work and smoking.</p> <p>No further information is expected. Case closed.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000411	UNITED STATES Report From Study	35 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory			he had a cold [NASOPHARYNGITIS] N / N / Y he sounded "ridiculous" [DYSPHONIA] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 04-Oct-2015 Event Intensity: Unknown Unknown Case Narrative: Verbatim: he had a cold; he sounded "ridiculous"</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 04-Oct-2015 and forwarded to Safety department on 02-Dec-2015.</p> <p>This report concerns a 35-year-old male subject (Respondent Study ID: 453172) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medication were reported.</p> <p>The smoking status of the respondent was not reported.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number J343KDKLYC0) on an unknown date.</p> <p>The respondent stated that he had a cold which was why he sounded "ridiculous" during a call on 04-Oct-2015. The start date of the event was unknown.</p> <p>The event severity was not reported. The event was assessed as non-serious.</p> <p>The respondent's smoking habits with heatstick was not reported. The number of heatsticks and cigarettes used on the day of the event was not reported.</p> <p>No information was provided about the action taken with the product.</p> <p>No information was provided about the outcome of the event.</p> <p>No further information is expected. Case closed.</p>								
PMI000483	UNITED STATES Report From Study	30 Years Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	SEP-2015 to DEC-2015	10-JAN-2016	Pregnancy [MATERNAL EXPOSURE T MING UNSPECIFIED] N / Y / N	Unknown
<p>THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]</p> <p>Case Initial Receipt Date: 03-Feb-2016 Case Followup Receipt Date: 16-Feb-2016 00:00 Case Comment Text: Maternal exposure timing unspecified was assessed as non-serious.</p> <p>Expectedness and causality assessments are not applicable for Maternal exposure timing unspecified. However, expectedness for Maternal exposure timing unspecified has been captured as unlisted, by default, in the safety database.</p> <p>No adverse events were reported in association with Maternal exposure timing unspecified.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>This pregnancy report shall be followed-up until an outcome is reached, as per protocol.</p> <p>Case Narrative: Verbatim: Pregnancy</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 03-FEB-2016 and forwarded to Safety department on 05-FEB-2016.</p> <p>This report concerns a 30-year-old female subject (Respondent Study ID: 751296) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medication were reported.</p> <p>The respondent was a daily smoker (approximately 2 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) and Regular (Dorado II / Ron) (kit numbers not provided) on an unknown date in Sep-2015.</p> <p>The respondent reported a pregnancy. Date of awareness of pregnancy was 10-Jan-2016. Last menstrual period was in Dec-2015 (not further specified). The pregnancy was confirmed by a HCP. Delivery date was uncertain. It was reported that the respondent was not using any contraception at time of report.</p> <p>The respondent had one previous pregnancy and one delivery (no therapeutic or planned abortion).</p> <p>The study respondent used the THS products up to an unspecified date in Dec-2015 (prior to awareness of pregnancy).</p> <p>Further information is expected.</p> <p>FOLLOW-UP INFORMATION received on 16-Feb-2016 and forwarded to Safety Department on 17-Feb-2016.</p> <p>The following kit number was provided: V4P4S3WB2REL (not specified if it corresponds to THS 2.2 Regular or Menthol. Start date of product use was reported as Sep-2015, with a comment that the study participant was unsure of exact date and stated it took place at end the month. The respondent's eDiary entries showed initial recorded use of IQOS device on 26-Oct-2015 (Enrollment center issued kit on 26-Oct-2015).</p> <p>The product stop date was reported as Dec-2015, with a comment that the study participant was unsure of exact date, and stated it took place at beginning of month. The respondent's eDiary entries showed that the last date of recorded use was 08-Dec-2015.</p> <p>First day of last menstrual period was reported as Dec-2015, with a comment that the study participant was unsure of exact date, and stated it took place in middle of month.</p> <p>Estimated delivery date was reported as 28-Aug-2016.</p> <p>Participant denied history of any ongoing medical conditions, for which she was seeing a healthcare professional, for which she was taking medications, or for which she was previously assessed.</p> <p>Participant reported that initial doctor visit on 10-Jan-2016 resulted in a blood test which confirmed pregnancy (follow-up appointment with her doctor was scheduled on 18-Feb-2016).</p> <p>Further information is expected.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000589	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015 2015	The smell of the Heatsticks makes me feel sick [MALAISE] N / Y / Y The smell of the Heatsticks makes me feel sick [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 09-Nov-2015 Case Narrative: Verbatim: The smell of the Heatsticks makes me feel sick.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 09-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 43-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 184275) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that the smell of the heatstick made her feel sick.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000590	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	Gave me a headache [HEADACHE] N / N / Y	Unknown
<p>Case Initial Receipt Date: 09-Nov-2015 Case Narrative: Verbatim: gave me a headache</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 09-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 29-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 351426) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that the product gave her a headache.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000592	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	Got sick [MALAISE] N / Y / Y	Unknown
<p>THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]</p> <p>Case Initial Receipt Date: 09-Nov-2015 Case Narrative: Verbatim: got sick</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 09-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 21-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 458445) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unreported date.</p> <p>The respondent stated that she got sick.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000593	UNITED STATES Report From Study	Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015 2015	too much work and gives headache [HEADACHE] N / N / Y too much work and gives headache [DEVICE DIFFICULT TO USE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 16-Nov-2015 Case Narrative: Verbatim: too much work and gives headache</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 16-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 45-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 536655) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that the product was too much work and gave him headache.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000595	UNITED STATES Report From Study	Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015 2015	made me feel kinda groggy, dragged me [SOMNOLENCE] N / Y / Y I wasn't comfortable with them [DEVICE DIFFICULT TO USE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 16-Nov-2015 Case Narrative: Verbatim: made me feel kinda groggy, dragged me, I wasn't comfortable with them.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 16-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 47-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 351842) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unreported date.</p> <p>The respondent stated that the heatsticks made him feel kind of groggy, dragged him, and hat he wasn't comfortable with them.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000596	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015 2015	gives me a headache and it's a hassle [HEADACHE] N / N / Y gives me a headache and it's a hassle [DEVICE DIFFICULT TO USE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 16-Nov-2015 Case Narrative: Verbatim: gives me a headache and it's a hassle</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 16-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 72-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 358759) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that the heatsticks gave her a headache and that it was a hassle.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000597	UNITED STATES Report From Study	Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015 2015	irritates my throat [THROAT IRRITATION] N / Y / Y too much menthol [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
