PMI RESEARCH & DEVELOPMENT

Safety Summary Report

Passive Safety Surveillance for Perception & Behavior Assessment Study n° THS-PBA-07-US

Appendix 5 Line Listings of Adverse Events

Report Number:	PMI_SURV_2016_SSR02
Study Title:	Actual Use Study of THS 2.2 – THS-PBA-07-US
Study ID:	THS-PBA-07-US
Safety ID	THS-PBA-07-US_PSS
Products Name:	Tobacco Heating System 2.2 / Regular and Menthol
Passive Safety Surveillance by:	Philip Morris Products S.A. PMI Research & Development Quai Jeanrenaud 5 2000 Neuchâtel, Switzerland
Version:	Final v 2.0
Date:	30-Aug-2016
Author:	Nicoleta Ciuria Senior Medical Safety Associate Philip Morris Products S.A.
Reviewed and approved by:	Alexandr Mészáros, MD Senior Medical Scientist – Surveillance Philip Morris Products S.A.

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-2016

Advanced Condition used in this report:

Advanced Condition: JCo - Study THS-PBA-07-US minus Non-Valid QS (Created by Joshua Cox)
Query Set Selection Criteria:
JCo - Study ID = THS-PBA-07-US MINUS
Case Classification = Non Valid Case

Advanced Conditions used in this query set:
Advanced Condition: JCo - Study ID = THS-PBA-07-US (Created by Joshua Cox)
Selection Criteria:
Study ID equal to THS-PBA-07-US
Advanced Condition: Case Classification = Non Valid Case (Created by nicole.miller)
Selection Criteria:
Case Classification equal to Non valid case

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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 (**40**)								
PMI000341	UNITED STATES Report From Study	26 Years Female	**THS 2.2 Regular (Dorado II / Ron) / N/A** UNK [UNK] UNK [UNK]	Respiratory Respiratory	01-OCT-2015 to Unknown 01-OCT-2015 to 26-OCT-2015	03-OCT-2015 03-OCT-2015 2015 03-OCT-2015	I have a blister on my lip [LIP BLISTER] N / Y / Y chemical burn or machine heated up too hot and created blisters [BURNS SECOND DEGREE] N / Y / Y burns on hands [THERMAL BURN] N / Y / Y machine heated up too hot [DEVICE ISSUE] N / Y / N	Recovered/Resolved

Study ID: THS-PBA-07-US
Case Initial Receipt Date: 10-Oct-2015
Case Followup Receipt Date: 09-Nov-2015 00:00
27-Oct-2015 00:00
Event Intensity: Moderate
Moderate
Event Stop Date: 23-OCT-2015
23-OCT-2015
23-OCT-2015

Case Narrative: Verbatim: I have a blister on my lip, chemical burn or machine heated up too hot and created blisters, burns on hands. Machine heated up too hot.

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 10-Oct-2015 and forwarded to Safety department on the same day.

This report concerns a 26-year-old female subject (Respondent Study ID: 828735) who took part in the above mentioned market research study.

The subject's medical history included heart disease (POTS), hypothyroid, adrenal insufficiency, low blood pressure and fibromyalgia. The following concomitant medications were reported: Inderal (propranolol hydrochloride), "Sanept", Ambien (zolpidem tartrate), Adderall (amfetamine aspartate, amfetamine sulfate, dexamfetamine saccharate, dexamfetamine sulfate), "Florisus", Klonipin (clonazepam), "Xanaflax", Bactrim (sulfamethoxazole, trimethoprim) and Zofran (ondansetron hydrochloride), doses, treatment dates and indications not provided.

The respondent was a daily smoker (approximately 15 conventional cigarettes per day).

The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (Kit number BCCJD1TSDDW) on 07-Oct-2015.

On 08-Oct-2015, the respondent had a blister on her lip. The respondent mentioned that she was not sure if it was from the THS or from her regular cigarettes and smoking it too close to the filter. She went to see her doctor to have it looked at because she thought it might be herpes. The respondent said her doctor told her it was a blister caused by a burn and that it could have been caused by smoking a cigarette too close to the filter. She has not had a blister like this before and only noticed the blister after she had started using the iQOS device.

The event severity was reported as moderate and required medical advice on 09-Oct-2015. The event was considered to be non-serious.

The respondent used the Heatsticks occasionally and used one stick on the day of the event. The event did not improve when usage of the product was stopped and the product was not restarted.

At time of reporting, the respondent had not recovered.

No follow-up information is expected. Case closed.

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
			FOLLOW-UP INFORMATION was received on 27-Oct-2015 and forwarded to the Safety department on the same day. Verbatim: chemical burn or machine heated up too hot and created blisters. No additional medical history was reported. The following additional concomitant medications were reported: "Florines", "Coonevpan" and Fanapt (dosages, indications, treatment dates not provided). The respondent was a daily smoker (approximately 8 conventional cigarettes per day, previously reported as 15 conventional cigarettes per day). The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number 5410706815337) on 01-Oct-2015 (previously reported as 07-Oct-2015). The respondent reported that on 03-Oct-2015, she experienced chemical burn, or the machine heated up too hot and created a blister (previously reported as blister on my lip). The events' severity was reported as moderate. The events were considered to be non-serious. The respondent used the product every day (2 heatsticks and 5 conventional cigarettes on the day of the event). It was reported that the events improved when usage of the product was stopped and returned when the product was restarted (dates not further specified). Last day of product usage was indicated as 26-Oct-2015. However, the final action taken with the product was unknown. The events resolved on 23-Oct-2015. FOLLOW-UP INFORMATION WAS RECEIVED ON 09-NOV-2015 and forwarded to Safety department on 05-Apr-2016. Burns on hands were reported (no further information provided). No follow-up information is expected. 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 12-OCT-2015 13-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	Recovered/Resolved

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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
						12-OCT-2015	having a headache [HEADACHE] N / N / Y	
						12-OCT-2015	was not able to get the device to work [DEVICE ISSUE] N / Y / N	
						12-OCT-2015	tasted a very strong menthol taste [PRODUCT TASTE ABNORMAL] N / Y / N	

Study ID: THS-PBA-07-US
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.

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 15-Oct-2015 and forwarded to Safety department on 16-Oct-2015.

This report concerns a 66-year-old female subject (Respondent Study ID: 538801) who took part in the above mentioned market research study.

Medical history of high blood pressure, breast cancer, hypothyroid and high cholesterol was reported. The following concomitant medications were reported: Synthyroid (levothyroxine sodium), Cadeut (presumably Caduet, amlodipine besilate, atorvastatin calcium), Advil (ibuprofen), doses, treatment dates and indications not provided.

The consumer was a daily smoker (approximately 10 conventional menthol cigarettes per day).

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.

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 heatstcik 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.

The intensity of the events was reported as severe. The events were considered to be non-serious. Participant did not seek medical advice.

