U.S. Food & Drug Administration
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www.fda.gov

PMTA Coversheet: Environmental Science

SUBMISSION INFORMATION			
Applicant	Philip Morris Products S.A.		
Product Manufacturer	Philip Morris Products S.A.		
Submission Date	05-15-2017	**FDA Receipt Date**	05-15-2017
Primary STN(s)	PM0000424	Marlboro Heatsticks[1]	
	PM0000425	Marlboro Smooth Menthol Heatsticks[1]	
	PM0000426	Marlboro Fresh Menthol Heatsticks[1]	
	PM0000479	IQOS System Holder and Charger[1]	
Cross-referenced Submission(s)	**Cross-referenced STN**	**Primary STN(s)**	
	MR0000059	APPLIES TO PM0000424-PM0000426, PM0000479	
	MR0000060		
	MR0000061		
	MR0000133		
	MF0000013		
	MF0000243		
	MF0000264		

[1] May be sold individually or as co-packaged product.

Amendments			
Amendment STN	**Primary STN**	**Description**	**FDA Receipt Date**
PM0000440	PM0000424-426, PM0000479	Resubmitted label images	06-21-2017
PM0000443	PM0000424-426, PM0000479	Request for A/I Request letter response extension; confirmed battery samples	08-31-2017
PM0000457	PM0000424-426, PM0000479	Response to 11/22/17 A/I Request letter	12-26-2017
PM0000458	PM0000424-426, PM0000479	Response to 11/22/17 A/I Request letter	12-22-2017
PM0000461	PM0000424-426, PM0000479	Ongoing study data	12-08-2017
PM0000464	PM0000424-426, PM0000479	Response to 3/2/18 EA A/I Request letter	03-29-2018
PM0000466	PM0000424-426, PM0000479	P1 Characterization study update	04-26-2018
PM0000467	PM0000424-426, PM0000479	Response to 4/23/18 A/I Request letter	05-23-2018
PM0000468	PM0000424-426, PM0000479	Response to 6/6/18 teleconference questions	06-13-2018
PM0000475	PM0000424-426, PM0000479	Response to 7/18/18 teleconference questions	08-03-2018
PM0000476	PM0000424-426, PM0000479	Response to 8/20/18 A/I Request	09-05-2018
PM0000478	PM0000424-426, PM0000479	Corrected versions of two study reports	09-25-2018

NEW TOBACCO PRODUCT	
STN	PM0000424
Product Name	Marlboro Heatsticks[1]
Product Category	Cigarettes
Product-Sub Category	Non-Combusted
Package Type	Box
Package Quantity	20 Heatsticks
Characterizing Flavor	None
Length	45 mm
Diameter	7.42 mm
Ventilation	Not Applicable[2]
Source of Energy	Electric (rechargeable battery)[3]
STN	PM0000425
Product Name	Marlboro Smooth Menthol Heatsticks[1]
Product Category	Cigarettes
Product-Sub Category	Non-Combusted
Package Type	Box
Package Quantity	20 Heatsticks
Characterizing Flavor	Menthol
Length	45 mm
Diameter	7.42 mm
Ventilation	Not Applicable[2]
Source of Energy	Electric (rechargeable battery)[3]
STN	PM0000426
Product Name	Marlboro Fresh Menthol Heatsticks[1]
Product Category	Cigarettes
Product-Sub Category	Non-Combusted
Package Type	Box
Package Quantity	20 Heatsticks
Characterizing Flavor	Menthol
Length	45 mm
Diameter	7.42 mm
Ventilation	Not Applicable[2]
Source of Energy	Electric (rechargeable battery)[3]
STN	PM0000479
Product Name	IQOS System Holder and Charger[1]
Product Category	Cigarettes
Product-Sub Category	Non-Combusted
Package Type	Box
Package Quantity	1 Holder, 1 Charger

[2] For this product neither filter efficiency or ventilation are used to control aerosol deliveries.

[3] The components and assemblies control the delivery of energy. The critical items include the Heater Printed Circuit Board Assembly (PCBA) including the heating blade and the battery.

Characterizing Flavor	None
Length	93.60 mm (Holder)
Diameter	15.04 mm (Holder)
Length	112.50 mm (Charger)
Width	51.20 mm (Charger)
Ventilation	Not Applicable[2]
Source of Energy	Electric (rechargeable battery)[3]
Additional Properties	Depth: 21.86 mm (Charger)
	Battery Capacity: (b) (4) Holder)
	Wattage: (b) (4) Charger)[4]
	Battery Capacity: (b) (4) (Charger)

[4] Wattage provided for the charger battery

Programmatic Environmental Assessment:

Marketing Orders
for
Marlboro Heatsticks,
Marlboro Smooth Menthol Heatsticks,
Marlboro Fresh Menthol Heatsticks, and IQOS System Holder and Charger
by
Philip Morris Products S.A.

Prepared by:
Center for Tobacco Products
U.S. Food and Drug Administration

March 15, 2019

Cover Sheet

Responsible Agency:	U.S. Food and Drug Administration
Proposed Action:	Marketing orders for Philip Morris Products S.A.'s Marlboro Heatsticks, Marlboro Smooth Menthol Heatsticks, Marlboro Fresh Menthol Heatsticks, and IQOS System Holder and Charger
Location:	United States
Agency contact:	Hoshing Chang, Center for Tobacco Products, U.S. Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-2707
Designation:	Final programmatic environmental assessment
Abstract:	This document reviews the potential environmental impacts from marketing three flavors of tobacco heatsticks and a heated tobacco product holder and charger in the United States, and from the no-action alternative of the Agency not issuing marketing orders for these products. The Agency did not identify any significant environmental impacts from the proposed actions.
Comments Due Date:	Not applicable

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Acronyms and Abbreviations

CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations
CITES	Convention on International Trade in Endangered Species of Wild Flora and Fauna
CO_2	carbon dioxide
CO_2-eq	carbon dioxide equivalents
ETS	environmental tobacco smoke
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDA	Food and Drug Administration
FONSI	finding of no significant impact
GHG	greenhouse gas
HPHC	harmful or potentially harmful chemical
MRTPA	modified risk tobacco product application
MSW	municipal solid waste
NEPA	National Environmental Policy Act
PEA	programmatic environmental assessment
PMP	Philip Morris Products, S.A.
PMTA	premarket tobacco product application
THS	tobacco heating system
WARM	Waste Reduction Model

1. Introduction

1.1 Background

On May 12, 2017, Philip Morris Products S.A. (PMP) submitted premarket tobacco product applications (PMTAs) for three flavors of heatsticks and the IQOS system holder and charger. In the PMTAs, PMP requests the U.S. Food & Drug Administration (FDA) to permit marketing of these new tobacco products by issuing marketing orders under section 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (Public Law 111-31).