Case Initial Receipt Date: 16-Nov-2015 Case Narrative: Verbatim: irritates my throat, too much menthol Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2. INITIAL INFORMATION RECEIVED ON 16-Nov-2015 and forwarded to Safety department on 05-Apr-2016. This report concerns a 56-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 185025) who took part in the above mentioned market research study. No medical history was reported. No concomitant medication was reported. No information on smoking habits was reported (conventional cigarettes and heatsticks). The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unreported date. The respondent stated that the product irritated his throat, and that there was too much menthol. The severity of the event was not reported. The event was assessed as non-serious. The outcome of the event was not reported. Action taken with the THS product was not reported. No further information is expected. Case closed.								
PMI000599	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	Sick [MALAISE] N / Y / Y	Unknown
Case Initial Receipt Date: 23-Nov-2015 Case Narrative: Verbatim: sick Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2. INITIAL INFORMATION RECEIVED ON 23-Nov-2015 and forwarded to Safety department on 05-Apr-2016. This report concerns a 23-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 757519) who took part in the above mentioned market research study. No medical history was reported. No concomitant medication was reported.								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent reported: "sick".</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000600	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015 2015	breathing trouble [DYSпноEA] N / Y / Y Sore throat [OROPHARYNGEAL PAIN] N / N / Y	Unknown
<p>THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]</p> <p>Case Initial Receipt Date: 23-Nov-2015 Case Narrative: Verbatim: sore throat, breathing trouble</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 23-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 55-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 181832) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent reported sore hroat and breathing trouble.</p> <p>The severity of the events was not reported. The events were assessed as non-serious.</p> <p>The outcome of the events was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000601	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015 2015	Taste and smell gave her headaches [HEADACHE] N / N / Y Taste and smell gave her headaches [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
<p>Case Initial Receipt Date: 30-Nov-2015 Case Narrative: Verbatim: Taste and smell gave her headaches.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 30-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 55-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 182351) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that the taste and smell of the heatstick gave her headaches.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000602	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	Problem with my throat [PHARYNGEAL DISORDER] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-Nov-2015 Case Narrative: Verbatim: Problem wi h my throat</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 30-Nov-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 55-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 533787) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent reported a problem with her throat.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000603	UNITED STATES Report From Study	Female	THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	2015 to Unknown	2015	I think they were giving me an upset stomach [ABDOMINAL DISCOMFORT] N / Y / Y	Unknown
<p>THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]</p> <p>Case Initial Receipt Date: 07-Dec-2015 Case Narrative: Verbatim: I think they were giving me an upset stomach</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 07-Dec-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 58-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 650514) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) and THS 2.2 Regular (Dorado II / Ron) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that she thought the heatsticks were giving her an upset stomach.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000604	UNITED STATES Report From Study	Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK] Case Initial Receipt Date: 07-Dec-2015 Case Narrative: Verbatim: it too strong for my throat	Respiratory	2015 to Unknown	2015	it too strong for my throat [LARYNGEAL DISCOMFORT] N / Y / Y	Unknown
<p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 07-DEC-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 48-year-old female (approximate age, at the time of reporting) subject (Respondent Study ID: 533722) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.</p> <p>The respondent stated that the product was too strong for her throat.</p> <p>The severity of the event was not reported. The event was assessed as non-serious.</p> <p>The outcome of the event was not reported.</p> <p>Action taken with the THS product was not reported.</p> <p>No further information is expected. Case closed.</p>								
PMI000605	UNITED STATES Report From Study	Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK] Case Initial Receipt Date: 07-Dec-2015 Case Narrative: Verbatim: chewed it	Buccal	2015 to Unknown	2015	chewed it [WRONG TECHNIQUE IN PRODUCT USAGE PROCESS] N / Y / N	Unknown
<p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 07-DEC-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>This report concerns a 22-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 820149) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p> <p>No information on smoking habits was reported (conventional cigarettes and heatsticks).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unreported date.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
The respondent mentioned that he chewed the product. No associated adverse event was reported.								
The case was considered to be non-serious.								
Action taken with the THS product was not reported.								
No further information is expected. Case closed.								
PMI000606	UNITED STATES Report From Study	Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK] Case Initial Receipt Date: 21-Dec-2015 Case Narrative: Verbatim: heart burn	Respiratory	2015 to Unknown	2015	heart burn [DYSPEPSIA] N / Y / Y	Unknown
Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.								
INITIAL INFORMATION RECEIVED ON 21-DEC-2015 and forwarded to Safety department on 05-Apr-2016.								
This report concerns a 22-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 759773) who took part in the above mentioned market research study.								
No medical history was reported. No concomitant medication was reported.								
No information on smoking habits was reported (conventional cigarettes and heatsticks).								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date.								
The respondent reported heartburn.								
The severity of the event was not reported. The event was assessed as non-serious.								
The outcome of the event was not reported.								
Action taken with the THS product was not reported.								
No further information is expected. Case closed.								
Yes (7)								
³ PMI000128	KOREA, REPUBLIC OF Report From Study	40 Years Male	THS 2.2 Regular (Ginebra / Fitz) / N/A UNK [UNK] THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory Respiratory	24-APR-2015 to Unknown 24-APR-2015 to Unknown	03-MAY-2015 03-MAY-2015 03-MAY-2015	Fire breaks out on the charger: gets injured / was hurt Recovered/Resolved by debris [INJURY ASSOCIATED WITH DEVICE] Y / Y / Y get something stuck in to his hand / his hand was smeared with ash / burned issue [THERMAL BURN] Y / Y / Y Fire breaks out on the charger: gets injured [DEVICE BATTERY ISSUE] N / Y / N	