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
			It was reported that the events improved when the usage of the product was discontinued. Product was not restarted. Consumer stated that she felt fine on 15-Oct-2015. The events were resolved. No follow-up information is expected. Case closed. FOLLOW-UP INFORMATION was received on 26-Oct-2015 and forwarded to the Safety department on 2-Nov-2015. Verbatim: they made me sick In addition to the previous reported events, the respondent stated that "They made me sick". The event severity was not reported. The event was considered to be non-serious. The outcome of the event was not reported. No further information was provided. No follow-up information is expected. Case closed.					
PMI000346	UNITED STATES Report From Study	27 Years Female	**THS 2.2 Regular (Dorado II / Ron) / N/A** UNK [1 DF-UNK]	Respiratory	11-OCT-2015 to 11-OCT-2015	OCT-2015 16-OCT-2015 11-OCT-2015 11-OCT-2015 11-OCT-2015	she has a bad sinus infection [SINUSITIS] N / Y / Y she came down with a cold [NASOPHARYNGITIS] N / N / Y she took one puff of her first Heatstick and within 1 minute she threw up. [VOMITING] N / N / Y She stated that she was nauseated most of the day, and a little bit nauseated on 12/Oct/2015. [NAUSEA] N / N / Y The participant has not used another Heatstick since 11/Oct/2015 because the holder is stuck in the charger and she cannot get it out. [DEVICE ISSUE] N / Y / N	Not Recovered/Not Resolved

Study ID: THS-PBA-07-US
Case Initial Receipt Date: 17-Oct-2015
Case Followup Receipt Date: 19-Oct-2015 00:00
21-Oct-2015 00:00
Event Intensity: Moderate
Moderate
Moderate
Mild
Event Stop Date: 11-OCT-2015
13-OCT-2015
Case Narrative: Verbatim:

Initial information: Participant stated that, on 11-Oct-2015, she took one puff of her first Heatstick and within 1 minute she threw up. She stated that she was nauseated m
and a little bit nauseated on 12-Oct-2015. She stated she was not nauseated 13-Oct-2015. She also stated that she came down with a cold 16-Oct-2015, which has not resolved.
is all congested, and she is coughing now and then. The participant has not used another Heatstick since 11-Oct-2015 because the holder is stuck in the charger and she cann

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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
			Follow-up #1 information: Participant called in today, 19-Oct-2015, stating she was still not feeling well. She stated she still had her cold and was coughing, and would no enrollment center today to pick up her new IQOS device. During the call, she stated the onset date of her cold was 16-Oct-2015. Follow-up #2 information: Participant called in today, 21-Oct-2015, to report her cold has not resolved and she is still sick. She reported to experiencing the following co her whole head hurts, sneezing, headaches, and head is pounding. The participant also reported she has a bad sinus 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 17-Oct-2015 and forwarded to Safety department on the same day. Additional information to the case was received on 19-Oct-2015 and on 21-Oct-2015. This report concerns a 27-year-old female subject (Respondent Study ID: 188110) 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 (approximately 5 conventional cigarettes per day). The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number 5410706815337) on 11-Oct-2015. On 11-Oct-2015, the respondent took one puff of her first Heatstick and within 1 minute she threw up. She stated that she was nauseated most of the day, and a little bit na 12-Oct-2015. She came down with a cold on 16-Oct-2015. Symptoms of the cold included head congestion/head hurting, coughing now and then, sneezing, headaches, and pounding head. The participant also reported she had a bad sinus infection. She had not used another Heatstick since 11-Oct-2015 because the holder was stuck in the charger and she could not get it out. The events severity was reported as moderate on 17-Oct-2015 and 19-Oct-2015, and as mild on 19-Oct-2015. The events were considered to be non-serious. The respondent used the heatstick occasionally (once - she used 1 heatstick) and 2 conventional cigarettes on 11-Oct-2015. The events vomiting and nausea improved/stopped when usage of the product was stopped, and the other reported events did not improve when usage of product was stopped. The product was not restarted. The respondent took ibuprofen and a lot of juice. The outcome of the events were reported as 'not recovered'. However, the respondent mentioned that her vomiting resolved o 11-Oct-2015 and she was not nauseated on 13-Oct-2015. No follow-up information is expected ? case closed.				
PMI000349	UNITED STATES Report From Study	61 Years Female	**THS 2.2 Regular (Dorado II / Ron) / N/A** UNK [qd]	Respiratory	12-OCT-2015 to Unknown	12-OCT-2015 12-OCT-2015	it burns her lips/she experiences the burning of her lips each time she uses the device [ORAL DISCOMFORT] N / Y / Y the HeatStick holder itself is often too hot to hold [DEVICE ISSUE] N / Y / N	Not Recovered/Not Resolved
			Study ID: THS-PBA-07-US Case Initial Receipt Date: 19-Oct-2015 Event Intensity: Mild					

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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
PMI000359	UNITED STATES Report From Study	41 Years Male	**THS 2.2 Regular (Dorado II / Ron) / N/A** UNK [qd]	Respiratory	26-SEP-2015 to 25-OCT-2015	14-OCT-2015	He had to draw hard on the product to smoke it and the sucking gave him a headache / he continued to only smoke the product in the evenings, and each evening he got a headache [HEADACHE] N / N / Y	Recovered/Resolved
						14-OCT-2015	He had to draw hard on the product to smoke it [DEVICE DIFFICULT TO USE] N / Y / N	

Study ID: THS-PBA-07-US
Case Initial Receipt Date: 26-Oct-2015
Event Intensity: Mild
Event Stop Date: 25-OCT-2015

Case Narrative: Verbatim: He stated that he had to draw hard on the product to smoke it and the sucking gave him a headache. Each subsequent day, he continued to only smoke the product in evenings, and each evening he got a headache.

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 26-Oct-2015 and forwarded to Safety department on the same day.

Case Narrative: Verbatim: The participant stated that, while using the IQOS, she does not puff that heavy, but reported it burns her lips. Participant stated the HeatStick holder itself is Participant stated she experiences the burning of her lips each time she uses the device. Participant reported the events resolve after she stops using the device.

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 19-Oct-2015 and forwarded to Safety department on 20-Oct-2015.

This report concerns a 61-year-old female subject (Respondent Study ID: 823066) who took part in the above mentioned market research study.

No medical history was reported. Unspecified pain medication was reported as concomitant medication, for spine problem (NOS).

The respondent was a daily smoker (approximately 20-30 conventional cigarettes per day). The respondent reported she was a heavy smoker. When asked how many cigarettes she smokes per day, she stated “nearly 1 per minute”.

The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number 60JNA8677NVS) on 12-Oct-2015.

On 12-Oct-2015, the respondent experienced burning on her lips. She mentioned that she experienced this each time she used the device. In addition, she also reported that t was often too hot to hold.

The event's severity was reported as mild. The events were considered to be non-serious.

The respondent used the Heatsticks every day. She used 7 Heatsticks and 15 cigarettes on the day of the event. The event improved when usage of the product was stopped and returned when the product was restarted.

Action taken with study product is unknown.

At time of reporting, the events were not resolved.

No follow-up information is expected ? case closed.

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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
			This report concerns a 41-year-old male subject (Respondent Study ID: 532578) who took part in the above mentioned market research study. No medical history and no concomitant medications were reported. The consumer was a daily smoker (approximately 30 conventional cigarettes per day). The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number VV5VYCF2F8KP) on 26-Sep-2015. The participant started using the product on 26-Sep-2015, during the day and evening, as well as conventional cigarettes. He did not experience headaches during that time. 14-Oct-2015, he stopped using the product during the day, and began to use the product only in the evening (no conventional cigarettes in the evening). He continued to smok conventional cigarettes during the day. On 14-Oct-2015, he had a headache by the time he went to bed. He stated that he had to draw hard on the product to smoke it and the gave him a headache. He reported he had no headache when he woke up. Each subsequent day, he continued to only use the product in the evenings, and each evening he got a headache. On 25-Oct-2015, he stated that he realized using the product was giving him the headaches. He had used 1 or 2 that evening when he realized the connection, he did use the product anymore and he did not get a headache. The events severity were reported as mild. The events were considered to be non-serious. The consumer used the Heatsticks every day (8-9 sticks per day) in combination with about 20 cigarettes per day. The participant discontinued the use of the product on 25-Oct-2015. The event resolved on 25-Oct-2015. No follow-up information is expected ? case closed. ?					
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
						26-OCT-2015	he started coughing up green stuff [SPUTUM DISCOLOURED] N / Y / Y	
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	25-OCT-2015 to 27-OCT-2015	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	
	Study ID:	THS-PBA-07-US						
	Case Initial Receipt Date:	27-Oct-2015						
	Event Intensity:	Moderate Moderate Moderate 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.					

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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
			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)MHZKNOLUZYZR, (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
			Study ID: THS-PBA-07-US 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. This report concerns a 28-year-old female subject (Respondent Study ID: 535255) who took part in the above mentioned market research study. Medical history included gallbladder removal ten years ago. No concomitant medication was reported. The consumer was a daily smoker (approximately 10 conventional cigarettes per day).					