Issuing new tobacco product marketing orders is a federal action for which FDA must consider environmental impacts before deciding to proceed, in accordance with the requirements of the National Environmental Policy Act (NEPA). FDA prepared this programmatic environmental assessment (PEA) to evaluate the potential for significant environmental impacts from the proposed marketing orders for the new products. This PEA conforms to the Council on Environmental Quality's (CEQ's) NEPA regulations applicable to all agencies (40 Code of Federal Regulations [CFR] Part 1500) and FDA's agency-specific NEPA regulations (21 CFR Part 25). If a PEA concludes that a proposed action would not have significant environmental impacts, then an agency issues a finding of no significant impact (FONSI) to document this conclusion, completing the NEPA process. If a potentially significant impact is identified, then the agency proceeds to prepare an environmental impact statement.

Section 1 of this PEA describes the purpose of and need for action, identifies relevant laws and requirements, describes a related action, and summarizes the scope of this PEA. Section 2 identifies the proposed actions and alternative. Section 3 presents the environmental impact analysis. Sections 4 and 5 list the preparers and the agencies and persons consulted, respectively.

1.2 Purpose of and Need for Action

Purpose: Upon receipt of a PMTA, FDA considers the submission, using criteria detailed in section 910(c) of the FD&C Act, and issues an order that either allows or denies introduction or delivery for introduction of the new product into interstate commerce. The purpose of FDA's PMTA review and subsequent order is to make a finding as to whether marketing orders for the new products would be appropriate for the protection of public health. The determination is made with respect to the risk and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account (a) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (b) the increased or decreased likelihood that those who do not use tobacco products will start using such products (section 910(c)(4) of the FD&C Act).

Need: FDA's responsibility to review a PMTA, make a finding as described in the previous paragraph, and subsequently determine whether or not to issue a marketing order for the new product is a statutory requirement under section 910(c) of the FD&C Act.

1.3 Relevant Laws and Requirements

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), comprising Chapter IX of the FD&C Act, was signed into law on June 22, 2009. The Tobacco Control Act gives FDA authority to

regulate the manufacture, distribution, and marketing of tobacco products, including reviewing PMTAs and determining whether to issue marketing orders.

NEPA and CEQ's implementing regulations (40 CFR Part 1500) apply to all federal agency actions, including actions mandated by other laws such as the Tobacco Control Act. FDA's NEPA regulations detail procedures for applying NEPA to FDA programs, and specifically require compliance with three additional environmental protection programs.

- FDA's NEPA regulations specifically require compliance with the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES) (21 CFR 25.21 (b)). CITES provides varying degrees of protection to more than 35,000 species, aiming to ensure that international trade in specimens of wild animals and plants does not threaten their survival. There are currently 183 nations and regional economic integration organizations, known as parties, that have voluntarily agreed to be bound by CITES. In January 1974, the United States was the first party to join CITES.
- Compliance with the U.S. Endangered Species Act is also specifically required by FDA's NEPA regulations (21 CFR 25.21 (b)). This Act is intended to prevent the further decline of endangered and threatened species in the United States and to restore these species and their habitats. Section 7 of the Act requires that, when federal agency actions may affect an endangered or threatened species, the federal agencies must consult with the U.S. Fish and Wildlife Service or the National Marine Fisheries Service to ensure the action does not jeopardize the species or destroy its habitat.
- The third specific requirement named in FDA's NEPA regulations (21 CFR 25.60) is Executive Order 12114, "Environmental Effects Abroad of Major Federal Actions." FDA must consider potentially significant impacts that occur in other nations or the global commons when conducting a NEPA analysis of actions under an agency program.

CEQ's NEPA regulations state that the significance of environmental impacts (and thus the justification for a FONSI) is in part indicated by whether the action may violate federal, state, or local laws or requirements imposed for the protection of the environment (40 CFR 1508.27(b)(10)). Therefore, compliance with resource-specific requirements is evaluated where applicable throughout this PEA.

1.4 Related Actions

On December 5, 2016, PMP submitted modified risk tobacco product applications (MRTPAs) requesting marketing orders under section 911(g) of the FD&C Act for the same three flavors of heatsticks and IQOS system holder and charger that are the subject of this PEA. For an applicant to commercially market a modified risk product, FDA must determine that the applicant has demonstrated that the product, as actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users, and benefit the health of the population as a whole taking into account users of tobacco products and persons who do not currently use tobacco products (sections 911(g)(1) and 911(g)(2) of the FD&C Act). Although the potential environmental impacts would be like those from the PMTA marketing orders, FDA would prepare a separate PEA for the distinct agency action of issuing modified risk tobacco product marketing orders for these same new products. FDA's review of the IQOS MRTPAs is ongoing as of the date of this PEA.

1.5 Scope of Environmental Assessment

Scoping is the process for determining the scope of issues to be addressed in a NEPA document and for identifying the significant issues related to a proposed action. For this PEA, scoping methods consisted of (1) internal Agency scoping, in which environmental and other scientific staff within the FDA Center for Tobacco Products reviewed the products' manufacturing, use, and disposal information to identify potential areas of environmental impact for review in this PEA; and (2) reviewing each of the 252 public comment submissions posted to date in docket FDA-2017-D-3001 (www.regulations.gov) for MRTPAs for the same three products. Internal Agency scoping served as the basis for the format and content of this PEA. The MRTPA docket did not contain any public comments that identified potential environmental concerns within the scope of this analysis in addition to those evaluated in this PEA.

The scope of a NEPA analysis is defined by the range of actions, alternatives, and impacts that it considers (40 CFR 1508.25). Using input from the scoping process described above, this PEA evaluates the following:

- The ***actions*** in this PEA are issuing marketing orders for four new tobacco products. The decision on whether to take these actions and issue the marketing orders is a result of FDA's reviews of the PMTAs for the new products. FDA did not identify any connected actions.[1] FDA also did not identify any cumulative or similar actions, given that FDA acceptance, filing, and detailed review and consideration of any future marketing applications from this or other applicants for products that are similar or have similar environmental impacts would be speculative.
- The ***alternatives*** in this PEA are the courses of action available to FDA under Chapter IX of the FD&C Act, described in detail in Sections 2.1 and 2.2. As the proposed actions, FDA may issue marketing orders for one or more of the new products. The no-action alternative in this PEA is the case in which FDA would deny the PMTAs and not issue marketing orders.
- The ***impacts*** evaluated in this PEA, described in Section 3, include direct, indirect, and cumulative impacts to environmental resources.

2. Proposed Actions and Alternative

2.1 Proposed Actions

FDA proposes to issue marketing orders authorizing introduction or delivery for introduction of four new tobacco products into interstate commerce in the United States. The applicant's PMTAs seek FDA's marketing orders under section 910(c)(A)(i) of the FD&C Act for the four products listed in Table 1.

[1] Actions are connected if they automatically trigger other actions, cannot or will not proceed unless other actions are taken previously or simultaneously, or are interdependent parts of a larger action and depend on the larger action for their justification (40 CFR 1508.25).

