Memorandum

To:	The Food and Drug Administration's Center for Tobacco Products
From:	Environmental Resources Management, Inc. on behalf of Philip Morris Products S.A.
Date:	12 March 2020
Subject:	**Environmental Impact Assessment (EIA) - Addendum** Modifications to the Tobacco Heating Device (THD) - CONFIDENTIAL

This memorandum is an Addendum to the Environmental Impact Assessment (EIA), dated 10 August 2016, and its subsequent addendum and responses to FDA Advice/Information Requests, dated 29 March 2018. This Addendum is to address any environmental impact that may result from proposed upgrades and modifications to the Tobacco Heating Device (THD) known as the *IQOS* 3 System.

The Addendum is to consider the environmental impacts from the differences between the Authorized *IQOS* System, which was the focus of the original EIA with subsequent amendments and responses, and the *IQOS* 3 System. The *IQOS* 3 System is the next milestone in the evolution of the *IQOS* product. The upgrades and modifications are primarily from an ergonomic, user convenience and device robustness perspective. Among other modifications, the *IQOS* 3 System has a more compact and ergonomic design, improved firmware, improved reliability, improved user interface, improved user convenience (ease of use), increased battery lifespan, and decreased battery charging time. The major parts of the holder (front housing with extractor, rear housing, middle part, staple, magnetic connector, power button and heater frame assembly containing among other parts the battery and printed circuit board (PCB)) and the charger (hull, door cover and frame assembly containing among other parts also cradle, frame subassembly, battery, and PCB) have been modified to accommodate these changes to the product. The Holder battery operates for approximately two years, when the user consumes 20 *HeatSticks* per day (approximately 15,000 inhalation experiences).

This Addendum provides a revision to the following sections:

3.1.3 Device

3.1.4 Packaging

3.3.6 Disposal of the *IQOS* 3 System Kit and Packaging Following Use

3.4 Use of Energy and Resources

5 Conclusion

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3.1.3 [1] (Revised) Device

The *IQOS* 3 System comprises of a Holder and a Charger, and is sold with accessories such as an AC adaptor, a USB cable and a cleaner. In general, these components are comprised of plastics, metals, elastomers, ceramic, glass, electronic parts, batteries, adhesives, potting materials and lubricants. The modifications to the *IQOS* 3 System involve improvements from a user convenience and robustness perspective. The *IQOS* 3 System is more compact and its major components have been modified to accommodate the changes to the product, but those major components are generally similar to the Authorized *IQOS* System addressed in the original EIA. The components of the Holder and Charger are further characterized in the following figures (Figures 1-1, 1-2, 2-1 and 2-2).

Figure 1-1 Parts of the *IQOS* 3 System Holder

No.	Description	Base Materials (Composition)
10	Power button	Plastic and adhesive
	Heater frame assembly	
11	Holder battery	Battery and metal
6	Heater PCB	Electronic part
	Overmold frame assembly	
3	Overmolded heater seal	Glass, metal, ceramic, plastic and potting compound
14	X ring	Elastomer
4	Frame	Plastic and metal
7	Heater wire surface mount left	Metal
8	Heater wire surface mount right	Metal
5	Vibration motor	Electronic part
9	High viscosity UV cured adhesive	Adhesive
1	Front housing with extractor	Plastic and metal
12	Magnetic connector - female	Electronic part
16	Staple	Metal
13	Rear housing	Plastic
2	Middle part	Metal

(table continues)

[1] EIA Menthol Appendix A5.2.1 Section 3.1.3 and EIA Regular Appendix A5.1.1 Section 3.1.3.

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No.	Description	Base Materials (Composition)
	Hydrophobic lubricant	Lubricant
15	Low to medium viscosity instant adhesive	Adhesive

Note: As the *IQOS* 3 System will be available in multiple colors, some parts are painted with corresponding device color.