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
							the device pieces were physically damaged due to external causes, including dismantling of the charger and of the battery [DEVICE DAMAGE] N / Y / N the device pieces were physically damaged due to external causes, including dismantling of the charger and of the battery [DEVICE USE ERROR] N / Y / N	
			Case Initial Receipt Date: 03-May-2015 Case Followup Receipt Date: 14-May-2015 00:00 21-May-2015 00:00 18-Apr-2016 00:00 Event Stop Date: 04-MAY-2015 04-MAY-2015 04-MAY-2015 Case Comment Text: The Injury associated with device and Thermal burn were assessed as serious (medically significant). The Device battery issue was assessed as non-serious.					
			Injury associated with device and Thermal burn are unlisted for THS 2.2 Regular or THS 2.2 Menthol, according to the Investigator Brochure.					
			The causality and listedness assessments are not applicable for Device battery issue.					
			There is limited information in this case. However, considering the temporal relationship and the knowledge about the product in question, the Company assesses the reported adverse events as related to the use of the THS 2.2 Regular and THS 2.2 Menthol.					
			Case Narrative: Verbatim: fire breaks out on the charger: gets injured					
			Market Research Study P1_WOT1_KO: Whole Offer Test - Quantitative survey with a 4 week home usage to assess adult smoker interest in Platform 1 (P1).					
			INITIAL INFORMATION RECEIVED ON 03-May-2015: This report concerns a 40-year-old male subject (Respondent Study ID: 1410947) who took part in the above mentioned market research study.					
			No medical history and no concomitant medications were reported.					
			No information on smoking habits was provided.					
			The respondent started using the Tobacco Heating System (THS) 2.2 on an unspecified date (reported as 24-May-2015 which is subsequent to report date, therefore, most likely, 24-Apr-2015). According to the information received, the respondent used both products, THS 2.2 Regular (Genebra / Fitz) and THS 2.2 Men hol (Dorado I / Vinny low menthol) (Kit numbers not provided).					
			On 03-May-2015, the respondent experienced fire breaking out of the charger and got injured (not further specified). The events were considered to be non-serious. Severity of the adverse events was not reported.					
			Action taken with the use of the product was not reported.					
			At the time of reporting, the outcome of the events was not reported.					
			Follow-up information is expected.					
			FOLLOW-UP INFORMATION RECEIVED ON 14-MAY-2015:					