Table 1. Description of New Products

STN*	Name	Description
PM0000424	Marlboro Heatsticks	• pack of 20 heatsticks • carton of 10 packs
PM0000425	Marlboro Smooth Menthol Heatsticks	• pack of 20 heatsticks • carton of 10 packs
PM0000426	Marlboro Fresh Menthol Heatsticks	• pack of 20 heatsticks • carton of 10 packs
PM0000479	IQOS System Holder and Charger	As packaged for sale to the consumer, the IQOS system is accompanied by the following accessories: AC adaptor, USB charging cable, cleaning brush, user guide.

*STN = submission tracking number.

The products would be manufactured outside of the United States, as follows:

(b) (4)

Figure 1 depicts the IQOS system components and details of the holder and heatstick designs.

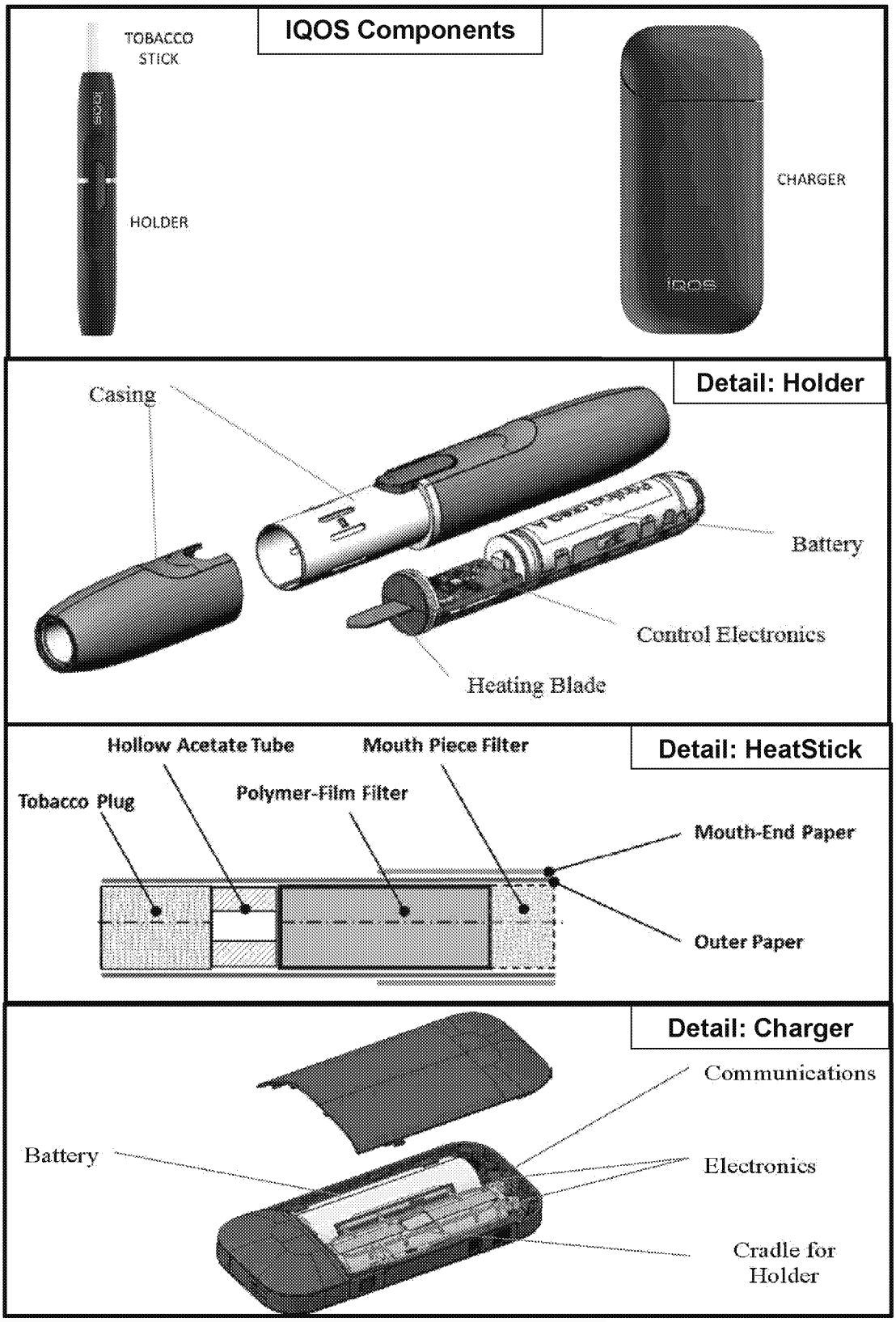

Figure 1. IQOS System Components Source: PMP 2017.

The heatstick, which resembles a short cigarette, contains tobacco that is ground and reconstituted into sheets (termed cast-leaf) following the addition of water, glycerin, guar gum, and cellulose fibers. The heatstick contains two filters: a polymer-film filter to cool the aerosol and a low-density cellulose acetate mouthpiece filter that mimics a cigarette. When the user places the heatstick in the open end of the holder, a ceramic blade with a platinum heating element inserts into the tobacco plug. The user turns on a switch and the electronically controlled blade heats the tobacco to produce an aerosol, inhaled by the user through the mouthpiece filter. The blade heats the tobacco for a fixed period of approximately six minutes and allows up to fourteen puffs to be taken during that time. The tobacco does not ignite and the heatstick is not consumed or decreased in size during use. Electronic controls prevent the temperature of the blade from exceeding 350°C. The material inhaled from one heatstick contains approximately 70 percent of the nicotine as the material inhaled from a combusted cigarette.

The holder has sufficient electrical charge for use of a single heatstick. After each heatstick use, the holder must be recharged by inserting it into the charger. The charger stores an amount of energy to recharge the holder approximately 20 times and is itself recharged using an included AC adaptor. (b) (4)

(b) (4)

The applicant estimated that approximately 17 percent of combusted cigarette users in the United States would be exclusive or dual users of the new products within 10 years. The new products – IQOS devices including the holder and charger, accessories, and heatsticks in packs and cartons – would be available for purchase at IQOS-branded stores as well as traditional convenience stores nationwide. The new products would be sold in paper, cardboard, and plastic packaging materials typical of consumer tobacco and electronic products.

2.2 No Action

The no-action alternative is for FDA to deny the PMTA applications. The new products would not be marketed in the United States and, for the purposes of the analysis in this PEA, it is assumed that the combusted cigarette market would retain its current and projected future user base.

2.3 Comparison of Proposed Actions and Alternative

Environmental Resource	Potential Environmental Impacts	
	Proposed Actions	**No Action**
Air quality	Negligible to minor impacts from secondhand IQOS aerosol on indoor air quality based on available data.	No exposure to secondhand IQOS aerosol. Continued environmental tobacco smoke exposure for non-users from combusted cigarettes, at levels proportional to the overall rate of cigarette use.
	No greenhouse gases (GHGs) in IQOS aerosol.	GHG emissions from comparable level of combusted cigarette use would be negligible compared to total U.S. greenhouse gas emissions from all sources.
	Negligible GHG emissions from disposing of the product waste and packaging from new products.	Negligible GHG emissions from disposing of product waste and packaging from comparable volume of combusted cigarettes.