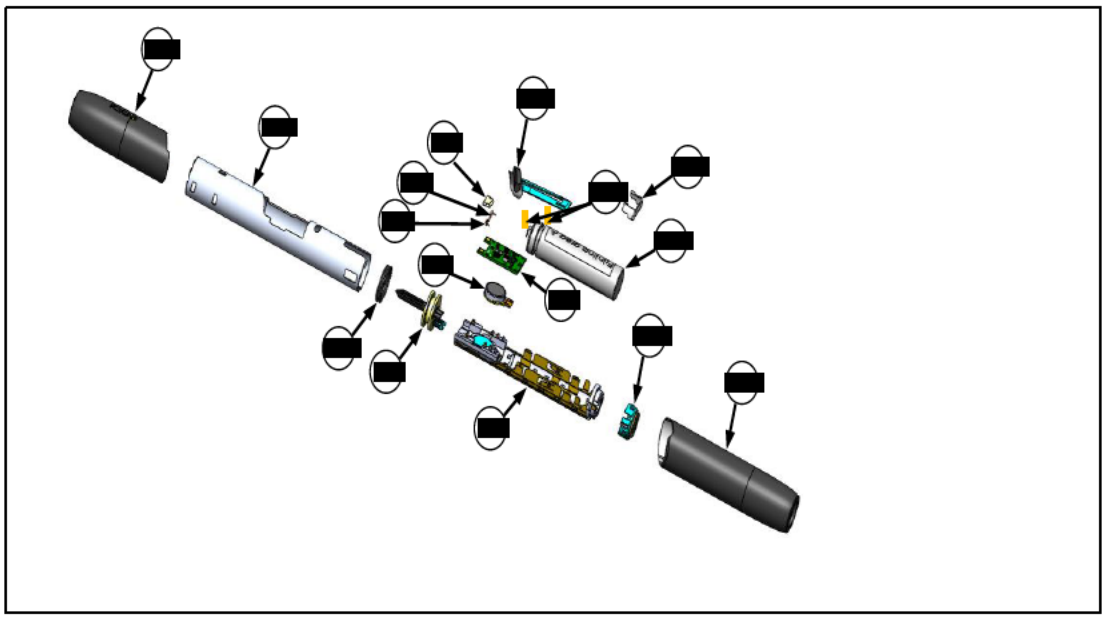


Figure 1-2 Components of the *IQOS* 3 System Holder

Figure 2-1 Components of the *IQOS* 3 System Charger

No.	Description	Base Materials (Composition)
9	Hull	Plastic, metal and elastomer
1	Door cover	Plastic, metal and adhesive
	Frame assembly	
11	Charger PCB	Electronic part
3	Cradle	Plastic, magnet and adhesive
7	Flexible printed circuit	Electronic part
4	Frame subassembly	Metal, elastomer and plastic

(table continues)

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No.	Description	Base Materials (Composition)
5	Charger battery	Battery, elastomer and electronic part
15	Magnetic connector - male	Electronic part
8	Light channel	Plastic
12	Retainer	Plastic
10	Kapton tape	Adhesive film
14	Screw M 2x6/6 Torx	Metal
13	Screw M 2x7/5 Torx	Metal
6	Spring	Metal
2	Screw M 2x8/8 Torx	Metal

Note: As the *IQOS* 3 System will be available in multiple colors, some parts are painted with corresponding device color.

