



PMI RESEARCH & DEVELOPMENT

# Safety Summary Report

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

### Appendix 6 Index of Serious 15-day Reports

<b>Report Number:</b>	PMI_SURV_2016_SSR02
<b>Study Title:</b>	Actual Use Study of THS 2.2 – THS-PBA-07-US
<b>Study ID:</b>	THS-PBA-07-US
<b>Safety ID</b>	THS-PBA-07-US_PSS
<b>Products Name:</b>	Tobacco Heating System 2.2 / Regular and Menthol
<b>Passive Safety Surveillance by:</b>	Philip Morris Products S.A. PMI Research & Development Quai Jeanrenaud 5 2000 Neuchâtel, Switzerland
<b>Version:</b>	Final v 2.0
<b>Date:</b>	30-Aug-2016
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**Table 1 Index of Serious 15-day Reports Submitted to FDA**

<b>Case ID</b>	<b>Subject ID</b>	<b>THS product</b>	<b>SAE Criteria</b>	<b>SAE [PTs]</b>	<b>Date of submission</b>
<b>General disorders and administration site conditions</b>					
PMI000410	759911	Menthol	H	Adverse Event	17 Dec 2015
<b>Infections and infestations</b>					
PMI000404	656993	Menthol	H, IME	Bronchitis, Ear infection	09 Dec 2015
PMI000394	652030	Regular	H	Sepsis, Cholecystitis infective, Pneumonia	03 Dec 2015
PMI000409	184377	Menthol	IME	Tonsillar cyst	15 Dec 2015
<b>Injury, poisoning and procedural complications</b>					
PMI000347	200851	Regular	H	Road traffic accident, Concussion, Joint injury, Muscle strain, Skin abrasion	03 Nov 2015
PMI000367	654390	Regular Menthol	H	Accident, Limb Injury, Skeletal injury, Osteomyelitis, Nerve injury	13 Nov 2015
PMI000381	821416	Menthol	H	Head injury	23 Nov 2015
<b>Surgical and medical procedures</b>					
PMI000365	209653	Menthol	H	Hospitalisation	13 Nov 2015