Environmental Resource	Potential Environmental Impacts	
	Proposed Actions	**No Action**
Biological resources	No effects to aquatic species expected from urinary biomarkers in surface water.	No change in current levels of aquatic species exposure to excreted biomarkers.
	Slight increase in the potential for tobacco exposure to terrestrial wildlife but impact cannot be concluded to be significant.	No change in current terrestrial wildlife exposures to littered combusted cigarette butts.
	Leachate exposure to aquatic species from littered heatsticks is possible but impact cannot be concluded to be significant.	No change in current aquatic species exposures to leachate from littered combusted cigarette butts.
Environmental justice	No indication that never smokers in low-income or minority populations would disproportionately adopt use of the new products.	Minority and low-income populations would continue to initiate, use, and quit combusted cigarettes at rates seen in current trends for each subpopulation. No changes in any disproportionate impacts to minority or low-income populations would occur.
Human health (NEPA context only)	*Only within the context of and for the purposes of NEPA analysis,* health impacts to users are classified as "not significant" if Agency review recommends issuing marketing orders under the Tobacco Control Act.	No change in current levels of health impacts to users from combusted cigarettes.
	Negligible to minor impacts from secondhand IQOS aerosol on indoor air quality based on available data.	No exposure to secondhand IQOS aerosol. Continued environmental tobacco smoke exposure for non-users from combusted cigarettes, at levels proportional to the overall rate of cigarette use.
	No significant impacts related to battery safety.	—
Solid waste and hazardous materials	Negligible addition to nationwide levels of recycling and MSW generation from disposal of used heatsticks and packaging.	Negligible contribution to nationwide levels of recycling and MSW generation from disposal of combusted cigarette butts and packaging.
	Negligible increase (by weight) in tobacco product litter as heatsticks are not consumed during use.	No change in overall level of cigarette butt litter.
	Negligible risk of littered heatstick igniting a wildland fire.	Continued risk at same levels of fire from unattended cigarettes or unextinguished littered cigarette butts.
	No significant impacts from electronic device and lithium battery disposal.	—
Water resources	No effects to water quality expected from urinary biomarkers from use of new products in surface water.	No change in levels of excreted biomarkers from combusted cigarette use in surface water.
	Leachate entering surface water bodies from littered heatsticks is possible but impact on water quality cannot be concluded to be significant.	No change in levels of leachate from littered combusted cigarette butts entering surface water bodies.

2.4 Mitigation Measures

No mitigation measures are identified.

3. Affected Environment and Potential Environmental Impacts

Potential impacts from product manufacturing and the proposed actions and no action are discussed in Section 3.1. Sections 3.2 to 3.8 discuss the potential direct, indirect, and cumulative impacts on environmental resources from product use and disposal under the proposed actions and no action.

In this PEA, the relevant impacts from the no-action alternative are those associated with ongoing use and disposal of 17 percent of the combusted cigarette market in the United States, the percent estimated by the applicant that would switch to the new product.

The following environmental resources typically evaluated in a NEPA document are not affected by the proposed actions or no action and are not evaluated further in this PEA: historic and cultural resources; floodplains, wetlands, and coastal zones; soils; land use and zoning; and socioeconomic conditions.

3.1 Potential Impacts from Manufacturing

In this PEA, FDA has used compliance with relevant laws and regulations as a reasonable indicator of the environmental impacts from manufacturing from the proposed actions. Detailed site-specific analysis of impacts at the current manufacturing facilities would not be comprehensive since (1) the applicant has published several announcements of plans for additional manufacturing locations for this product line, and (2) FDA's marketing orders for new tobacco products are not limited to the output of a specific manufacturing facility, as long as the product itself meets the exact specifications identified in the order.

The applicant stated that the three manufacturing facilities that currently contribute to IQOS production each comply with all environmental laws and regulations that apply to their location. The applicant provided, where applicable to each facility, documentation in the form of air emissions permits and monitoring data, wastewater permits and analyses, workplace noise levels, offsite noise measurements, hazardous waste management systems, occupational health and safety management systems, and environmental management systems. No significant environmental impacts are expected from manufacturing the new products under the proposed actions.

No environmental impacts would occur from a lack of manufacturing for the U.S. market if the marketing orders were not issued under the no-action alternative.

3.2 Air Quality

3.2.1 Affected Environment

This PEA qualitatively evaluated impacts to air in the immediate vicinity of IQOS from the chemical aerosol mixture emitted by the product. Users may dispose of waste products and packaging anywhere in the United States.

3.2.2 Potential Impacts from Proposed Actions

3.2.2.1 Use

An individual uses the IQOS system by inhaling the mainstream aerosol generated by the product and exhaling secondhand aerosol to the environment. The applicant stated that the IQOS system does not emit sidestream aerosol directly from the heatstick during use; however, FDA did not identify any study that evaluated this question.

When used outdoors, localized aerosol would be present during and following IQOS use. Aerosol in an outdoor environment would disperse quickly with negligible impact to outdoor air quality.

Information on IQOS mainstream aerosol chemistry and toxicity provides data relevant to analyzing impacts from secondhand exposure to non-users. FDA reviewed studies submitted by the applicant as well as reported in published scientific literature (FDA, 2018a). The agency's conclusions to date are summarized as follows:

- ***Aerosol chemistry.*** The applicant claims that the IQOS system heats but does not burn tobacco, resulting in significantly reduced concentrations of harmful or potentially harmful constituents (HPHCs) compared to combusted cigarettes. HPHCs were present at lower levels in aerosol from the IQOS heatsticks compared to mainstream cigarette smoke. HPHCs are 54 to 99.9 percent lower in IQOS aerosol when compared per unit (heatstick vs. cigarette) and 25 to 99.8 percent lower for comparable nicotine levels. Since the IQOS system heats tobacco at a temperature lower than 350°C (compared to 600°C for combusted cigarettes), it is expected that the amounts of compounds formed by combustion and pyrolysis will be substantially lower than for combusted cigarettes. However, other compounds would still be expected to be present in the aerosol. These compounds could include pyrolysis products of glycerol and propylene glycol that evaporate at temperatures less than 350°C; compounds transferred intact from the IQOS heatstick to the aerosol by evaporation; and pesticides that are not burned and evaporate at temperatures less than 350°C. The applicant identified between 53 and 62 compounds that are at higher levels in the aerosol of the heatsticks compared to the smoke of the 3R4F reference cigarette. These compounds include propylene glycol and its known degradation products of glycerol, glycidol, and acetol. FDA's laboratory independently tested two more compounds produced by pyrolysis of glycerol—acrolein and formaldehyde—and found them to be significantly lower in the IQOS aerosol than in the smoke from cigarettes.
- ***Nonclinical studies.*** Nonclinical studies reported biomarkers of exposure to several constituents commonly measured in smoking studies. Apart from nicotine, the measured biomarkers of exposure in the blood and urine of test subjects were considerably reduced from those found after combusted cigarette exposure, to levels comparable to those in test subjects that were not exposed to cigarette smoke. Similar results were seen in clinical studies. FDA review of a carcinogenicity study of IQOS is ongoing and results were not available at the time of this PEA. Overall, data from the nonclinical studies submitted by the applicant indicated that IQOS aerosol did not produce any new adverse effects in addition to those produced by exposure to cigarette smoke. These studies suggest that IQOS aerosol has lower toxic potential than cigarette smoke under the conditions used in the assays and for the non-cancer endpoints measured. To be clear, IQOS aerosols did induce toxicity in in vitro and in vivo studies, but only at higher concentrations when compared to reference cigarette smoke.