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 (Dorado I / Vinny Low Menthol) (kit number 5410706815337) on 09-Oct-2015. 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. The events severity was reported as mild. The events were considered to be non-serious. 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. Participant last used the device on 23-Oct-2015 but stated she planned to continue using the device. At time of reporting, the events were not resolved. No follow-up information is expected. Case closed.					
PMI000366	UNITED STATES Report From Study	20 Years Female	**THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A** UNK [UNK] Study ID: THS-PBA-07-US 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 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 29-Oct-2015 and 1-Nov-2015 and forwarded to Safety department on 2-Nov-2015. This report concerns a 20-year-old female subject (Respondent Study ID: 201662) 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 10 conventional cigarettes per day). The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number 72QGCBL189GV) on 15-Oct-2015. The respondent stated that she experienced headaches after using the Heatsticks from 15-Oct-2015. The event severity was reported as moderate. The respondent used the Heatsticks occasionally. She used 1 Heatstick and 15 cigarettes on the day of the event. 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. At time of reporting, the event was not resolved.	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

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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.					
PMI000370	UNITED STATES Report From Study	53 Years Male	**THS 2.2 Regular (Dorado II / Ron) / N/A** UNK [UNK]	Respiratory	22-OCT-2015 to Unknown	25-OCT-2015	flu; started feeling off (NOS) on 25/OCT/2015; symptoms were described as alternating hot and cold sensation, sweating, exhaustion, loss of appetite, weakness and breathlessness (dyspnea) [INFLUENZA] N / Y / Y	Recovering/Resolving

Study ID: THS-PBA-07-US
Case Initial Receipt Date: 04-Nov-2015
Case Followup Receipt Date: 16-Nov-2015 00:00
Event Intensity: Severe
Event Stop Date: NOV-2015
Case Narrative: Verbatim: he had had the flu (NOS) for the past week

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-Nov-2015 and forwarded to Safety department on the same day.

This report concerns a 53-year-old male subject (Respondent Study ID: 655433) who took part in the above mentioned market research study.

No medical history was reported. No concomitant medication was reported.

No information was provided regarding the respondent's smoking status.

The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number R8D4R2EWDD22) on an unknown date.

The respondent stated that he started "feeling off" on 25-Oct-2015. He reported that he did not smoke while he had the flu and when he stopped using the product (date unknown) it was easier to breathe. He stated that he was seen by a doctor before 31-Oct-2015 (exact date unknown). The respondent was administered an inhaler and antibiotics (NOS).

The event severity was reported as severe. The events were assessed as non-serious.

The respondent used the Heatsticks every day. The number of Heatsticks and cigarettes used on the day of the event was not reported.

It was reported that the event improved when usage of the product was stopped (stop date unknown). The product was not restarted.

At time of reporting, the event was not resolved.

Follow-up information will be requested.

FOLLOW-UP INFORMATION RECEIVED on 16-Nov-2015 and forwarded to Safety department on the same day.

Start date of the product THS 2.2 Regular (Dorado II / Ron) was reported as 22-Oct-2015.

The participant stated that, for influenza, he was not formally diagnosed by a doctor. The participant stated that he was unsure when the symptoms began but believes that they began at the end of October 2015 (previously reported as 25-Oct-2015). The symptoms were described as alternating hot and cold sensation, sweating, exhaustion, loss of appetite, weakness and breathlessness (dyspnea). The participant denied using any medication to treat his flu related symptoms, opting to stay home.

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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
			When asked about his previously reported symptom of breathlessness (dyspnea), the participant clarified that he had a prior history of asthma, for which he had been prescribed the as-needed inhaled medication ProAir (salbutamol sulfate) inhaled. Participant reported no other relevant medical history within the last year and denies using antibiotics or any other medications. The participant reported that the symptoms of alternating hot and cold sensation, sweating, exhaustion, loss of appetite, and breathlessness (dyspnea) resolved two weeks after onset; exact date is unknown. The symptom of weakness is ongoing, with an 80% subjective improvement reported by participant. No further information is expected. Case closed.					
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
			THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory				
			Study ID: THS-PBA-07-US Case Initial Receipt Date: 26-Oct-2015 Event Intensity: Unknown Case Narrative: Verbatim: gave me headaches; didn't like the taste. 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 26-Oct-2015 and forwarded to Safety department on 2-Nov-2015. This report concerns a female subject born in 1959 (Respondent Study ID: 181262) 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 (number of conventional cigarettes per day not provided). 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). The respondent stated that the use of the device gave her headaches and that she didn't like its taste. The severity of the event was not reported. The event was assessed as non-serious. 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. No information regarding the action taken with the drug was provided. At time of reporting, the outcome of the event was not reported. No follow-up information is expected. Case closed.					

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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

Study ID: THS-PBA-07-US
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.

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 22-Oct-2015 and forwarded to Safety department on 02-Nov-2015.

This report concerns a female subject born in 1963 (Respondent Study ID: 187828) 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 (number of conventional cigarettes per day not provided).

The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number and start date not provided).

On an unspecified date, the respondent experienced burning of her throat and coughing.

The severity of the events was not reported. The events were assessed as non-serious.

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.

No information regarding the action taken with the product was provided.

At time of reporting, the outcome of the event 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 made his chest hurt.

No follow-up information is expected. Case closed.

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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

Study ID: THS-PBA-07-US
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.

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 20-Oct-2015 and forwarded to Safety department on 2-Nov-2015.

This report concerns a male subject born in 1980 (Respondent Study ID: 829559) 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 (number of conventional cigarettes per day not provided).

The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number and start date not provided).

The respondent stated that he was feeling nauseated after using the Heatsticks. He also reported that the device was cumbersome and that it was an inconvenience to clean it and to carry it.

The severity of the events were not reported. The events were assessed as non-serious.

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.

No information regarding the action taken with the product was provided.

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.

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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
PMI000380	UNITED STATES Report From Study	49 Years Male	**THS 2.2 Regular (Dorado II / Ron) / N/A** UNK [UNK]	Respiratory	07-OCT-2015 to 07-NOV-2015	31-OCT-2015 31-OCT-2015	Participant reported feeling sick after using regular HeatSticks. Feeling sick was described as an upset stomach after smoking HeatSticks [MALAISE] N / Y / Y Participant reported feeling sick after using regular HeatSticks. Feeling sick was described as an upset stomach after smoking HeatSticks [ABDOMINAL DISCOMFORT] N / Y / Y	Recovered/Resolved

Study ID: THS-PBA-07-US
Case Initial Receipt Date: 09-Nov-2015
Event Intensity: Mild
Mild
Event Stop Date: 02-NOV-2015
02-NOV-2015
Case Narrative: Verbatim: Participant reported feeling sick after using regular HeatSticks. Feeling sick was described as an upset stomach after smoking HeatSticks

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 the same day.

This report concerns a 49-year-old male subject (Respondent Study ID: 650328) who took part in the above mentioned market research study.

The following medical history was reported: high blood pressure (additional information not provided). The following concomitant medication was reported: lisonipril (additional information not reported).

The respondent was a daily smoker (approximately 30 conventional cigarettes per day).

The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number 5410706815337) on 07-Oct-2015.

On 31-Oct-2015, the respondent reported feeling sick after using regular HeatSticks. Feeling sick was described as an upset stomach after smoking HeatSticks. He is still smoking conventional cigarettes, and does not have the same sick feeling as he did after using the HeatSticks.

The events severity was reported as mild. The events were assessed as non-serious.

The respondent used the Heatsticks every day. He used 5 Heatsticks and 20 cigarettes on the day of the events.

The events improved when usage of the product was stopped. The events reoccurred when the product was restarted. The last day of product use was on 07-Nov-2015 (final action taken with study product unknown).

The events resolved on 02-Nov-2015.

No further information is expected. Case closed.

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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

Study ID: THS-PBA-07-US
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.

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.