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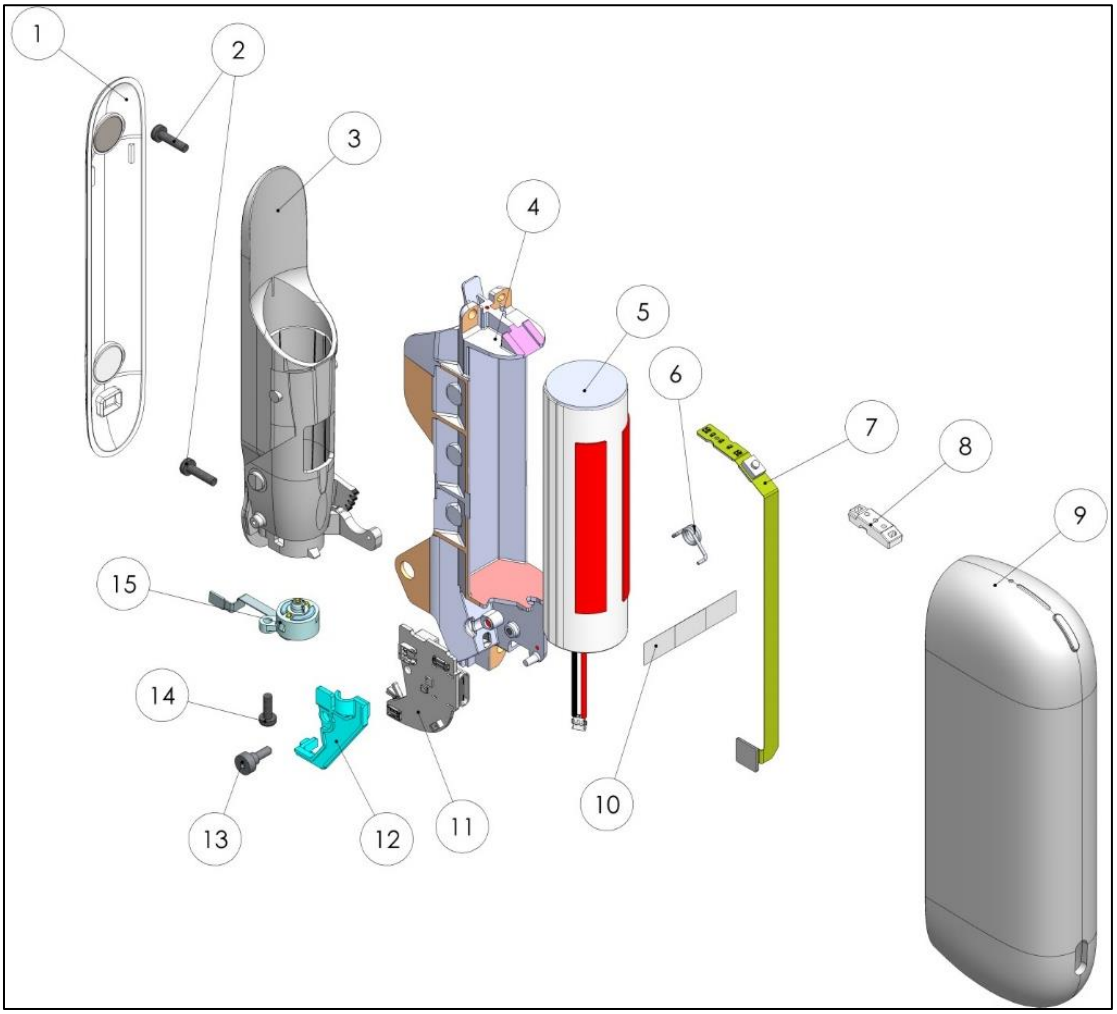


Figure 2-2 Components of the *IQOS* 3 System Charger

3.1.4 [2] (Revised) Packaging

The packaging material in direct contact with the *HeatSticks* consists of an inner frame, an inner liner and, when the pack is opened, the hinge lid. These materials comprise paperboard, inks/varnishes, lacquer, adhesives, aluminum foil, and cardboard.

Further packaging material not in contact with the *HeatSticks* comprises a plastic wrapping film and a tear tape. Ten individual *HeatSticks* packs are packed in a cardboard box. Shipping cases are used during transport and display cartons might be used at the point of sales.

[2] EIA Menthol Appendix A5.2.1 Section 3.1.4 and EIA Regular Appendix A5.1.1 Section 3.1.4.

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Packaging material for the *IQOS* 3 System include plastic, paperboard, ink, film, glue and tape. This Addendum includes an updated description of components of the *IQOS* 3 System packaging (Figure 6-1 and 6-2).

Figure 6-1 Packaging Components of the *IQOS* 3 System Kit

Product	Packaging Component[3]	Material	Weight (grams)[4]
IQOS System Pack/Kit containing charger, USB plug and cable, power adapter, cleaning elements / sticks	W&CC[5] / SWI[6]	Paper	3
	QSG[7]	Paper	6
	QSG/W&CC/SWI Envelope	Laminated paperboard	7
	Hat	Paperboard	11
	Tray Electrical Elements	Pulp from natural fibers	12
	Tray Cleaning Elements	Pulp from natural fibers	9
	Tray Device	Pulp from natural fibers	16
	Box	Laminated paperboard	138
	Box overwrap film	Plastic shrink film	2
	Shipping Case (contains 30 device boxes)	Cardboard	1200

[3] Packaging components for accessories are not included in this table.

[4] Weights are approximate.

[5] W&CC: Warranty & Customer Care Information.

[6] SWI: Safety Warning and Instructions.

[7] QSG: Quick Start Guide.