The applicant referenced three publications comparing indoor air quality after IQOS or combusted cigarette use.

- A Philip Morris USA study reported substantial reductions (41 percent or more) in all analytes tested in the air of a room after use of a heated tobacco product compared to combusted cigarettes (Frost-Pineda et al., 2008). It is not clear how the tested system compares to the current IQOS system, the methods are not fully described, the discussion of results is incomplete (however, the results appear to favor the heated tobacco system), and the health significance of the reported results as well as untested emissions is not evaluated in the study or the applicant's summary of the study.
- Another Philip Morris-led study (Tricker et al., 2009) similarly reported reductions of 80 to 90 percent or more for approximately 30 endpoints in each of four test room scenarios after use of a heated tobacco product compared to combusted cigarettes. It is not clear how the tested system compares to the current IQOS system. The authors summarized results in terms of percent relative concentration for the respective changes from background for the heated tobacco product and combusted cigarettes, although the study did present the actual levels measured. The published report did not account for notable variations in background concentrations among the scenarios that were compared to each other and affected the conclusions drawn.
- The applicant provided a presentation (Goujon-Ginglinger, 2015) and a published journal article (Mitova et al., 2016) for a third Philip Morris study. The study compared the levels of 18 chemical endpoints—6 markers of environmental tobacco smoke, 4 carbonyls, 5 volatile organic compounds, and 3 gases—in the air of a study room after use of combusted cigarettes or the IQOS product. The authors concluded using IQOS increased only acetaldehyde and nicotine concentrations above background levels, and that these increases were less than the levels measured after use of combusted cigarettes. While informative, the pre-determined set of analytes evaluated, all of which are associated with combusted cigarettes, limits the application of the conclusions.

The applicant submitted additional aerosol chemistry studies in the months since FDA prepared the January 2018 summary (FDA, 2018a), with similar findings that did not change the conclusions for the purposes of this NEPA analysis. Overall, the information available at this time indicates that exhaled aerosol (assumed similar to mainstream aerosol) from IQOS is not free of HPHCs or other toxic chemicals. An exposure-response relationship specific to secondhand aerosol exposure has not been established that could quantify health risks to non-users from inhaling this complex mixture of chemicals. Thus, in absolute terms, the potential impact of IQOS use on indoor air quality is considered a data gap in this NEPA evaluation. However, comparing the substances identified in mainstream IQOS aerosol to those found in smoke from combusted cigarettes, the overall indication at this time is that relative impacts to indoor air quality would be less than those from combusted cigarette use. Accepting that the applicant's stated marketing focus is for IQOS to replace (partially or completely) combusted cigarette use by current smokers, impacts from secondhand IQOS aerosol on indoor air quality are considered, on balance, to be minor to negligible based on data available at this time. This qualitative conclusion is subject to change in the case of new data, applies only to exposure of non-users to secondhand IQOS aerosol, and does not offer any finding as to the relative risk to users from IQOS compared to combusted cigarettes.

Greenhouse gases (GHGs), such as carbon dioxide (CO_2), methane, nitrous oxide, and others, can contribute to climate change. Studies submitted by the applicant did not identify any GHGs in IQOS aerosol. Therefore, use of the new products would not contribute to climate change.

3.2.2.2 Disposal

Landfill disposal or incineration of the used products and packaging will produce GHGs. Landfills are the third largest source of human-related methane emissions in the United States, accounting for approximately 15.4 percent of these emissions in 2015 (EPA, 2017).

FDA estimated the GHG emissions from disposal of the product and packaging waste using the emission rates in the Waste Reduction Model (WARM), v. 14 (EPA, 2016a). WARM calculates GHG emissions from different material types commonly found in municipal solid waste (MSW). FDA estimated the product and packaging waste generated from the new products as well as a representative combusted cigarette product (Confidential Appendix) and applied rates for recycling, landfill disposal, and combustion with energy recovery for the various material types (EPA, 2016b). Total GHG emissions from disposing of the product waste and packaging from the new products is estimated to be a negligible fraction (less than 0.00005 percent) of the approximately 6.511 billion metric tons of CO_2-eq generated in the United States from all sources in 2016 (the most recent year for which an estimate is available).

3.2.3 Potential Impacts from No Action

3.2.3.1 Use

There would be no exposure to secondhand IQOS aerosol under the no-action alternative.

Smokers of combusted cigarettes who converted to using the new products are assumed to continue smoking cigarettes. When using combusted cigarettes, the user inhales mainstream smoke and exhales secondhand smoke to the environment. This secondhand smoke, along with sidestream smoke emitted directly by the burning tip of a cigarette, is referred to as environmental tobacco smoke (ETS). There is no safe level of exposure to ETS (HHS, 2006a, 2006b). Even low levels of ETS can harm children and adults in many ways, including the following:

- The U.S. Surgeon General estimates that living with a smoker increases a nonsmoker's chances of developing lung cancer by 20 to 30 percent (HHS, 2006a, 2006b).
- Exposure to ETS increases school children's risk for ear infections, lower respiratory illnesses, more frequent and more severe asthma attacks, and slowed lung growth. ETS exposure can cause coughing, wheezing, phlegm, and breathlessness (HHS, 2006a, 2006b).
- ETS causes more than 40,000 deaths a year (HHS, 2014).

Under the no-action alternative, individuals would continue to have ETS exposure from combusted cigarettes at levels proportional to the overall rate of cigarette use, as influenced by indoor smoking restrictions in any specific location. Exposed individuals would continue to be at risk for health effects such as those described above.

Cigarette combustion releases CO_2, methane, and nitrous oxide. FDA estimated that cigarette use under the no-action alternative would emit less than 0.00005 percent of the total GHGs emitted in the United States from all sources (Confidential Appendix).