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Clarification was received that the respondent used two study products (THS 2.2 Regular (Genebra / Fitz) and THS 2.2 Menthol (Dorado I / Vinny low menthol)) with a start date of 24-Apr-2015. It was not specified with which one of the products the event occurred. No further information on the type of injury was received.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 21-MAY-2015:</p> <p>The device kit number WL9 L4K MN7 RSY was provided (not specified if it is for Menthol or Regular).</p> <p>The respondent mentioned that "he was hurt by debris of something", that "he got something stuck into his hand" (not further explained) and that he went to the emergency room due to his problem. He further clarified that "what he described as something stuck into his hand was because his hand was smeared with ash (but didn't explain more about the burned issue)".</p> <p>Regarding the charger, it was reported that the charger caught fire, and possibly exploded. It was also mentioned that "He dropped charger (the holder was in it) on the floor during they were charging. He also told that the holder was too hot because he dropped holder on the floor." It was not clearly explained if the charger was dropped before or after the injury occurred.</p> <p>The event improved when use of the product was stopped, and the product was not restarted.</p> <p>The outcome of the events was indicated as resolved on 04-May-2015.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 18-APR-2016:</p> <p>A technical investigation had been conducted. It appeared that the device pieces were physically damaged due to external causes, including dismantling of the charger and of the battery.</p> <p>No further information is expected. Case closed.</p>							
PMI000365	UNITED STATES Report From Study	43 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [qd]	Respiratory	15-OCT-2015 to (b) (6)	22-OCT-2015	Health related problem requiring hospitalization / in hospital [HOSPITALISATION] Y / Y / N
<p>Case Initial Receipt Date: 30-Oct-2015 Case Followup Receipt Date: 12-Nov-2015 00:00 Event Stop Date: 29-OCT-2015 Case Comment Text: Hospitalization was assessed as serious.</p> <p>Hospitalization is unlisted for THS 2.2 Menthol, as per Reference Safety Information (i.e. IB).</p> <p>Hospitalisation is not an adverse event per se. In this case, the reason for hospitalisation, which would potentially be the actual adverse event, was vaguely provided as health problems, which were assessed by the reporter as being not related to the product in question. The information provided in this report with regard to the medical history, relevant investigations, and treatment received during hospitalisation, is also limited. Based on reporter's causality assessment, the Hospitalisation is assessed as not related to the use of THS 2.2 Menthol, in this patient, who had been a smoker of conventional cigarettes.</p> <p>Case Narrative: Verbatim: Health related problem requiring hospitalization; in hospital.</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 30-Oct-2015 and forwarded to Safety department on the same day.</p> <p>This report concerns a 43-year-old male subject (Respondent Study ID: 209653) who took part in the above mentioned market research study.</p> <p>No medical history was reported. No concomitant medication was reported.</p>							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency] Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>The respondent was a daily smoker (approximately 8 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number W834WAQ1LAN4) on 15-Oct-2015.</p> <p>On (b) (6), the study respondent was hospitalized for health-related reasons. As per reporter, the hospitalization was not related to the product.</p> <p>On 29-Oct-2015, the event resolved (hospital discharge date not provided).</p> <p>The hospitalization (underlying reason not reported) was considered as serious.</p> <p>The consumer used the Heatstick every day. The use of the IQOS device was stopped on 22-Oct-2015. The study respondent used 4 Heatsticks and 7 conventional cigarettes on the day of the event. It was reported that the event did not improve when usage of the product was stopped, and that the event did not return when usage of the product was restarted. A re-start date was indicated for usage of the product.</p> <p>Further information is expected.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 12-Nov-2015 and forwarded to Safety department on 13-Nov-2015.</p> <p>Three follow-up attempts were performed, unsuccessfully. No additional information was provided.</p> <p>No further information is expected. Case Closed.</p>							
PMI000367	UNITED STATES	51 Years Female	THS 2.2 Regular (Dorado I / Ron) / N/A UNK [UNK]	09-SEP-2015 to 28-OCT-2015	(b) (6)	was in an accident; a 400 lb table slid down her leg pushing her into a garden bed where there were some rocks and she fell [ACCIDENT] Y / Y / Y	Unknown
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	09-SEP-2015 to 28-OCT-2015	(b) (6)	injured her left leg and foot, the bone had been smashed (in an accident); received intravenous antibiotics, a tetanus shot, and leg staples [LIMB INJURY] Y / Y / Y	
					(b) (6)	injured her left leg and foot, the bone had been smashed (in an accident) [SKELETAL INJURY] Y / Y / Y Participant stated her foot is infected and that the infection had gotten into the bone [OSTEOMYELITIS] Y / Y / Y the nerves are dead and there is no flow (NOS) [NERVE INJURY] Y / Y / Y	
<p>Case Initial Receipt Date: 02-Nov-2015</p> <p>Case Followup Receipt Date: 10-Nov-2015 00:00</p> <p>Event Intensity: Severe Severe Severe Severe Severe</p> <p>Event Stop Date: 16-SEP-2015</p>							