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Figure 6-2 Depiction of the Packaging Components of the *IQOS* 3 System Kit

3.3.6 [8] (Revised) Disposal of the *IQOS* 3 System Kit and Packaging Following Use

As described in the response to Question #1 and #3 of the FDA Information Request, dated 29 March 2018, the Authorized *IQOS* System is expected to be recycled. Proper disposal of the Authorized *IQOS* System Kit (which includes the *IQOS* System, adapter, and USB cable) and the packaging (packaging of both the Authorized *IQOS* System Kit and *HeatSticks*) will be recycled but may be disposed of as household waste. Disposal to MSW landfills will not result in adverse effects to the environment based on landfill design and regulatory requirements. Disposed waste streams within a landfill are prevented from entering the environment and ultimately landfill leachate is treated and/or sent to POTWs (or similar wastewater treatment systems) for effective treatment.

This Addendum includes a revision to the potential disposal volume of the *IQOS* 3 System Kit and the packaging to account for the changes in the *IQOS* 3 System size and the packaging composition and weight. The total weight of the *IQOS* 3 System Kit and packaging has slightly changed but results in the same percentage as before when compared to total municipal solid waste (MSW) generated and disposed of via landfills annually in the United States.

Assuming the entire maximum anticipated annual shipping quantity is disposed of via landfill, the *IQOS* 3 System Kit and packaging for the *IQOS* 3 System is expected to

[8] This section and the response to Question #3 of the FDA Information Request, dated 29 March 2018, make up Section 3.3.6 of the EIA Menthol Appendix A5.2.1 and EIA Regular Appendix A5.1.1. This is replacing the new Section 3.3.6 of the EIA Addendum, dated 26 March 2018.

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generate an absolute maximum of 1,524 tons of MSW per year[9], which is a minimal change as compared to the previous *IQOS* System EIA submittal. This represents up to 0.0006% of the total MSW in the country and up to 0.001% of MSW that is disposed of in landfills in the country[10]. Thus, the contribution of the *IQOS* 3 System Kit and packaging (packaging of both the *IQOS* 3 System Kit and accessories) to total MSW disposed annually in the United States is negligible.

Regarding the *HeatSticks*, the *HeatSticks* Regular product (with packaging) is expected to generate waste which represents up to 0.005% of the total MSW in the country and up to 0.010% of the MSW that is disposed of in landfills in the country. Similarly, the *HeatSticks* Menthol product (with packaging) is expected to generate waste which represents up to 0.006% of the total MSW in the country and up to 0.012% of the MSW that is disposed of in landfills in the country.

If the *HeatSticks* Regular product and the *IQOS* 3 System Kits (as described above) along with all packaging are considered[11], the potential waste generation represents a maximum of 14,212 tons of MSW per year which represents 0.005% of the total MSW in the country and up to 0.010% of MSW that is disposed of in landfills in the country. Regarding the *HeatSticks* Menthol product and the *IQOS* 3 System Kits (and packaging), it is expected to generate a maximum of 16,626 tons of MSW per year which represents up to 0.006% of the total MSW in the country and up to 0.012% of MSW that is disposed of in landfills in the country. Again, the contribution of the *HeatSticks*, the *IQOS* 3 System, accessories, and all the packaging to total MSW disposed annually in the United States is miniscule.

The materials used in the packaging of the products are common packaging materials; there is nothing special or unique about these materials relative to materials used to package other cigarette products or consumer products in general. If improper disposal as litter occurs, the *IQOS* 3 System Kit and the packaging are not expected to result in new or additional compounds emitted to the environment. The *IQOS* 3 System Kit and the packaging are designed to remain intact and are not intended to release chemical substances. Also, the *IQOS* 3 System (Holder and Charger) is compliant with RoHS[12] and

[9] *IQOS* System kit (maximum of 3.1 million kits), accessories, and packaging including the shipping case (30 kits in a shipping case).

[10] According to the USEPA document *Advancing Sustainable Materials Management: 2015 Fact Sheet Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States*, 262 million tons of MSW were generated across the United States in 2015. Of this, over 91 million tons (34.7%) were recycled and composted, more than 137 million tons (52.5%) were discarded in a landfill, and more than 33 million tons (12.8%) were combusted with energy recovery (USEPA, 2018). Tobacco sticks are not expected to be recycled.

[11] Includes Maximum Annual Shipping Quantity (between 1st Year and 5th Year) of the *HeatSticks* and their packaging (20 *HeatSticks* per pack; 10 packs in a carton; 50 cartons in a shipping case); and the *IQOS* System Kits, accessories, and packaging.