3.2.3.2 Disposal

FDA estimated cigarette and packaging waste disposal volumes for a representative cigarette product, assuming use rates equal to the marketing projections for heatsticks under the proposed actions (Confidential Appendix). WARM was used to estimate GHG emissions from disposal of this cigarette-related waste, as adjusted for rates of recycling, landfill disposal, and combustion with energy recovery for the various material types. GHG emissions from product and packaging disposal of this volume of combusted cigarettes is estimated to be a negligible fraction (approximately 0.00002 percent) of the 6.511 billion metric tons of CO_2-eq emitted in the United States from all sources.

3.3 Biological Resources

3.3.1 Affected Environment

The new products could interact with any terrestrial or aquatic environment nationwide where the products are used, disposed of, or transported through environmental fate processes. Aquatic species could be exposed to excreted biomarkers in receiving waters for municipal wastewater. Terrestrial and aquatic species could contact or ingest littered heatsticks or leachate from heatsticks at locations of improper disposal.

3.3.2 Potential Impacts from Proposed Actions

3.3.2.1 Use

Potential Impacts to Terrestrial Species

No impacts to terrestrial wildlife were identified from use of the new products.

Potential Impacts to Aquatic Species

Inhaling a heated tobacco product exposes the user to the range of chemicals in that product, as well as chemicals formed by pyrolysis or thermal degradation. Some of these parent chemicals or their metabolites can be identified and measured in the user's blood, saliva, exhaled breath, tissues, or urine. These are called biomarkers of exposure. Multiple published studies have documented the presence in municipal wastewater of biomarkers of tobacco exposure. Examples include Andra and Makris (2011), Bradley et al. (2007), Bueno et al. (2011), Gao et al. (2018), and Kolpin et al. (2002). Aquatic species could be exposed to excreted biomarkers in natural waters receiving treated municipal wastewater. There is little to no information on how much these concentrations may be reduced during municipal wastewater treatment or data on the toxicity of these chemicals to aquatic species.

The applicant submitted studies comparing several biomarkers of exposure to HPHCs following IQOS use to the same biomarkers following combusted cigarette use (PMP, 2017). In general, the studies found that 15 of 16 biomarkers of exposure to HPHCs or HPHC metabolites were reduced among smokers completely switching to IQOS and that reductions were similar in magnitude to the reductions seen in smokers who abstained. Biomarkers of exposure to nicotine were similar for IQOS and combusted cigarette use. These findings are consistent with a recently published study funded by another tobacco company that included the IQOS system in the products assessed (Gale et al., 2018).

Comparing predicted toxicity levels based on structural analysis (OECD, 2018) to levels measured or estimated in wastewater in the studies cited above indicates that effects to aquatic species would not be expected from the potential urinary biomarker levels in surface water, based on the limited available information.

3.3.2.2 Disposal

Potential Impacts to Terrestrial Species

Users of the new products are assumed to litter a portion of the used heatsticks at a rate similar to the littering rate for combusted cigarette butts. Section 3.6.3.2 discusses the estimated littering rates. Terrestrial wildlife may encounter and interact with littered heatsticks, and may use them as nesting materials, exposing their young at vulnerable life stages. Because the tobacco in a heatstick is not consumed during use, there is increased potential compared to combusted cigarettes for wildlife exposure to tobacco and the toxic chemicals it contains, specifically nicotine and tobacco-specific nitrosamines. Using the solid waste estimates for the new products (Section 3.6.3.2) and assuming the same littering rate applies to used heatsticks as for cigarette butts, the potential tobacco filler material (not including the filters) littered in the environment could be increased by approximately 0.16 percent[2] under the proposed actions. No methodology is available to reasonably estimate the fraction of the total cigarette or heatstick litter that finds its way into animal or bird nests, or to estimate population-level impacts to terrestrial wildlife from this or other routes of tobacco exposure. Therefore, although an increase in the potential for tobacco exposure to terrestrial wildlife is likely, a significant impact as a result of the proposed actions cannot be concluded.

Potential Impacts to Aquatic Species

As summarized by Wallbank et al. (2017), leachate from cigarette butts has demonstrated toxicity to fish and aquatic invertebrates in laboratory studies, but real-world concentrations of leachate have not been reliably estimated for purposes of assessing risk to aquatic wildlife. Information supplied by the applicant identified the chemicals found in used and un-used heatsticks. Toxicity data are available for many of these chemicals, and the toxicity of the mixture of these chemicals in heatstick leachate could be estimated based on their solubilities and individual toxicities. However, risk estimation would also require measuring or modeling the concentration of leachate in the water inhabited by aquatic species. Any concentrations can vary greatly, including in the same location at different times, because aquatic habitats have distinct volumes, inflows, outflows, and evaporative loss rates; and the number of heatsticks or cigarette butts polluting any specific habitat can vary from none to many, depending on human activity and transfer from upstream locations. Without a basis for estimating water concentrations, this analysis cannot quantitatively predict the aquatic species impact from littered heatsticks or cigarette butts at this time.

The applicant's submissions assessed risk to aquatic species from the chemicals in all un-used heatsticks produced in one year diluted in the entire wastewater volume of the United States. They concluded that the estimated aquatic concentrations were below potential levels of concern in the aquatic

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[2] Estimated based on projected tobacco filler in littered heatsticks (Confidential Appendix) compared to 110 mg tobacco per cigarette butt multiplied by 34 percent littering rate of the 247 billion cigarettes consumed in the United States in 2017 (TTB, 2018).

environment. The Agency expects that there would be wide (likely orders of magnitude) variation in aquatic concentrations in various real-world locations.

In summary, although there is a potential for aquatic species to be exposed to leachate from littered heatsticks, it is difficult to frame an analysis to predict the level of risk from the illegal activity of littering on a nationwide basis. Therefore, a significant impact to aquatic species as a result of the proposed actions cannot be concluded with any certainty.

3.3.3 Potential Impacts from No Action

3.3.3.1 Use

Under the no-action alternative, aquatic wildlife would have continued exposure to excreted biomarkers in natural waters receiving treated municipal wastewater. Comparing predicted toxicity levels based on structural analysis (OECD, 2018) to levels measured or estimated in wastewater in the studies cited in Section 3.3.2.1 indicates that effects to aquatic species would not be expected from the potential urinary biomarker levels in surface water, based on the limited available information. Risk levels could change with trends in rates of combusted cigarette use.

3.3.3.2 Disposal

Under the no-action alternative, terrestrial wildlife would continue to be exposed to littered combusted cigarette butts. Aquatic species would continue to be exposed to leachate from littered combusted cigarette butts at levels that vary with the littering rate near or upstream of the habitat and the characteristics of the water body. The occurrence of both impacts would vary with trends in rates of combusted cigarette use.

3.4 Environmental Justice

Executive Order 12898 requires federal agencies to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects of programs, policies, and activities on minority populations and low-income populations.

3.4.1 Affected Environment

The new products could be used and disposed of nationwide under the proposed actions. Minority and low-income populations throughout the United States are the affected environment for environmental justice.