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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
PMI000398	UNITED STATES Report From Study	33 Years Male	**THS 2.2 Regular (Dorado II / Ron) / N/A** UNK [UNK]	Respiratory	19-AUG-2015 to 26-OCT-2015	2015 16-OCT-2015 16-OCT-2015 16-OCT-2015	make me sick [MALAISE] N / Y / Y Participant reported headaches, lightheadedness, and nausea while using HeatSticks [HEADACHE] N / N / Y Participant reported headaches, lightheadedness, and nausea while using HeatSticks [DIZZINESS] N / N / Y Participant reported headaches, lightheadedness, and nausea while using HeatSticks [NAUSEA] N / N / Y	Recovered/Resolved

Study ID: THS-PBA-07-US
Case Initial Receipt Date: 16-Nov-2015
Case Followup Receipt Date: 09-Nov-2015 00:00
Event Intensity: Moderate
Moderate
Moderate
Event Stop Date: 26-OCT-2015
26-OCT-2015
26-OCT-2015

Case Narrative: Verbatim: Participant reported headaches, lightheadedness, and nausea while using HeatSticks. Make me 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 16-Nov-2015 and forwarded to Safety department on 17-Nov-2015.

This report concerns a 34-year-old male subject (Respondent Study ID: 180716) who took part in the above mentioned market research study.

Medical history was not reported. Concomitant medication was not reported.

The respondent was an occasional smoker (approximately 20 conventional cigarettes per week).

The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number TE3HH5DSY0VWGD) on 19-Aug-2015.

On 16-Oct-2015, the respondent experienced headaches, lighteadedness and nausea while using HeatSticks.

The events severity was reported as moderate. The events were assessed as non-serious.

The respondent used the heatsticks occasionally. He mentioned that he was a light smoker overall and did not further specify. He used 3 Heatsticks and 2 cigarettes on the day of the events.

The events improved when usage of the product was stopped, and the product was not restarted. The last day of product use was on 26-Oct-2015.

The events resolved on 26-Oct-2015.

FOLLOW-UP INFORMATION RECEIVED ON 09-NOV-2015 and forwarded to Safety department on 05-Apr-2016.

The study respondent mentioned that the product made him sick. No further information was given.

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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.					
PMI000400	UNITED STATES Report From Study	57 Years Female	**THS 2.2 Regular (Dorado II / Ron) / N/A** UNK [UNK]	Respiratory	17-OCT-2015 to 19-NOV-2015	17-OCT-2015 17-OCT-2015 17-OCT-2015 19-NOV-2015	tastes an aftertaste [DYSGEUSIA] N / Y / Y it makes her gag [RETCHING] N / Y / Y she feels sick to her stomach / feels like she wants to throw up [NAUSEA] N / N / Y she also noticed a headache [HEADACHE] N / N / Y	Recovered/Resolved

Study ID: THS-PBA-07-US
Case Initial Receipt Date: 19-Nov-2015
Event Intensity: Moderate
Moderate
Moderate
Moderate
Event Stop Date: 19-NOV-2015
19-NOV-2015
19-NOV-2015
19-NOV-2015

Case Narrative: Verbatim: tastes an aftertaste / it makes her gag / she feels sick to her stomach / feels like she wants to throw up / she also noticed a headache

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 19-Nov-2015 and forwarded to Safety department on the same day.

This report concerns a 57-year-old female subject (Respondent Study ID: 200663) who took part in the above mentioned market research study.

Medical history of allergies, high blood pressure, eczema, deaf in left ear was reported (no further information provided). The following concomitant medications were reported: Benadryl (diphenhydramine hydrochloride), Lisinopril, Ranitidine (ranitidine hydrochloride), Loratadine, Hydrocortisone, Bactroban ointment (mupirocin calcium) (no further information provided).

The respondent was an occasional smoker (approximately 20 conventional cigarettes per week).

The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number PPQ30Z3MGJ47) on 17-Oct-2015.

The respondent stated that, every time she smoked a heatstick, she tasted an aftertaste and it made her gag. While smoking the heatsticks, she felt sick to her stomach and felt like she wanted to throw up. On 19-Nov-2015, she also noticed a headache, after using the heatsticks.

The events' severity was reported as moderate. The events were assessed as non-serious.

The respondent used the heatsticks occasionally. She used the heatstick when she didn't have any cigarettes. The respondent used 3 Heatsticks and 3 cigarettes on the day of the event (presumably event of headache, occurring on 19-Nov-2015).

The events improved when usage of the product was stopped, and the product was not restarted. The last day of product use was on 19-Nov-2015.

The events resolved on 19-Nov-2015.

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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.					
PMI000401	UNITED STATES Report From Study	45 Years Male	**THS 2.2 Regular (Dorado II / Ron) / N/A** UNK [UNK]	Respiratory	08-OCT-2015 to 15-OCT-2015	10-OCT-2015	throat burn [THROAT IRRITATION] N / Y / Y	Recovered/Resolved
			Study ID: THS-PBA-07-US Case Initial Receipt Date: 19-Nov-2015 Event Intensity: Mild Event Stop Date: 15-OCT-2015 Case Narrative: Verbatim: throat burn 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 19-Nov-2015 and forwarded to Safety department on 20-Nov-2015. This report concerns a 45-year-old male subject (Respondent Study ID: 188933) who took part in the above mentioned market research study. No medical history was reported. It was reported that the respondent took as concomitant medication vitamins once a day (no further information provided). 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 II / Ron) (kit number SQ9 ZUA GHS M5A) on 08-Oct-2015. On 10-Oct-2015, when he inhaled the smoke, the respondent experienced throat burn while using Heatsticks, which lasted about 5 minutes. The severity of the event was reported as mild. The event was assessed as non-serious. The respondent used the heatsticks every day. The respondent used 4 heatsticks and 20 cigarettes on the day of the event. The event improved when usage of the product was stopped, and the product was not restarted. The last day of product use was on 15-Oct-2015. The event resolved on 15-Oct-2015. No follow-up 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 Respiratory	17-OCT-2015 to 11-NOV-2015 17-NOV-2015 to Unknown	10-NOV-2015 10-NOV-2015	strep throat [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			
			Study ID: THS-PBA-07-US Case Initial Receipt Date: 24-Nov-2015 Event Intensity: Severe					

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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
			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 menthol 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. On 11-Nov-2015, 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.					
			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	35 Years	**THS 2.2 Menthol**	Respiratory			he had a cold [NASOPHARYNGITIS]	Unknown
	Report From Study	Male	**(Dorado I / Vinny low menthol) / N/A**				N / N / Y	
			UNK [UNK]				he sounded "ridiculous" [DYSPHONIA]	
							N / Y / Y	
		Study ID:	THS-PBA-07-US					
		Case Initial Receipt Date:	04-Oct-2015					
		Event Intensity:	Unknown					
			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.					

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 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 TIMING UNSPECIFIED] N / Y / N	Unknown
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	SEP-2015 to DEC-2015			
			Study ID: THS-PBA-07-US Case Initial Receipt Date: 03-Feb-2016 Case Followup Receipt Date: 16-Feb-2016 00:00 Case Narrative: Verbatim: Pregnancy					
			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 03-FEB-2016 and forwarded to Safety department on 05-FEB-2016. This report concerns a 30-year-old female subject (Respondent Study ID: 751296) who took part in the above mentioned market research study. No medical history and no concomitant medication were reported. The respondent was a daily smoker (approximately 2 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 numbers not provided) on an unknown date in Sep-2015. 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. The respondent had one previous pregnancy and one delivery (no therapeutic or planned abortion). The study respondent used the THS products up to an unspecified date in Dec-2015 (prior to awareness of pregnancy).					

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. FOLLOW-UP INFORMATION received on 16-Feb-2016 and forwared to Safety Department on 17-Feb-2016. 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). 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. 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. Estimated delivery date was reported as 28-Aug-2016. 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. 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). Further information is expected.				
			Case Comment Text: Maternal exposure timing unspecified was assessed as non-serious. 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. No adverse events were reported in association with Maternal exposure timing unspecified. This pregnancy report shall be followed-up until an outcome is reached, as per protocol.					
PMI000587	UNITED STATES Report From Study	Male	**THS 2.2 Regular (Dorado II / Ron) / N/A** UNK [UNK]	Respiratory	2015 to Unknown	2015	gave me a headache [HEADACHE] N / N / Y	Unknown
			Study ID: THS-PBA-07-US Case Initial Receipt Date: 09-Nov-2015 Case Narrative: Verbatim: gave me a headache 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 05-Apr-2016. This report concerns a 56-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 351173) 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 Regular (Dorado II / Ron) (kit number not provided) on an unspecified date.				