[12] RoHS (Restriction of Hazardous Substances) is a European Union Directive to address consumer electronics waste. RoHS applies to restrictions of certain hazardous substances in the design phase of Electrical & Electronic Equipment (EEE); and primarily to consumer products and waste thereof. RoHS bans certain hazardous substances and has declaration of conformity.

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REACH[13]. Therefore, release of chemical substances contained in these items and packaging materials to the terrestrial environment are expected to be negligible.

Considering the possibility of improper disposal of the *IQOS* 3 System to terrestrial compartment, it should be noted the *IQOS* 3 System is smaller, in size and volume, than other electronic consumer devices (cell phones, laptops, etc.) and the extended lifespan of the *IQOS* 3 System as compared to the Authorized *IQOS* System (from approximately one year to two years) should correspond to less disposal of waste or recyclable materials over time. The *IQOS* 3 System and the battery are also compliant with the applicable safety requirements of the IEC 60335[14] and IEC 62133, respectively.

As stated in the 29 March 2018 Addendum, the U.S. *IQOS* product marketing program will inform and encourage consumers of responsible recycling through messaging in the *IQOS* System User Guide and other avenues, and will direct consumers to a third party recycling program. As stated earlier, proper disposal of the *IQOS* 3 System Kit is recycling. A global e-waste report (Baldé et al. (2017)) indicates that in 2016 22% of the total e-waste in the U.S. was collected for recycling with a collection rate of approximately 70% for common e-waste items. Also, this report indicates that e-waste production and collection continues to increase in the U.S.

Available studies indicate the primary concern associated with small lithium-based batteries is leaching of metals from batteries improperly disposed of as litter, which is expected to represent a small portion of batteries used in the *IQOS* 3 System. Electronic waste (e-waste) in general has been studied and characterized in the literature. Gaidajis et al. (2010) noted that electronic waste is characterized by a complex chemical composition and the difficulty in quantifying its flow at a local and international level; pollution caused by irregular management of electronic waste substantially degraded the environment mostly in poorer countries, receiving it for recycling and recovery of its valuable metals; and that introduction of rechargeable batteries is a positive change driven by the motivation to minimize environmental effects caused by the generation of electronic waste.

Much of the published literature on environmental impacts of waste lithium ion batteries focuses on recycling of automotive lithium ion batteries. As it relates to small, electronic devices, the environmental impact of waste lithium-based batteries used in cell phones has been studied (Kang et al., 2013 and Lincoln et al., 2007). Kang et al. (2013) used

[13] REACH (Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals) is a European Union regulation to address the production and use of chemical substances, and their potential impacts on both human health and the environment. REACH is chemical regulation regarding the registration, evaluation, authorization and restriction of chemical substances. All manufacturers and importers of chemicals must identify and manage risks linked to the substances they manufacture and market. REACH requires these companies (that manufacture or import chemical substances into the European Union in certain quantities) to demonstrate that they have appropriately done so by means of a registration dossier which must be submitted to European Chemical Agency (ECHA).

[14] International Electrotechnical Commission (IEC) 60335 are safety requirements that pertain to the safety of electrical appliances for household and similar purposes including battery-operated appliances. IEC 62133 are safety requirements that pertain to portable sealed secondary cells, and for batteries made from them, for use in portable applications.

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standardized leaching tests as a way to assess the environmental impact of waste lithium-based cell phone batteries. Various metals, including lead, chromium, thallium, cobalt, copper and nickel, leached from the batteries at levels that exceed regulatory thresholds for hazardous waste in the United States under the conditions of the study. Lincoln et al. (2007) conducted a similar study and found that lead, copper, nickel, antimony and zinc exceeded regulatory thresholds for hazardous waste in the United States under the condition of the study. Gaidajis et al. (2010) found that landfill sites where electronic waste is disposed of did not produce leachates with heavy metal concentrations exceeding the environmental limits and leachates from the batteries themselves did produce elevated levels of heavy metals.

Again, landfill design and regulatory requirements will limit environmental impacts. Disposed waste streams within a landfill are prevented from entering the environment and ultimately landfill leachate is treated and/or sent to POTWs (or similar wastewater treatment systems) for effective treatment.