3.4.2 Potential Impacts from Proposed Actions

3.4.2.1 Use

Because the new products consist of heating and inhaling a tobacco product, there is an inherent human health impact from their use. Section 3.5.2 discusses the significance in terms of NEPA of this human health impact. This section addresses whether the health impact would disproportionately affect minority or low-income populations.

The applicant submitted studies evaluating adult former and never smokers' intentions to use the new products following exposure to product information, labeling, and advertising. These studies found that former and never smokers' intentions to use the new products appeared similar to their intentions to use e-cigarettes, although the applicant provided no statistical tests of these differences. Among never-smokers, young adults and youth are at higher risk than others of initiating use of tobacco products; logically, this would also apply to IQOS. Most people who use tobacco products begin when they are adolescents or young adults (DHHS, 2014) for various psychological reasons (Reyna and Farley, 2006). The IQOS device and its labels, labeling, and advertising materials have a sophisticated, high-tech appearance that may be attractive to the general population (similar to other "tech" items), including young people. The applicant stated that its marketing and advertising plans have features that will reduce the risk of youth uptake, such as advertising and promotion targeted directly at adult smokers and age restrictions to access its product website. Age restrictions on buying tobacco products vary among the city, county, and state laws across the United States, with a baseline nationwide restriction against individuals under 18 years old purchasing any category of tobacco products.

FDA reported that cross-sectional data from Wave 1 of the Population Assessment of Tobacco and Health study (FDA, 2018b) - a uniquely large, long-term study of tobacco use and health in the United States - indicate that 35.6 percent of adult (25 years or older) established cigarette smokers use menthol-flavored cigarettes. Studies summarized by the Truth Initiative (2016)[3] show that youth, female smokers, racial/ethnic minorities, sexual minorities, and those with mental illness strongly favor menthol-flavored cigarettes. The three new heatstick products are two menthol products and one unflavored product. Regardless of the comparative sales plans for the new menthol products and the new unflavored product, the Agency does not have any indication that never smokers in low-income or minority populations would disproportionately adopt use of the new products, particularly since there is an upfront cost that could partially or completely offset any particular appeal to low-income populations.

3.4.2.2 Disposal

No significant human health or environmental impacts were identified as a result of disposal of the new products. Thus, no disproportionate impacts to minority or low-income populations would occur.

3.4.3 Potential Impacts from No Action

3.4.3.1 Use

Under the no-action alternative, minority and low-income populations would continue to initiate, use, and quit combusted cigarettes at rates seen in current trends for each subpopulation. No changes in disproportionate impacts to minority or low-income populations would occur.

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[3] The Truth Initiative is a national public health foundation established as part of the Master Settlement Agreement between the attorneys general of 46 states, the District of Columbia, 5 U.S. territories, and the tobacco industry. It was previously known as the American Legacy Foundation. The Truth Initiative is reducing U.S. youth tobacco product use and youth substance abuse, and preventing diseases associated with use of tobacco products in the United States.

3.4.3.2 Disposal

Under the no-action alternative, no changes are expected to the human health and environmental impacts associated with disposal of combusted cigarettes. Thus, no changes in any disproportionate impacts to minority or low-income populations would occur.

3.5 Human Health and Safety

3.5.1 Affected Environment

The new products could be used and disposed of nationwide under the proposed actions. Individuals throughout the United States comprise the affected environment for human health impacts.

3.5.2 Potential Impacts from Proposed Actions

3.5.2.1 Use

The Tobacco Control Act states "A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects." Section 910(c) of the Act specifies FDA's considerations, including public health concerns, in determining whether or not to issue marketing orders for new tobacco products. FDA's Center for Tobacco Products conducts a multidisciplinary scientific review of applications for new products to make these determinations. The potential for health impacts from use of the new products is classified as "not significant" within this PEA *only within the context of and for the purposes of a NEPA analysis*.

Section 3.2.2.1 of this PEA analyzes impacts to non-users of the new products who would be exposed to exhaled aerosol. This analysis concludes that impacts from secondhand IQOS aerosol on indoor air quality are considered, on balance, to be minor to negligible based on data available at this time.

The new products are powered by lithium ion batteries, one each in the holder and charger (Section 2.1). Safety issues, including injuries from explosion or fire, have been reported for lithium ion batteries in some pocket-carried rechargeable consumer products such as e-cigarettes and mobile phones. The applicant stated that the new products and batteries incorporate design features and have been tested to international industry standards to mitigate and reduce the risk of battery explosion or overheating. Also, there have been no incidents to date of these batteries exploding in the foreign markets where the new products have already been available (FDA, 2018c). The applications reported that the batteries comply with the following standards: IEC 62133,[4] UL 1642,[5] and UN38.3[6] (PMP, 2017). Based on this information, no significant impacts are expected related to battery safety.

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[4] International Electrotechnical Commission: IEC 62133 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.

[5] Underwriters Laboratories: UL 1642–Standard for Lithium Batteries.

[6] United Nations: Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria. Section 38.3–Lithium metal and lithium ion batteries.

3.5.2.2 Disposal

For the new products, no significant human health impacts were identified as a result of disposal of used heatsticks, packaging materials, and devices. Section 3.6 provides additional analysis of impacts from proper and improper (littering) disposal.

3.5.3 Potential Impacts from No Action

3.5.3.1 Use

Under the no-action alternative, there would be no new or different health impacts to users or non-users. Combusted cigarette smokers and nearby non-users would continue to have the known risks of using tobacco (Section 3.5.2.1, first sentence) or exposure to ETS (Section 3.2.3.1). There would be no changes in current levels of these impacts.

3.5.3.2 Disposal

There would be no new or different health impacts. Disposal of cigarette butts and packaging would continue at rates corresponding to current and future rates of combusted cigarette use. Section 3.6 provides additional analysis of impacts from proper and improper (littering) disposal.

3.6 Solid Waste and Hazardous Materials

3.6.1 Affected Environment

The new products could be used and disposed of nationwide under the proposed actions.

3.6.2 Potential Impacts from Proposed Actions

3.6.2.1 Use

Generation and management of solid waste and hazardous materials would not be affected by use of the new products under the proposed actions.

3.6.2.2 Disposal

Municipal Solid Waste

After using the new products, users may recycle the packaging material or dispose of the used heatsticks and packaging as MSW or litter. Used heatstick and packaging disposal contributes to using landfill capacity.

In 2014, approximately 258.46 million tons of trash were generated in the United States, and approximately 89.4 million tons of this material were recycled and composted, equivalent to an overall 34.6 percent recycling rate. Paper and paperboard account for 68.61 million tons (26.5 percent) of the total MSW generated in 2014. Of the total paper and paperboard MSW, 44.4 million tons (64.7 percent) were recycled, 19.47 million tons (28.4 percent) were disposed of in landfills, and 4.74 million tons (6.9 percent) were combusted with energy recovery (EPA, 2016b).