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
Case Comment Text: The Accident, Limb injury, Lower limb fracture, Osteomyelitis, and Nerve injury were assessed as serious, due to requiring hospitalization.								
Accident, Limb injury, Lower limb fracture, Osteomyelitis, and Nerve injury are unlisted for THS 2.2 Menthol and THS 2.2 Regular, as per the Reference Safety Information (i.e. the IB).								
Considering the circumstances provided in this report, the Accident and the ensuing adverse events (i.e. Limb injury, Lower limb fracture, Osteomyelitis, Nerve injury) are assessed as not related to the use of the products, in this patient, who had been a smoker of conventional cigarettes.								
Case Narrative: Verbatim: was in an accident; a 400 lb table slid down her leg pushing her into a garden bed where there were some rocks and she fell / injured her left leg and foot, the bone had been smashed (in an accident); received intravenous antibiotics, a tetanus shot, and leg staples / Participant stated her foot is infected and that the infection had gotten into the bone / the nerves are dead and there is no flow (NOS)								
Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.								
INITIAL INFORMATION RECEIVED ON 2-Nov-2015 and forwarded to Safety department on the same day.								
This report concerns a 51-year-old female subject (Respondent Study ID: 654390) who took part in the above mentioned market research study.								
No medical history was reported. No concomitant medications were reported.								
The respondent was a daily smoker (approximately 10 - 20 conventional cigarettes per day).								
The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) and THS 2.2 Regular (Dorado II / Ron) (kit number JXT0TVB1ZHS6) on an unknown date.								
The respondent stated that she was in an accident on 16-Sep-2015. Her left leg and foot were injured and the bone had been smashed. She was hospitalized on an unknown date. On an unknown date, she had been released from the hospital, had been bed-ridden for 3 weeks, and had gone back to work on 8-Oct-2015. On (b) (6), she was hospitalized for the second time. She stated her foot was infected and that the infection had gotten into the bone, further stating that it was probably infected from the beginning. She also stated the nerves were dead, there was no flow and they will be doing who-knows how many surgeries. She stated that she would be in the hospital at least 4 months and that she was on a lot of medications. The study respondent requested to be withdrawn from the study.								
The events severity was reported as severe. The events were assessed as serious due to hospitalization.								
The respondent used the Heatsticks every day. No information was provided regarding the number of Heatsticks and cigarettes used by the respondent on the day of the event. Last day of product usage was indicated as 28-Oct-2015.								
At time of reporting, the outcome of the events was unknown; however, the respondent was in hospital at time of reporting.								
Further information is expected.								
FOLLOW-UP INFORMATION was received on 10-Nov-2015 and forwarded to the Safety department on 13-Nov-2015.								
The recipient stated that she was unsure of when she started to use the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) and THS 2.2 Regular (Dorado II / Ron) (kit number JXT0TVB1ZHS6) but she felt that it may have been around 09-SEP-2015.								
She stated that it was a wonderful morning (70 degrees), she was at work, when a 400 lb table slid down her leg pushing her into a garden bed where there were some rocks and she fell. She mentioned that she was unsure of what exactly happened.								
The respondent stated that, after the accident, one of her supervisors or somebody at her work that was in a position of responsibility drove her to the hospital or (b) (6). Once at the hospital, the respondent stated that she was not formally admitted, but spent a few hours in the emergency room (ER) where she received intravenous antibiotics, a tetanus shot, and								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>leg staples. On the same day, after being released from the ER, she was able to walk around and went to the mall site to explain her situation. The respondent stated that, since her release from the ER, her condition worsened and she was admitted to the hospital; she was unsure of the date, but that she believed it was about two Wednesdays prior to reporting date. She was currently still in the hospital.</p> <p>The respondent stated that the events were still ongoing as of 10-Nov-2015.</p> <p>No additional information was provided. The respondent refused to provide any more information. She wanted to know why these questions were asked stating that they sound like questions that a lawyer may ask. She stated that she was unwilling to provide these answers until she gets her explanation. The respondent stated that she is willing to be called back.</p> <p>Further information is expected.</p>								
PMI000381	UNITED STATES Report From Study	57 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	01-OCT-2015 to Unknown	(b) (6) (b) (6) (b) (6) (b) (6) 2015	<p>he was in a fight during which he was hit over the head with a baseball bat and a 2x4 [HEAD INJURY] Y / Y / Y</p> <p>Since that incident occurred, he has been having dizzy spells and blacking out due to low blood pressure [HYPOTENSION] N / Y / Y</p> <p>Since that incident occurred, he has been having dizzy spells and blacking out due to low blood pressure [LOSS OF CONSCIOUSNESS] N / Y / Y</p> <p>Since that incident occurred, he has been having dizzy spells and blacking out due to low blood pressure [DIZZINESS] N / N / Y</p> <p>device had broken [DEVICE DEFECTIVE] N / Y / N</p>	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 09-Nov-2015 Case Followup Receipt Date: 23-Nov-2015 00:00 Event Intensity: Moderate Moderate Moderate Moderate</p> <p>Case Comment Text: The Head injury was assessed as serious, due to requiring hospitalization. The Hypotension, Loss of consciousness, Dizziness, and Device defective were assessed as non-serious, based on the provided information.</p> <p>Head injury, Hypotension, and Loss of consciousness (described as blackout) are considered unlisted, as per the Reference Safety Information (i.e. the IB). Dizziness is listed, as per the IB.</p> <p>Listedness and causality assessments are not applicable for Device defective.</p> <p>The information provided in this non-medically confirmed report is limited. It was reported that the Head injury was the results of a blow to the head sustained during a fight. Therefore, the Head injury is assessed as not related to the use of Tobacco Heating System (THS) 2.2. Although Hypotension, Loss of consciousness, and Dizziness were reportedly following the Head injury, and despite their persistence even after stopping the use of product (due to Device defective), considering the current knowledge on the product in question, the causality relationship between the use of THS 2.2 and Hypotension, Loss of consciousness, and Dizziness cannot be excluded and, therefore, is assessed as related.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: he was in a fight during which he was hit over the head with a baseball bat and a 2x4 and ended up in the hospital / since hat incident occurred he has been having dizzy spells and blacking out due to low blood pressure / device had broken</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 09-Nov-2015 and forwarded to Safety department on he same day.</p> <p>This report concerns a 57-year-old male subject (Respondent Study ID: 821416) who took part in the above mentioned market research study.</p> <p>The following medical history was reported: back broken, low blood platelets, glaucoma, degenerative rheumatoid arthritis, fractured right knee cap, broken teeth, eye problems (additional information not provided).</p> <p>The respondent was a daily smoker (approximately 15 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number 5U85BNX8J7JR) on 01-Oct-2015.</p> <p>The respondent stated that, on (b) (6), he was in a fight during which he was hit over the head with a baseball bat and a 2x4 and ended up in the hospital on the same day. The respondent stated he was in the hospital for 4 days. Following that incident, he went to the enrolment center to pick up a replacement device. While waiting for the replacement he reported he felt asleep and attributed the fact that he felt asleep to having low blood pressure and the recent hospitalization/fight, date unknown. Since hat incident occurred, he has been having dizzy spells and blacking out due to low blood pressure (as per reporter).</p> <p>The events severity was reported as moderate. The events were assessed as serious due to hospitalization.</p> <p>He used 15 cigarettes on the day of the event however the respondent did not remember about the number of Heatsticks used.</p> <p>The event improved when usage of the product was stopped and product was not restarted. Respondent stated he liked the device but that his device had broken. Due to device being broken he has not resumed use.</p> <p>At time of reporting, the events were not resolved.</p> <p>Further information is expected.</p> <p>NOTE:</p> <p>New information received on 23-Nov-2015. 3 unsuccessful follow-up attempts were made on 19-Nov-2015, 20-Nov-2015, 23-Nov-2015 respectively. No further information is expected. Case closed.</p>								
PMI000404	UNITED STATES Report From Study	48 Years Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A	Respiratory	OCT-2015 to OCT-2015	2015	she was diagnosed with both Acute Bronchitis and a double ear infection [BRONCHITIS] Y / Y / Y	Recovered/Resolved
			UNK [UNK] 1 DF [1 DF-qd]	Respiratory	2015 Ongoing	2015	she was diagnosed with both Acute Bronchitis and a double ear infection [EAR INFECTION] Y / Y / Y	
						OCT-2015	nerve damage pain in her hands [NERVE INJURY] N / Y / N	
						OCT-2015	nerve damage pain in her hands [NEURALGIA] N / Y / N	