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 stated that the product gave him a headache. 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.					
PMI000588	UNITED STATES Report From Study	Male	**THS 2.2 Regular (Dorado II / Ron) / N/A** UNK [UNK]	Respiratory	2015 to Unknown	2015 2015 2015	gave me headache [HEADACHE] N / N / Y bad taste lingered for hours, everything afterwards had that taste still [DYSGEUSIA] N / Y / Y bad taste [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
			Study ID: THS-PBA-07-US Case Initial Receipt Date: 09-Nov-2015 Case Narrative: Verbatim: bad taste, gave me headache, bad taste lingered for hours, everything afterwards had that taste still. 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 05-Apr-2016. This report concerns a 46-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 820835) 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 Regular (Dorado II / Ron) (kit number not provided) on an unspecified date. The respondent stated that the product gave him a headache. In addition, he mentioned that the product had a bad taste, the bad taste lingered for hours, everything afterwards had that taste still. The severity of the events was not reported. The events were assessed as non-serious. The outcome of the events were not reported. Action taken with the THS product was not reported. No further information is expected. Case closed.					

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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

Study ID: THS-PBA-07-US
Case Initial Receipt Date: 09-Nov-2015
Case Narrative: Verbatim: The smell of the Heatsticks makes me feel 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 09-Nov-2015 and forwarded to Safety department on 05-Apr-2016.

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.

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 stated that the smell of the heatstick made her feel sick.

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.

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
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

Study ID: THS-PBA-07-US
Case Initial Receipt Date: 09-Nov-2015
Case Narrative: Verbatim: gave me a headache

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 05-Apr-2016.

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.

No medical history was reported. No concomitant medication was reported.

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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 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 stated that the product gave her a headache. 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.					
PMI000591	UNITED STATES Report From Study	Male	**THS 2.2 Regular (Dorado II / Ron) / N/A** UNK [UNK]	Respiratory	2015 to Unknown	2015 2015	Tobacco is stronger, hurts my chest [CHEST PAIN] N / Y / Y Tobacco is stronger, hurts my chest [PRODUCT QUALITY ISSUE] N / Y / N	Unknown
			Study ID: THS-PBA-07-US Case Initial Receipt Date: 09-Nov-2015 Case Narrative: Verbatim: tobacco is stronger, hurts my chest 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 05-Apr-2016. This report concerns a 39-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 355431) 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 Regular (Dorado II / Ron) (kit number not provided) on an unspecified date. The respondent stated that the tobacco was stronger, and hurt his chest. 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.					

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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
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
			THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	2015 to Unknown			

Study ID: THS-PBA-07-US
Case Initial Receipt Date: 09-Nov-2015
Case Narrative: Verbatim: got 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 09-Nov-2015 and forwarded to Safety department on 05-Apr-2016.

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.

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 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unreported date.

The respondent stated that she got sick.

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.

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

Study ID: THS-PBA-07-US
Case Initial Receipt Date: 16-Nov-2015
Case Narrative: Verbatim: too much work and gives headache

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.

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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
			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. 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 stated that the product was too much work and gave him headache. 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.					
PMI000594	UNITED STATES Report From Study	Female	**THS 2.2 Regular (Dorado II / Ron) / N/A** UNK [UNK] Study ID: THS-PBA-07-US Case Initial Receipt Date: 16-Nov-2015 Case Narrative: Verbatim: it makes me feel sick	Respiratory	2015 to Unknown	2015	it makes me feel sick [MALAISE] 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 16-Nov-2015 and forwarded to Safety department on 05-Apr-2016. This report concerns a 20-year-old (approximate age, at the time of reporting) female subject (Respondent Study ID: 202403) 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 Regular (Dorado II / Ron) (kit number not provided) on an unreported date. The respondent stated that the product made her feel sick. 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.					

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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
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

Study ID: THS-PBA-07-US
Case Initial Receipt Date: 16-Nov-2015
Case Narrative: Verbatim: made me feel kinda groggy, dragged me, I wasn't comfortable with them.

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 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.

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 heatsticks made him feel kind of groggy, dragged him, and that he wasn't comfortable with them.

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.

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
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

Study ID: THS-PBA-07-US
Case Initial Receipt Date: 16-Nov-2015
Case Narrative: Verbatim: gives me a headache and it's a hassle

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 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.

No medical history was reported. No concomitant medication was reported.

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 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 stated that the heatsticks gave her a headache and that it was a hassle. 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.					
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
			Study ID: THS-PBA-07-US 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.					

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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
PMI000598	UNITED STATES Report From Study	Male	**THS 2.2 Regular (Dorado II / Ron) / N/A** UNK [UNK]	Respiratory	2015 to Unknown	2015	It gave me a headache [HEADACHE] N / N / Y	Unknown
			Study ID: THS-PBA-07-US					
			Case Initial Receipt Date: 23-Nov-2015					
			Case Narrative: Verbatim: It gave me a headache.					
			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 25-year-old (approximate age, at the time of reporting) male subject (Respondent Study ID: 658140) 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 Regular (Dorado II / Ron) (kit number not provided) on an unspecified date.					
			The respondent stated that the product gave him a headache.					
			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
			THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	2015 to Unknown			
			Study ID: THS-PBA-07-US					
			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.					

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 information on smoking habits was reported (conventional cigarettes and heatsticks). 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. The respondent reported: "sick". 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.					
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 [DYSPNOEA] N / Y / Y Sore throat [OROPHARYNGEAL PAIN] N / N / Y	Unknown
			THS 2.2 Regular (Dorado II / Ron) / N/A UNK [UNK]	Respiratory	2015 to Unknown			
			Study ID: THS-PBA-07-US Case Initial Receipt Date: 23-Nov-2015 Case Narrative: Verbatim: sore throat, breathing trouble 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 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. 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 Regular (Dorado II / Ron) and THS 2.2 Menthol (Dorado I / Vinny low menthol) (kit number not provided) on an unspecified date. The respondent reported sore throat and breathing trouble. The severity of the events was not reported. The events were assessed as non-serious. The outcome of the events was not reported. Action taken with the THS product was not reported.					

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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.					
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
			Study ID: THS-PBA-07-US Case Initial Receipt Date: 30-Nov-2015 Case Narrative: Verbatim: Taste and smell gave her headaches. 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-Nov-2015 and forwarded to Safety department on 05-Apr-2016. 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. 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 stated that the taste and smell of the heatstick gave her headaches. 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.					
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
			Study ID: THS-PBA-07-US Case Initial Receipt Date: 30-Nov-2015 Case Narrative: Verbatim: Problem with my throat 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-Nov-2015 and forwarded to Safety department on 05-Apr-2016. 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.					

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 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 a problem with her throat. 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.					
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
			THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A UNK [UNK]	Respiratory	2015 to Unknown			
			Study ID: THS-PBA-07-US Case Initial Receipt Date: 07-Dec-2015 Case Narrative: Verbatim: I think they were giving me an upset stomach 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 07-Dec-2015 and forwarded to Safety department on 05-Apr-2016. 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. 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) and THS 2.2 Regular (Dorado II / Ron) (kit number not provided) on an unspecified date. The respondent stated that she thought the heatsticks were giving her an upset stomach. The severity of the event was not reported. The event was assessed as non-serious. The outcome of the event was not reported.					