Improper disposal (as litter) of the battery unit may have the potential to produce leachates toxic to wildlife, but any impact to the terrestrial environment is anticipated to be isolated and localized. Also, there is nothing unique about the battery unit that would increase or disproportionately contribute to the prevalence or toxicity as compared to any other electronic products or battery-containing products that are improperly disposed. Thus, no significant adverse effects resulting from environmental release or exposure of the *IQOS* 3 System (Holder and Charger) are anticipated. The introduction of released substances from disposal or littering of the *IQOS* 3 System is expected to be negligible from an environmental perspective.

3.4 [15] (Revised) Use of Energy and Resources

The product will be produced outside of the United States; therefore, consumption of energy and resources in the production process are not addressed here. Even though the battery has an increased lifespan and battery charging time has decreased, the energy consumption (rated power) information provided in the original EIA is still accurate for the holder battery, charger battery, and the power adapter.

The rated power of the batteries is 0.384Wh for the *IQOS* 3 Holder and 11Wh for the *IQOS* 3 Charger. When the *IQOS* 3 Charger is charging using AC adapter, it will limit its current consumption to 1.6A. The AC adapter is designed to deliver up to 2A at 5V (10W), its efficiency is around 81% at 2A, and better at lower currents.

From February 2016, the US Department of Energy (DOE) requires compliance with Average Efficiency and No Load Power Consumption Level VI requirements for all adaptors imported into the United States, as mandated in 10 CFR Part 430 Energy Conservation program. The applicable limits are provided in the following table. PMP S.A.'s AC Adaptor output is 10W. PMP S.A. has uploaded the relevant information to the DOE website under basic model number S21A22 in the 'External Power Supplies – Other

[15] This section is a revision to Section 3.4 of the EIA Menthol Appendix A5.2.1 and EIA Regular Appendix A5.1.1.

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Than Switch-Selectable and Adaptive Single-Voltage External Power Supplies' product group.

Table 1 Energy Conservation Standards for External Power Supplies

Single-Voltage External AC-DC Power Supply, Low-Voltage		
Nameplate Output Power (P_{out})	**Minimum Average Efficiency in Active Mode** (expressed as a decimal)	**Maximum Power in No-Load Mode [W]**
$P_{out} \leq 1$ W	$\geq 0.517 \times P_{out} + 0.087$	≤ 0.100
1 W < $P_{out} \leq 49$ W	$\geq 0.0834 \times \ln(P_{out}) - 0.0014 \times P_{out} + 0.609$	≤ 0.100
49 W < $P_{out} \leq 250$ W	≥ 0.870	≤ 0.210
$P_{out} > 250$ W	≥ 0.875	≤ 0.500

5 [16] (REVISED) CONCLUSION

This Addendum concludes that the modifications to the Authorized *IQOS* System and packaging result in a minimal change in environmental impact from the *IQOS* 3 System. This assessment still provides a basis for a Finding of No Significant Impact (FONSI) due to *de minimis* exposure. The overall conclusion from this assessment remains that there are no significant environmental risks identified and a FONSI for this environmental assessment of the *IQOS* 3 System by FDA is still warranted.

6 WORKS CITED

Baldé, C.P., Forti V., Gray, V., Kuehr, R., Stegmann, P. The Global E-waste Monitor – 2017, United Nations University (UNU), International Telecommunication Union (ITU) & International Solid Waste Association (ISWA), Bonn/Geneva/Vienna.

Gaidajis, G., Angelakoglou, K., Aktsoglou, D. (2010). E-waste: Environmental problems and current management. Journal of Engineering Science and Technology Review. 3(1), 193-199.

Kang, D.H.P., Chen, M., Ogunseitan, O.A. (2013). Potential environmental and human health impacts of rechargeable lithium batteries in electronic waste. Environmental Science and Technology. 47, 5495-5503.

[16] EIA Menthol Appendix A5.2.1 Section 5 and EIA Regular Appendix A5.1.1 Section 5.

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Lincoln, J.D., Ogunseitan, O.A., Shapiro, A.A., Saphores, J.D.M. (2007). Leaching assessments of hazardous materials in cellular telephones. Environmental Science and Technology. 41, 2572-2578.

USEPA. (2018). Advancing Sustainable Materials Management: 2015 Fact Sheet, EPA-530-R-17-01, July 2018, Washington, DC.

7 CERTIFICATION

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