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
						OCT-2015	She stated that after the neck surgery, her hand and arm pain was so severe it hurt to touch anything, making it difficult and painful to use the IQOS holder/arm and hand pain when using the holder [HYPERAESTHESIA] N / Y / N	
						2015	inhaling smoke from a fire that occurred when a cement truck caught on fire near her house; inhaling metal and chemicals from the fire [RESPIRATORY FUME INHALATION DISORDER] N / Y / N	
						2015	She stated that after the neck surgery, her hand and arm pain was so severe it hurt to touch anything, making it difficult and painful to use the IQOS holder/arm and hand pain when using the holder [DEVICE DIFFICULT TO USE] N / Y / N	
<p>Case Initial Receipt Date: 21-Nov-2015 Case Followup Receipt Date: 23-Dec-2015 00:00 Event Intensity: Severe Severe Unknown Severe Moderate Moderate Event Stop Date: OCT-2015 OCT-2015 OCT-2015 21-NOV-2015 21-NOV-2015 Case Comment Text: The Bronchitis and Ear infection were conservatively assessed as serious, due to the reported visit to hospital and required antibiotic treatment (i.e. medically important intervention).</p> <p>Nerve injury, Neuralgia, Hyperaesthesia, Respiratory fume inhalation disorder, and Device difficult to use were assessed as non-serious.</p> <p>Bronchitis, Ear infection, Nerve injury, Neuralgia, Hyperaesthesia, Respiratory fume inhalation disorder, and Device difficult to use are unlisted, as per the Reference Safety Information for THS 2.2 Regular (i.e. the IB).</p> <p>The information provided in this non-medically confirmed report is limited and unclear, particularly regarding the relevant medical history, respective adverse events' onset and resolution dates.</p> <p>Although the Bronchitis and Ear infection were diagnosed after reportedly inhaling smoke with chemicals from a fire occurred near her house, the causal relationship between the use of THS 2.2 and these two adverse events cannot be completely ruled out and, therefore, is assessed as possible. Of note, the subject, who had been a smoker of conventional cigarettes, used the product in question only occasionally. Although she continued to use the product during her acute bronchitis and ear infection, these adverse events resolved.</p> <p>The Nerve injury, Neuralgia, and Hyperaesthesia associated with Device difficult to use were reported as consequences of a traffic accident and its treatment (neck surgery). Therefore, these events are assessed as not related to the use of THS 2.2. Of note, these events have also resolved, despite the continued usage of the product.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>Case Narrative: Verbatim: she was diagnosed with both acute bronchitis and a double ear infection; hand and arm pain was so severe it hurt to touch anything; nerve damage pain in her hands; inhaling smoke from a fire; difficult and painful to use the IQOS holder/arm and hand pain when using the holder</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 21-Nov-2015 and forwarded to Safety department on 21-Nov-2015.</p> <p>This report concerns a 48-year-old female subject (Respondent Study ID: 656993) who took part in the above mentioned market research study.</p> <p>Medical history of hepatitis C was reported. It was also reported that in Oct-2015 he respondent had neck surgery related to injuries resulting from being hit by a drunk driver in 2014. The following concomitant medications were reported: Erythromycin, Celexa (citalopram hydrobromide) 10mg, low dosage of Aspirin (acetylsalicylic acid), Topamirate, Xanax (alprazolam) 0.25mg and a hair/skin/nails vitamin.</p> <p>The respondent was a daily smoker (approximately 1 to 7 conventional cigarettes per week).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number 4YDU57Q4UMSB) in early Oct-2015.</p> <p>The respondent stated that in October 2015 she had neck surgery related to injuries resulting from being hit by a drunk driver in 2014 which caused her to experience nerve damage pain in her hands. She stated that after the neck surgery, her hand and arm pain was so severe it hurt to touch anything, making it difficult and painful to use the IQOS holder. At that time, she stopped using the IQOS holder and she could not give an exact date as to when she stopped but stated it was sometime in October, before Halloween.</p> <p>After receiving a call from the enrollment center sometime after stopping use of the heatsticks, she resumed use of the device, so she could remain a participant in the study. At that time, she stated she was no longer experiencing the hand and arm pain (exact date not reported).</p> <p>The respondent stated that approximately two or three weeks prior to the date of this report, she went to the hospital after inhaling smoke from a fire that occurred when a cement truck caught on fire near her house. She stated she began coughing up phlegm and mucus after inhaling metal and chemicals from the fire and she stated she ended up going to the hospital. She stated she was diagnosed with both acute bronchitis and a double ear infection which required antibiotics. She said she was trying not to smoke because of the infections but continued to use her IQOS device and to use approximately one heatstick per day. Respondent stated that on the day of the report, it was the first day she felt better.</p> <p>The severity was reported as moderate for the events of acute bronchitis and double ear infection and as severe for hand and arm pain (not reported for the other events). The events acute bronchitis and double ear infection were assessed as serious. The remaining events were assessed as non-serious.</p> <p>The respondent used the heatsticks occasionally. She mentioned that she used HeatSticks every day until arm/hand pain began when using the holder, then she began using 0-1 Heatsticks a day after starting use of the product again. Numbers of Heatsticks and cigarette used on the day of the events are unknown.</p> <p>It was reported that the events of hand/arm pain improved when usage of the product was stopped and did not return when usage of the product was restarted (not specified for the other events). She continued to use Heatsticks during her acute bronchitis/double ear infection. The last day of product use was reported as unknown.</p> <p>The event of hand and arm pain resolved in Oct-2015. The events of ear infection and acute bronchitis resolved on 21-Nov-2015. The outcome of the other events was not reported.</p> <p>No further information is expected.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000409	UNITED STATES Report From Study	36 Years Female	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	Unknown to 24-OCT-2015	(b) (6) OCT-2015	developed cyst on throat / cyst at tonsils / cyst at palatine tonsils / surgery on tonsils [TONSILLAR CYST] Y / Y / Y seasonal sore hroat [OROPHARYNGEAL PAIN] N / Y / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 25-Nov-2015 Case Followup Receipt Date: 09-Nov-2015 00:00 23-Dec-2015 00:00 Event Intensity: Unknown Case Comment Text: The Tonsillar cyst was assessed as serious (medically important, requiring drainage). The Oropharyngeal pain was assessed as non-serious.</p> <p>Tonsillar cyst is unlisted, whereas Oropharyngeal pain is listed, as per the Reference Safety Information (i.e. he IB).</p> <p>The information provided in this non-medically confirmed report is limited. The temporal relationship cannot be accurately assessed, as the product usage start date was not provided. Judging by the pharmacological treatment (i.e. unspecified antibiotics) administered for the Tonsillar cyst, one may deduce that it was infectious cyst, which may had been associated with the reported seasonal sore throat. Considering the current knowledge on the product in question, the causality relationship between the use of THS 2.2 and Tonsillar cyst and Oropharyngeal pain cannot be excluded and, therefore, is assessed as related. Of note, the subject had been a smoker of conventional cigarettes.</p> <p>Case Narrative: Verbatim: developed cyst on throat / cyst at tonsils / cyst at palatine tonsils/ surgery on tonsils; seasonal sore throat</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 25-Nov-2015 and forwarded to Safety department on the same day.</p> <p>This report concerns a 36-year-old female subject (Respondent Study ID: 184377) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medication were reported. The respondent denied any other medical conditions within the last year.</p> <p>The respondent was a daily smoker (approximately 8 conventional cigarettes per day, 2.5-3 packs per week).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) on an unknown date. The respondent did not remember when she started using the product.</p> <p>The respondent stated that, 2-3 days before the 23-Oct-2015 or the 24-Oct-2015, the onset of symptoms began (also reported as 23-Oct-2015). These symptoms were described as what the respondent thought was seasonal sore throat. She went to the hospital on (b) (6), the respondent is unsure (call was disconnected before it was confirmed if she was hospitalized or if she went to emergency room). On the (b) (6), at the hospital, a cyst at palatine tonsils was found. Follow-up appointment with personal physician 3-4 days after the hospitalization confirmed the diagnosis.</p> <p>At hospital, drainage of cyst at tonsils and a biopsy were performed. Percocet (acetaminophen, oxycodone) treatment for pain and unknown antibiotic medication were administered to the respondent. At personal doctor, Percocet (acetaminophen, oxycodone) treatment for pain and unknown antibiotic medication (that was different than the one used at the hospital) were administered to the respondent (call disconnected before able to confirm route of antibiotics, dosage of medications).</p> <p>The event severity was not reported. The event required medical advice and treatment. The event was assessed as non-serious.</p> <p>The smoking status of the respondent with the heatstick was not reported. The number of Heatstick and cigarette used by the respondent on the day of the event was unknown.</p> <p>The use of the product was stopped on 24-Oct-2015.</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>At time of the report, the event was not recovered. Condition was ongoing with upcoming follow-up to drain remaining fluid.</p> <p>FOLLOW-UP INFORMATION RECEIVED ON 09-NOV-2015 and forwarded to Safety department on 05-Apr-2016.</p> <p>Surgery on tonsils was reported (no further information provided).</p> <p>No further information is expected. Case closed.</p>								
PMI000410	UNITED STATES Report From Study	46 Years Male	THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	19-OCT-2015 to Unknown	(b) (6)	had been hospitalized during the observation period (health problem) [ADVERSE EVENT] Y / Y / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 30-Nov-2015 Case Followup Receipt Date: 11-Dec-2015 00:00 Event Stop Date: 06-NOV-2015 Case Comment Text: The unspecified Adverse event was assessed as serious (due to hospitalization).</p> <p>Adverse event (not further unspecified, in this report) is considered unlisted for THS 2.2 Menthol, as per the Reference Safety Information (i.e. Investigator's Brochure).</p> <p>The information provided in this report is limited, particularly regarding to the patient's unspecified health problem, the reason and dates of hospitalisation, and the action taken with the product. However, considering the plausible temporal relationship, a causal relationship between the use of THS 2.2 Menthol and the reported event cannot be excluded and, therefore, is assessed as possible.</p> <p>Case Narrative: Verbatim: had been hospitalized during the observation period (health problem)</p> <p>Market Research Study THS-PBA-07-US: Comprehensive program to study consumer perception and behavior in relation to THS 2.2.</p> <p>INITIAL INFORMATION RECEIVED ON 30-Nov-2015 and forwarded to Safety department on 02-Dec-2015.</p> <p>This report concerns a 46-year-old male subject (Respondent Study ID: 759911) who took part in the above mentioned market research study.</p> <p>No medical history and no concomitant medication were reported.</p> <p>The respondent was a daily smoker (approximately 8 conventional cigarettes per day).</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) kit number 7JUFE86NJOKL) on 19-Oct-2015.</p> <p>The respondent stated that he had been hospitalised during the observation period. The respondent experienced a health problem (not further specified) from (b) (6) to (b) (6). No further information was provided.</p> <p>The event severity of the adverse event was not reported. The case was assessed as serious due to the hospitalisation.</p> <p>The smoking habits related to the heatstick was not reported. The respondent used 2 Heatsticks and 8 cigarettes on the day of the event (presumably, the unknown event which caused the hospitalisation, occurring on 31-Oct-2015).</p> <p>No information was provided about the action taken with the product.</p> <p>The unspecified health problem resolved or (b) (6)</p>								