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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
			Action taken with the THS product was not reported. No further information is expected. Case closed.					
PMI000604	UNITED STATES Report From Study	Female	**THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A** UNK [UNK]	Respiratory	2015 to Unknown	2015	it too strong for my throat [LARYNGEAL DISCOMFORT] N / Y / Y	Unknown
			Study ID: THS-PBA-07-US Case Initial Receipt Date: 07-Dec-2015 Case Narrative: Verbatim: it too strong for my throat 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 07-DEC-2015 and forwarded to Safety department on 05-Apr-2016. 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. 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 stated that the product was too strong for her throat. 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.					
PMI000605	UNITED STATES Report From Study	Male	**THS 2.2 Menthol (Dorado I / Vinny low menthol) / N/A** UNK [UNK]	Buccal	2015 to Unknown	2015	chewed it [WRONG TECHNIQUE IN PRODUCT USAGE PROCESS] N / Y / N	Unknown
			Study ID: THS-PBA-07-US Case Initial Receipt Date: 07-Dec-2015 Case Narrative: Verbatim: chewed it 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 07-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: 820149) who took part in the above mentioned market research study.					

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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 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 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] Study ID: THS-PBA-07-US Case Initial Receipt Date: 21-Dec-2015 Case Narrative: Verbatim: heart burn 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.	Respiratory	2015 to Unknown	2015	heart burn [DYSPEPSIA] N / Y / Y	Unknown

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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
Yes (**8**)								
PMI000347	UNITED STATES Report From Study	31 Years Male	**THS 2.2 Regular (Dorado II / Ron) / N/A** UNK [UNK] UNK [UNK]	Respiratory	08-OCT-2015 to 14-OCT-2015 27-OCT-2015 to Unknown	14-OCT-2015 14-OCT-2015 14-OCT-2015 14-OCT-2015 14-OCT-2015 15-OCT-2015 15-OCT-2015	Respondent was hit by a car [ROAD TRAFFIC ACCIDENT] Y / Y / Y concussion [CONCUSSION] Y / Y / Y knee strain [JOINT INJURY] Y / Y / Y back strain [MUSCLE STRAIN] Y / Y / Y abrasions [SKIN ABRASION] Y / Y / Y nausea [NAUSEA] N / N / Y dizziness [DIZZINESS] N / N / Y	Not Recovered/Not Resolved

Study ID: THS-PBA-07-US
Case Initial Receipt Date: 16-Oct-2015
Case Followup Receipt Date: 27-Oct-2015 00:00
Case Narrative: Verbatim: Respondent was hit by a car.

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-Oct-2015 and forwarded to Safety department on 19-Oct-2015.

This report concerns a 31-year-old male subject (Respondent Study ID 200851) who took part in the above mentioned market research study.

No medical history was reported. Information on concomitant medications was reported as "Perkacet and just an IV" (no further information provided).

The consumer was a daily smoker (approximately 10 conventional cigarettes per day).

The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) kit number LE8Q6KAQRBQ3 on 08-Oct-2015.

The consumer was hit by a car. The event required hospitalization on 14-Oct-2015. The event was assessed as serious (due to hospitalization).

The last Heatstick was used on 14-Oct-2015. It was reported that the consumer would continue with the study once he was out of hospital.

At time of reporting, the event had not recovered.

Follow-up information will be requested.

FOLLOW-UP INFORMATION was received on 27-Oct-2015 and forwarded to the Safety department on the same day.

Verbatim: Diagnosis of concussion, knee strain, back strain, abrasions

The participant stated that he was "feeling fine" right before his accident on 14-Oct-2015. He related that he was heading northbound riding his bicycle in the bike lane, when a vehicle that was heading southbound, turned into him striking him. The participant was then transported to the hospital via an ambulance where he was initially placed in the emergency room for 2

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
			hours and then admitted in order to assess and observe for any symptoms stemming from concussion. The caller reported being discharged at 2-3 am the following day on 15-Oct-2015. The caller then reported that he returned to the hospital later in the day of his discharge (15-Oct-2015) because of the symptoms of nausea and dizziness. He was not admitted at that time but released after a brief assessment. The participant denied receiving any treatment while en route to the hospital. He stated he was given intravenous solution while in the hospital but was unsure of what exactly was in that solution, although the participant believed it was a saline solution. The participant admits to Percocet by mouth, during hospital stay and for at least 2 days after discharge. The participant denied having taken any medications to treat any other conditions prior to the incident. The participant denied any pre-existing conditions prior to the accident (no previously diagnosed conditions, no seasonal conditions such as allergies, and no self limiting conditions such as cold, flu, or headache). Prior to the accident, the respondent used the THS product on 14-Oct-2015. The product was re-started on 27-Oct-2015. At time of reporting, the serious events were ongoing. The respondent mentioned that he still had a swollen knee with pain during weight bearing and back pain for which he was receiving daily chiropractic treatment. He was also still being assessed for concussion; a MRI was scheduled. Nausea and dizziness resolved on an unspecified date. No further information is expected. Case closed. Case Comment Text: The Road traffic accident, Concussion, Joint injury, Muscle strain, and Skin abrasion were assessed as serious, due to requiring hospitalization. Nausea and Dizziness were assessed as non-serious. Road traffic accident, Concussion, Joint injury, Muscle strain, and Skin abrasion are unlisted, whereas Nausea and Dizziness are listed, as per the Reference Safety Information (i.e. the IB). Based on the information (i.e. the participant was reportedly feeling fine before the accident; the participant was hit by a turning car, while cycling) provided in this report, the Road traffic accident and the directly derived adverse events (i.e. Concussion, Joint injury, Muscle strain, Skin abrasion), as well as the transient Nausea and Dizziness experienced while on treatment with Percocet initiated during hospitalisation, are assessed as not related to the use of Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron). Of note, the product use was restarted 12 days after the discharge from hospital.					
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 22-OCT-2015	22-OCT-2015	Health related problem requiring hospitalization / in hospital [HOSPITALISATION] Y / Y / N	Recovered/Resolved
			Study ID: THS-PBA-07-US Case Initial Receipt Date: 30-Oct-2015 Case Followup Receipt Date: 12-Nov-2015 00:00 Event Stop Date: 29-OCT-2015 Case Narrative: Verbatim: Health related problem requiring hospitalization; in hospital. 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. This report concerns a 43-year-old male subject (Respondent Study ID: 209653) 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 8 conventional cigarettes per day).					

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 (Dorado I / Vinny Low Menthol) (kit number W834WAQ1LAN4) on 15-Oct-2015. On 22-Oct-2015, the study respondent was hospitalized for health-related reasons. As per reporter, the hospitalization was not related to the product. On 29-Oct-2015, the event resolved (hospital discharge date not provided). The hospitalization (underlying reason not reported) was considered as serious. 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 conventionnal cigarettes on t 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 restart re-start date was indicated for usage of the product. Further information is expected. FOLLOW-UP INFORMATION RECEIVED ON 12-Nov-2015 and forwarded to Safety department on 13-Nov-2015. Three follow‐up attempts were performed, unsuccessfully. No additional information was provided. No further information is expected. Case Closed.				
			Case Comment Text: Hospitalization was assessed as serious. Hospitalization is unlisted for THS 2.2 Menthol, as per Reference Safety Information (i.e. IB). 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.				
PMI000367	UNITED STATES Report From Study	51 Years Female	**THS 2.2 Regular (Dorado II / Ron) / N/A** UNK [UNK]		09-SEP-2015 to 28-OCT-2015	16-SEP-2015	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	16-SEP-2015	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	
			Study ID: THS-PBA-07-US Case Initial Receipt Date: 02-Nov-2015					

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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 Followup Receipt Date: 10-Nov-2015 00:00

Event Intensity: Severe
Severe
Severe
Severe
Severe

Event Stop Date: 16-SEP-2015

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 28-Oct-2015, 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 16-Sep-2015. Once at

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 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 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. The respondent stated that the events were still ongoing as of 10-Nov-2015. 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. Further information is expected.					
			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.					
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	20-OCT-2015 OCT-2015 20-OCT-2015 20-OCT-2015 2015	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 Since that incident occurred, he has been having dizzy spells and blacking out due to low blood pressure [HYPOTENSION] N / Y / Y Since that incident occurred, he has been having dizzy spells and blacking out due to low blood pressure [LOSS OF CONSCIOUSNESS] N / Y / Y Since that incident occurred, he has been having dizzy spells and blacking out due to low blood pressure [DIZZINESS] N / N / Y device had broken [DEVICE DEFECTIVE] N / Y / N	Not Recovered/Not Resolved
			Study ID: THS-PBA-07-US Case Initial Receipt Date: 09-Nov-2015 Case Followup Receipt Date: 23-Nov-2015 00:00 Event Intensity: Moderate Moderate Moderate Moderate 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 that incident occurred he has been having dizzy spells and blacking out due to low blood pressure / device had broken 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 the same day.					