CUM LL Pre-Marketing THS Menthol D1 Vinny Low and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form		Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
			Daily Dose [Dose Frequency]	Route				
Follow-up information was expected, however, all attempts to obtain additional information from the respondent were unsuccessful. Case closed.								

Total number of case entries printed: 86

Total number of cases printed: 86

CUM LL THS Menthol excluding D1 Vinny Low Menthol and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Advanced Condition used in this report:

Advanced Condition: THS Menth Minus D1 Vinny Low Menth/Vin Ron (Created by nicole.miller)

Query Set Selection Criteria:

Report From Study/Other Studies INTERSECT

Ingredient Mint Veronica

Advanced Conditions used in this query set:

Advanced Condition: Report From Study/Other Studies (Created by nicole.miller)

Selection Criteria:

(Case Report Type equal to Report From Study AND

Observe Study Type equal to Other Studies)

Advanced Condition: Ingredient Mint Veronica (Created by nicole.miller)

Selection Criteria:

Ingredient equal to Mint Veronica

CUM LL THS Menthol excluding D1 Vinny Low Menthol and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
No (10)								
PMI000188	ITALY Report From Study	60 Years Female	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]	Respiratory	15-MAY-2014 to 16-MAY-2014	15-MAY-2014 15-MAY-2014 15-MAY-2014 15-MAY-2014	Nausea [NAUSEA] N / N / Y Headache [HEADACHE] N / N / Y Dizziness [DIZZINESS] N / N / Y Too strong menthol smell [PRODUCT ODOUR ABNORMAL] N / Y / Y	
<p>Case Initial Receipt Date: 16-May-2014 Event Intensity: Moderate Moderate Moderate Moderate</p> <p>Case Narrative: Verbatim: Nausea, headache, dizziness, too strong menthol smell.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 16-MAY-2014: This report concerns a 60-year-old female subject (Respondent Study ID: MIF0101101L) who took part in the above mentioned study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 7 cigarettes per day and was not using any other tobacco products/nicotine products.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number CU005515) on 15-May-2014. She reported that the product had a too strong menthol smell. On 15-May-2014, she experienced nausea, headache and dizziness. The events were considered to be non-serious and moderate in intensity. The respondent stopped using the product on 16-May-2014. At the time of reporting, the event of nausea was still ongoing. On the day of the occurrence of the events, the respondent smoked 8 cigarettes and used 3 sticks.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000200	ITALY Report From Study	67 Years Female	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]	Respiratory	15-MAY-2014 to 15-MAY-2014	15-MAY-2014	Dizzy [DIZZINESS] N / N / Y	Recovered/Resolved
<p>Case Initial Receipt Date: 26-May-2014 Event Intensity: Moderate Event Stop Date: 15-MAY-2014 Case Narrative: Verbatim: Dizzy</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p>								

CUM LL THS Menthol excluding D1 Vinny Low Menthol and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
<p>INITIAL INFORMATION RECEIVED ON 26-MAY-2014: This report concerns a 67-year-old female subject (Respondent Study ID: BUS0414102L) who took part in the above mentioned market research study.</p> <p>The respondent had no medical conditions and was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 20 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number CU004778) on 15-May-2014. On 15-May-2014, she felt dizzy. The event was considered to be non-serious and moderate in intensity. The respondent stopped using the product on 15-May-2014 and the event resolved on the same day. On the day of the occurrence of the event, the respondent used 2 sticks and smoked 15 cigarettes.</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000202	ITALY Report From Study	51 Years Female	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]	Respiratory	20-MAY-2014 to 28-MAY-2014	20-MAY-2014 20-MAY-2014 20-MAY-2014	Influenza [INFLUENZA] N / Y / Y Fever [PYREXIA] N / Y / Y Cough [COUGH] N / N / Y	Not Recovered/Not Resolved
<p>Case Initial Receipt Date: 29-May-2014 Event Intensity: Mild Mild Mild Case Narrative: Verbatim: Influenza, fever, cough</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 29-MAY-2014: This report concerns a 51-year-old female subject (Respondent Study ID: MIB0729101L) who took part in the above mentioned market research study.</p> <p>The respondent's medical conditions included anaemia. The respondent was not taking any concomitant medications.</p> <p>The respondent was a smoker who smoked on average 5 cigarettes per day.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number CU005021) on 20-May-2014. On 20-May-2014, she experienced cough, influenza and fever. However, she added that these symptoms were already present prior to using the THS. The events were considered to be non-serious and mild in intensity. The respondent was treated with unspecified antibiotics. The respondent stopped using the product on 28-May-2014 evening and at the time of this report, the events were ongoing. On the day of the occurrence of the events, the respondent used 3 sticks and smoked 2 cigarettes.</p> <p>No follow-up information has been requested ? case closed.</p>								