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

This report concerns a 57-year-old male subject (Respondent Study ID: 821416) who took part in the above mentioned market research study.

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).

The respondent was a daily smoker (approximately 15 conventional cigarettes per day).

The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number 5U85BNX8J7JR) on 01-Oct-2015.

The respondent stated that, on 20-Oct-2015, 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 that incident occurred, he has been having dizzy spells and blacking out due to low blood pressure (as per reporter).

The events severity was reported as moderate. The events were assessed as serious due to hospitalization.

He used 15 cigarettes on the day of the event however the respondent did not remember about the number of Heatsticks used.

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.

At time of reporting, the events were not resolved.

Further information is expected.

NOTE:

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.

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.

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.

Listedness and causality assessments are not applicable for Device defective.

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.

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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
PMI000394	UNITED STATES Report From Study	52 Years Male	**THS 2.2 Regular (Dorado II / Ron) / N/A** UNK [UNK]	Respiratory	OCT-2015 to 31-OCT-2015	30-OCT-2015 15-OCT-2015 NOV-2015 09-NOV-2015 2015	he was told he was septic [SEPSIS] Y / Y / Y his gallbladder had gangrene [CHOLECYSTITIS INFECTIVE] Y / Y / Y He got pneumonia while he was in the hospital [PNEUMONIA] Y / Y / Y COPD [CHRONIC OBSTRUCTIVE PULMONARY DISEASE] N / Y / Y decubitus ulcer on his back [DECUBITUS ULCER] N / Y / N Increased bowel movement frequency secondary to daily probiotic use [FREQUENT BOWEL MOVEMENTS] N / Y / N	Not Recovered/Not Resolved

Study ID: THS-PBA-07-US
Case Initial Receipt Date: 16-Nov-2015
Case Followup Receipt Date: 30-Nov-2015 00:00
10-Dec-2015 00:00
Event Intensity: Unknown
Unknown
Unknown
Unknown
Unknown
Event Stop Date: 07-NOV-2015
09-NOV-2015

Case Narrative: Verbatim: Verbatim: he was told he was septic; his gallbladder had gangrene; he got pneumonia while he was in the hospital; decubitus ulcer on his back

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 the same day.

This report concerns a 52-year-old male subject (Respondent Study ID: 652030) who took part in the above mentioned market research study.

Medical history was not reported. The following concomitant medications was reported: Atenolol, Lisinopril, Keppra (levetiracetam), Butatane (exact spelling unknown), Probiotic (Bifidobacterium lactis), others (NOS). The respondent stated there were 12 all together (additional information not provided).

The respondent was a daily smoker (approximately 10-15 conventional cigarettes per day).

The respondent started using the Tobacco Heating System (THS) 2.2 Regular (Dorado II / Ron) (kit number 015410786815337 / (21)SSKLOEB32GLA / (240) DK00024.01) on an unreported date.

The recipient stated that, on 30-Oct-2015, he was admitted to the hospital, where he was told he was septic, and where they did all kinds of tests (NOS). He stated that, on 31-Oct-2015, he was told his gall bladder had gangrene and had to be removed. He stated his gall bladder was removed on 31-Oct-2015. He stated that he got pneumonia while he was in the hospital, he was told not to smoke, and he was undergoing breathing treatments (NOS). He stated he had 15 staples across his abdomen. He stated he was discharged from the hospital on 12-Nov-2015. He stated he had completely quit smoking (both conventional cigarettes and the iQOS device) and reported to feeling better after he quit smoking. He was still undergoing

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

breathing treatments.

The events severity was not reported. The events were assessed as serious, due to hospitalization.

The number of cigarettes and Heatsticks used on the day of the event was not reported.

It was reported that the events improved when usage of the product was stopped (not specified if it was one event in particular that improved, or all events) and product was not restarted.

At time of reporting, the events were not resolved.

Further information is expected.

FOLLOW-UP INFORMATION RECEIVED on 30-Nov-2015 and forwarded to Safety department on the same day.

Medical history of high blood pressure and high cholesterol were reported. The respondent also reported that he had monthly visits to the doctor to have his International Normalized Ratio (INR) assessed. He denied any blood clotting issues, denied any conditions that may cause blood clots other than high blood pressure and cholesterol, and denied taking any medications that may require a monthly INR screening.

Lisinopril and Lovastatin were reported as concomitant medications.

The respondent reported that he was unsure of when he started using the THS product, but that he believed that he started using the THS product 3 weeks before he was admitted to the hospital on 30-Oct-2015.

The respondent confirmed diagnosis of gangrenous gallbladder and diagnosis of sepsis. The respondent was assessed as having gallbladder issues during regular doctor's visit on 15-Oct-2015. He said that he was not feeling well several days before and that he reported this during his monthly doctor's visit to have his INR pulled on 15-Oct-2015. The physician then ordered bloodwork that confirmed that the participant was having issues with his gallbladder. The respondent was admitted to the hospital for surgery on 30-Oct-2015.

An open cholecystectomy was found to be necessary because the gallbladder had become gangrenous and the respondent was found to be septic. The surgery was completed on 31-Oct-2015. The respondent described a possible Open Cholecystectomy, relating that the incision site crosses from the right upper quadrant to the left upper quadrant of abdomen and resembles a C-section scar just below his ribs. When asked if the procedure may not be an open-cholecystectomy the participant affirmed that this was in fact the name of the procedure. The participant related that it was used instead of the laparoscopic procedure because of the urgency of his condition.

The respondent initially reported that the cause of his gangrene was sepsis. Upon follow-up questioning, he stated that he did not know what caused his gallbladder to become gangrenous. He denied having gallstones. He affirmed that sepsis was the result of gangrenous gallbladder.

The respondent stated that the pneumonia started 3-4 days after surgery. He reported that pneumonia was the result of intubation and patient's insufficient turning by the hospital staff. He further clarified that the tracheal tube was in place for several days making it difficult for the medical staff to turn him regularly, which contributed to the pneumonia.

The respondent reported that he was given the inhaled medications Spiriva (tiotropium bromide) and Symbecort (budosenide, formoterol fumarate dehydrate) as a breathing treatment, nicotine replacement therapy in the form of transdermal patch, an antibiotic whose name he can't remember, probiotics, and a pain medication whose name he can't remember.

The respondent related that he stayed in the hospital for 10 days before he was discharged.

He stated that he experienced decubitus ulcers on his back, which were ongoing, as the result of hospitalization and improper turning by hospital staff that were ongoing. The event severity of decubitus ulcers was not reported.

The respondent stated that he stopped using the device after his surgery on 31-Oct-2015 because he was informed that smoking of any kind would delay healing at the incision site. He reported that he was still using his Spiriva and Symbecort.

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 the report, the respondent's condition was ongoing. The respondent reported healing at his incision site was ongoing. He reported that he required Physical Therapy twice a week and was visited by a nurse once a week.

Further information is expected.

FOLLOW-UP INFORMATION RECEIVED on 10-DEC-2015 and forwarded to Safety department on the same day.

Medical history of bilateral amputation below the knee and bilateral hip replacement, 6 years prior to current report was reported. In addition, the consumer was wheelchair bound for 6 years, at time of reporting.

The respondent reported that any symptoms of sepsis resolved 7 days after date of surgery on 31-Oct-2015.