CUM LL THS Menthol excluding D1 Vinny Low Menthol and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000212	ITALY Report From Study	19 Years Male	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]	Respiratory	24-MAY-2014 to Unknown	24-MAY-2014	Light feeling of nausea [NAUSEA] N / N / Y	Unknown
Case Initial Receipt Date: 24-May-2014 Case Narrative: Verbatim: Light feeling of nausea Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 24-MAY-2014: This report concerns a 19-year-old male subject who took part in the above mentioned market research study. The respondent was a smoker. The respondent's medical history and concomitant medications were not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number not provided) on 24-May-2014. On the same day, the respondent stated that he was used to his cigarettes and preferred the taste of tobacco. He reported that, after smoking for a while, he experienced a light feeling of nausea. The event was considered non-serious. The outcome was unknown. No follow-up information has been requested ? case closed.								
PMI000215	ITALY Report From Study	64 Years Female	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]			15-MAY-2014 15-MAY-2014	Makes me cough [COUGH] N / N / Y Menthol taste too strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
Case Initial Receipt Date: 15-May-2014 Case Narrative: Verbatim: Makes me cough. Menthol taste too strong. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 15-MAY-2014: This report concerns a 64-year-old female subject who took part in the above mentioned market research study. The respondent was a smoker. The respondent's medical history and concomitant medications were not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number not provided) on 15-May-2014. On the same day, the respondent reported that the product made her cough and that the product menthol taste was too strong. The events were considered to be non-serious. The outcome was unknown. No follow-up information has been requested ? case closed.								

CUM LL THS Menthol excluding D1 Vinny Low Menthol and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000234	ITALY Report From Study	59 Years Male	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]	Respiratory			It irritates the throat [THROAT IRRITATION] N / N / Y Causes a bit of cough [COUGH] N / N / Y	Unknown
<p>Case Initial Receipt Date: 23-May-2014 Case Narrative: Verbatim: It irritates the throat, causes a bit of cough.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responde in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interes the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week a interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 23-MAY-2014: This report concerns a 59-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent' s medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number not provided) on an unspecified date. The respondent reported that the irritated his throat, caused a bit of cough and that it did not satisfy him completely as he smoked a lot. The events were considered to be non-serious. The outcome was unk</p> <p>No follow-up information has been requested ? case closed.</p>								
PMI000241	ITALY Report From Study	37 Years Female	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]	Respiratory			Gives me headache [HEADACHE] N / N / Y Gives me nausea [NAUSEA] N / N / Y	Unknown
<p>Case Initial Receipt Date: 29-May-2014 Case Narrative: Verbatim: Gives me headache and nausea.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responde in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interes the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week a interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 29-MAY-2014: This report concerns a 37-year-old female subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent' s medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number not provided) on an unspecified date. The respondent reported that the gave her headache and nausea. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>								

CUM LL THS Menthol excluding D1 Vinny Low Menthol and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000243	ITALY Report From Study	49 Years Male	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]	Respiratory			It gave me nausea [NAUSEA] N / N / Y	Unknown
Case Initial Receipt Date: 03-Jun-2014 Case Narrative: Verbatim: It gave me nausea. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 03-JUN-2014: This report concerns a 49-year-old male subject who took part in the above mentioned market research study. The respondent was a smoker. The respondent's medical history and concomitant medications were not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number not provided) on an unspecified date. The respondent reported that the product gave him nausea. The event was considered to be non-serious. The outcome was unknown. No follow-up information has been requested ? case closed.								
PMI000259	ITALY Report From Study	21 Years Female	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]	Respiratory			Gave me a feeling of nausea [NAUSEA] N / N / Y Mint is too strong [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
Case Initial Receipt Date: 06-Jun-2014 Case Narrative: Verbatim: Mint is too strong, gave me a feeling of nausea. Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks. INITIAL INFORMATION RECEIVED ON 06-JUN-2014: This report concerns a 21-year-old female subject who took part in the above mentioned market research study. The respondent was a smoker. The respondent's medical history and concomitant medications were not provided. The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number not provided) on an unspecified date. The respondent reported that the product was too strong and the product gave her a feeling of nausea. The events were considered to be non-serious. The outcome was unknown. No follow-up information has been requested ? case closed.								

CUM LL THS Menthol excluding D1 Vinny Low Menthol and Vinny Ron
Period: 01-Jan-1900 through 31-Mar-2016

Case Number	Country Source	Age Sex	Product Name / Form Daily Dose [Dose Frequency]	Route	Dates of Treatment or Treatment Duration	Event Onset Date or Time to Onset	Event Verbatim [Preferred Term] Ser/UL/Causal	Patient Outcome
PMI000260	ITALY Report From Study	46 Years Male	THS 2.2 Menthol (Mint Veronica) / N/A UNK [UNK]	Respiratory			Something really heavy to breathe [CHEST DISCOMFORT] N / Y / Y Unpleasant taste [PRODUCT TASTE ABNORMAL] N / Y / Y	Unknown
<p>Case Initial Receipt Date: 30-May-2014 Case Narrative: Verbatim: Unpleasant taste, something really heavy to breathe.</p> <p>Market Research Study P1_BT1_IT: Blinded blend test to identify the THS 2.2 products with the most broadly appealing sensorial profile. In this study, adult smoker responded in an initial interview at a central location during which they were exposed to an unbranded description of THS 2.2 and, should they provide a non-negative purchase interest in the description, randomly assigned to one of five possible products for stick test and two week extended home usage. A face to face interview was conducted after one week and a follow-up interview, also at central location, after two weeks.</p> <p>INITIAL INFORMATION RECEIVED ON 30-MAY-2014: This report concerns a 46-year-old male subject who took part in the above mentioned market research study.</p> <p>The respondent was a smoker. The respondent's medical history and concomitant medications were not provided.</p> <p>The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Mint Veronica; Kit number not provided) on an unspecified date. The respondent reported that they had an unpleasant taste and it was something really heavy to breathe. The events were considered to be non-serious. The outcome was unknown.</p> <p>No follow-up information has been requested ? case closed.</p>								

Total number of case entries printed: 10
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