He reported that symptoms from treatment of gangrenous gallbladder are ongoing. Healing of skin at incision site had concluded and was resolved as of 15-Nov-2015. Muscle pain at incision site was ongoing. He reported that his doctor informed him that the timeline for resolution of healing and the resolution of pain is 6 months to a year.

He stated that pneumonia was resolved, meaning treatments for asthma had concluded, on day of hospital discharge, 10 days after the date of admittance (30-Oct-2015). He stated that breathing treatments were discontinued on day of discharge.

The respondent stated that decubiti were ongoing, that he received daily dressing changes from his caregiver, that he had seen a woundcare nurse on 4 different occasions to date, and that he had been referred to a woundcare specialist. He further insisted that the decubiti were healing, but that he needed the consult, in order to obtain assistive devices, such as doughnut padding.

He reported that the only medications he had as a result of his condition were probiotics and ProAir. He experienced increased bowel movement frequency secondary to daily probiotic use, described as having to go to the bathroom often. ProAir was prescribed at hospital discharge for Chronic Obstructive Pulmonary Disease (COPD) symptoms. The patient then reported a new condition, COPD, diagnosed at hospital discharge, 10 days after the admittance date of 30-Oct-2015.

The event severity of COPD and increased bowel movement frequency was not reported.

No further information is expected. Case closed.

Case Comment Text: The Sepsis and Cholecystitis infective were assessed as serious, due to requiring hospitalization. Pneumonia was assessed as serious, due to being considered a medically important event, requiring intervention. Chronic obstructive pulmonary disease, Decubitus ulcer, and Frequent bowel movements were assessed as non-serious, based on the provided information.
Sepsis, Cholecystitis infective, Pneumonia, Decubitus ulcer, Chronic obstructive pulmonary disease, and Frequent bowel movements are unlisted, as per the Reference Safety Information of THS 2.2 Regular (i.e. the IB).
The Sepsis was likely a consequence of the Cholecystitis infective (described as gallbladder gangrene, requiring open cholecystectomy). Considering the current knowledge on the product in question, the Sepsis and Cholecystitis infective are assessed as not related to the use of THS 2.2 Regular.
Despite the presence of alternative explanations (i.e. medical history, multiple concomitant medications, hospital environment, recent septic episode), the causal relationships between the use of THS 2.2 Regular and Pneumonia (in this case, nosocomial pneumonia) cannot be completely excluded and, therefore, is assessed as possible.
It was reported that the Chronic obstructive pulmonary disease (COPD) was diagnosed about a month after this patient, who had been a smoker of conventional cigarettes, started using the THS 2.2. Considering this implausible temporal sequence, the COPD is assessed as not related to THS 2.2.
A clear alternative explanation (i.e. inappropriate care during hospitalisation) was provided for the occurrence of the decubitus ulcers. As well, the Increased bowel frequency were reportedly due to the use of concomitant probiotics. Therefore, Decubitus ulcer and Increased bowel frequency are assessed as not related to the use of THS 2.2 Regular.

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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
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 Respiratory	OCT-2015 to OCT-2015 2015 Ongoing	2015 2015 OCT-2015 OCT-2015 OCT-2015 2015 2015	she was diagnosed with both Acute Bronchitis and a double ear infection [BRONCHITIS] Y / Y / Y she was diagnosed with both Acute Bronchitis and a double ear infection [EAR INFECTION] Y / Y / Y nerve damage pain in her hands [NERVE INJURY] N / Y / N nerve damage pain in her hands [NEURALGIA] N / Y / N 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 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 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	Recovered/Resolved

Study ID: THS-PBA-07-US
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 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

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-Nov-2015 and forwarded to Safety department on 21-Nov-2015.

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

This report concerns a 48-year-old female subject (Respondent Study ID: 656993) who took part in the above mentioned market research study.

Medical history of hepatitis C was reported. It was also reported that in Oct-2015 the 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.

The respondent was a daily smoker (approximately 1 to 7 conventional cigarettes per week).

The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) (kit number 4YDU57Q4UMSB) in early Oct-2015.

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.

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).

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.

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.

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 Heatstick and cigarette used on the day of the events are unknown.

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.

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.

No further information is expected.

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).

Nerve injury, Neuralgia, Hyperaesthesia, Respiratory fume inhalation disorder, and Device difficult to use were assessed as non-serious.

Bronchitis, Ear infection, Nerve injury, Neuralgia, Hyperaesthesia, Respiratory fume inhalation disorder, and Device difficult to use are unlisted, as per the Reference Saf THS 2.2 Regular (i.e. the IB).

The information provided in this non-medically confirmed report is limited and unclear, particularly regarding the relevant medical history, respective adverse events' ons well as the THS 2.2 usage dates.
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.

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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 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.					
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	23-OCT-2015 OCT-2015	developed cyst on throat / cyst at tonsils / cyst at palatine tonsils / surgery on tonsils [TONSILLAR CYST] Y / Y / Y seasonal sore throat [OROPHARYNGEAL PAIN] N / Y / Y	Not Recovered/Not Resolved

Study ID: THS-PBA-07-US
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 Narrative: Verbatim: developed cyst on throat / cyst at tonsils / cyst at palatine tonsils/ surgery on tonsils; seasonal sore throat

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 25-Nov-2015 and forwarded to Safety department on the same day.

This report concerns a 36-year-old female subject (Respondent Study ID: 184377) who took part in the above mentioned market research study.

No medical history and no concomitant medication were reported. The respondent denied any other medical conditions within the last year.

The respondent was a daily smoker (approximately 8 conventional cigarettes per day, 2.5-3 packs per week).

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.

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 23-Oct-2015 or 24-Oct-2015, 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.

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).

The event severity was not reported. The event required medical advice and treatment. The event was assessed as non-serious.

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.

The use of the product was stopped on 24-Oct-2015.

At time of the report, the event was not recovered. Condition was ongoing with upcoming follow-up to drain remaining fluid.

FOLLOW-UP INFORMATION RECEIVED ON 09-NOV-2015 and forwarded to Safety department on 05-Apr-2016.

Surgery on tonsils was reported (no further information provided).

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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.					
		Case Comment Text:	The Tonsillar cyst was assessed as serious (medically important, requiring drainage). The Oropharyngeal pain was assessed as non-serious. Tonsillar cyst is unlisted, whereas Oropharyngeal pain is listed, as per the Reference Safety Information (i.e. the IB). 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.					
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	31-OCT-2015	had been hospitalized during the observation period (health problem) [ADVERSE EVENT] Y / Y / Y	Recovered/Resolved
		Study ID:	THS-PBA-07-US					
		Case Initial Receipt Date:	30-Nov-2015					
		Case Followup Receipt Date:	11-Dec-2015 00:00					
		Event Stop Date:	06-NOV-2015					
		Case Narrative:	Verbatim: had been hospitalized during the observation period (health problem) 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-Nov-2015 and forwarded to Safety department on 02-Dec-2015. This report concerns a 46-year-old male subject (Respondent Study ID: 759911) who took part in the above mentioned market research study. No medical history and no concomitant medication were reported. The respondent was a daily smoker (approximately 8 conventional cigarettes per day). The respondent started using the Tobacco Heating System (THS) 2.2 Menthol (Dorado I / Vinny Low Menthol) kit number 7JUFE86NJOKL) on 19-Oct-2015. The respondent stated that he had been hospitalised during the observation period. The respondent experienced a health problem (not further specified) from 31-Oct-2015 to 06-Nov-2015. No further information was provided. The event severity of the adverse event was not reported. The case was assessed as serious due to the hospitalisation. 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). No information was provided about the action taken with the product. The unspecified health problem resolved on 06-Nov-2015. Follow-up information was expected, however, all attempts to obtain additionnal information from the respondent were unsuccessful. Case closed.					

Line Listing of All Cases from Premarket Study THS-PBA-07-US
Period: 01-Jan-1900 through 18-Apr-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 unspecified Adverse event was assessed as serious (due to hospitalization).

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).

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.

Total number of case entries printed: 48
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