The Agency used the projected market volumes for the first and fifth years of marketing the new products to estimate the waste from disposal of used heatsticks and packaging, accounting for recycling of packaging waste as part of overall U.S. recycling of MSW. The estimated waste from used heatstick and packaging disposal would be miniscule compared to the total MSW forecasted to be discarded in the United States (Confidential Appendix). No significant impact to MSW management capacity would occur.

Littered Used Heatsticks

In this PEA, used heatsticks were assumed to be littered at the same rate as cigarette butts from combusted cigarettes. Because a heatstick is not consumed during use, there would be an increased total amount of litter generated from the total number of heatsticks compared to the same number of cigarette butts. The total mass of heatsticks assumed to be littered would represent a negligible 0.03 percent (by weight) increase in the total litter from all 247 billion cigarette butts consumed in 2017 in the United States (TTB, 2018) (Confidential Appendix).

Improper disposal (littering) of used heatsticks was also evaluated for the potential to ignite dry vegetation and cause a fire. The applications stated that the temperature of the heater blade does not exceed 350°C; the temperature of the tobacco within the heatstick would be lower. The National Wildfire Coordinating Group (NWCG, 2016) stated that "Under normal conditions, forest fuels will ignite and burn when exposed to a heat source that is capable of raising them to a temperature of between 451 and 750°F [232 and 399°C]. Research places the average ignition temperature at about 500–600°F [260–316°C]." Although the temperature within a heatstick during use is within the range at which vegetation will ignite, "a competent ignition source must produce sufficient heat over a sufficient duration of time" to raise vegetation to its ignition temperature (NWCG, 2016). Because the heatstick does not support self-sustaining combustion (PMP, 2017) and would quickly cool when discarded, it is unlikely to be able to transfer enough heat for ignition. Therefore, the risk of causing a wildland fire would be negligible.

Device Disposal

(b) (4)

(PMP, 2017; FDA, 2018c). FDA estimated the volume of mixed-material waste that would be generated by discarded devices **(b) (4)** based on the applicant's sales projections for the new products (Confidential Appendix). Consumers may dispose of used devices similarly to other used small electronics, as household waste that enters the MSW management stream. Potential disposal of the devices as MSW was included in the MSW generation estimates described above, with no significant impact on waste management capacity identified.

The manufacturer stated that the device is guaranteed for one year (FDA, 2018c); it is likely then that some portion of the used devices would not enter the MSW stream but might be returned to the manufacturer for repair or replacement. Used devices disposed of by the applicant would be handled in accordance with their commercial or manufacturing recycling program and waste management policies, in compliance with applicable laws and regulations.

The holder and charger each contain a lithium ion battery. The user guide for the new products (PMP, 2017) states that the "product contains no user-serviceable parts. Do not attempt to ... replace any of the components' batteries" (PMP, 2017). Therefore, consumers are not expected to handle or dispose of

lithium ion batteries as separate items in either the recycling or MSW streams. Lithium ion batteries replaced by the applicant or disposed of as part of the used device disposal would be handled in accordance with the consumers' commercial or manufacturing recycling program and waste management policies, in compliance with applicable laws and regulations.

3.6.3 Potential Impacts from No Action

3.6.3.1 Use

Generation and management of solid waste and hazardous materials would not be affected by the absence of the new products or continued use of combusted cigarettes under the no-action alternative.

3.6.3.2 Disposal

Municipal Solid Waste

The no-action alternative would not change trends in the nationwide use of combusted, filtered cigarettes. Thus, no changes are expected in trends in the overall level of MSW generated from cigarette butts and cigarette packaging disposed of in the United States. In addition, for a representative cigarette type and its packaging, a volume of cigarettes comparable to the market projections for the new products would generate a negligible MSW volume of the 258.46 million tons of MSW generated nationwide (Confidential Appendix).

Littered Cigarette Butts

The environmental effects of cigarette butt litter were summarized as follows (Novotny et al., 2015):

> Cigarette butts are the most commonly discarded piece of waste globally and are the most frequent item of litter picked up on beaches and water edges worldwide... The non-biodegradable cellulose acetate filter attached to most manufactured cigarettes is the main component of cigarette butt waste... Hazardous substances have been identified in cigarette butts – including arsenic, lead, nicotine and ethyl phenol. These substances are leached from discarded butts into aquatic environments and soil.

Littered cigarette butts are a notable worldwide environmental concern. A 2009 study found that 65 percent of cigarettes disposed of in five types of non-residential public locations (recreation sites, bars/restaurants, retail stores, medical/hospital facilities, and a city center) were littered (Action Research, 2009). Adjusting this result for the proportion of time spent outside of the home compared to the time at home (not sleeping or bathing) (EPA, 2011), a littering rate of 34 percent of total used cigarettes was estimated.

Unattended and incompletely extinguished cigarettes can start fires in buildings and in the natural environment. Smoking is associated with 14 percent of fatal residential building fires and 11 percent of brush, grass, and forest fires (USFA, 2017; Ahrens, 2013).

The no-action alternative would not change trends in the nationwide use of combusted, filtered cigarettes. No changes are expected in the overall level of cigarette butt litter in the United States or fires ignited by unattended cigarettes or incompletely extinguished littered cigarette butts.

3.7 Water Resources

3.7.1 Affected Environment

The new products could interact with water resources nationwide where the products are used, disposed of, or transported through environmental fate processes.

3.7.2 Potential Impacts from Proposed Actions

3.7.2.1 Use

Excreted biomarkers could be released to water systems receiving municipal wastewater. There is little to no information on how much these concentrations may be reduced during municipal wastewater treatment. As described in Section 3.3.2.1, 15 of 16 biomarkers of exposure to HPHCs or HPHC metabolites were similar in magnitude to smokers who abstained, and biomarkers of exposure to nicotine were similar for IQOS and combusted cigarette use. Therefore, similar or lower levels of biomarkers in wastewater are expected under the proposed actions.

3.7.2.2 Disposal

Surface water could be contaminated by leachate from heatsticks littered directly into water or where stormwater runoff transports the littered heatsticks or their leachate to surface water. As described in Section 3.3.2.2, although there is a potential for leachate from littered heatsticks to contaminate surface water, it is difficult to frame an analysis to predict the level of risk from this illegal activity on a nationwide basis. Therefore, a significant impact to surface water quality as a result of the proposed actions cannot be concluded with any certainty.

3.7.3 Potential Impacts from No Action

3.7.3.1 Use

Under the no-action alternative, excreted biomarkers would continue to be released to natural waters receiving treated municipal wastewater. As described in Section 3.3.3.2, these levels would not be expected to affect water quality at levels impacting aquatic species habitat. There would be no new or increased risks from surface water used as a drinking water source. Risk levels could change with trends in rates of combusted cigarette use.

3.7.3.2 Disposal

Under the no-action alternative, surface water bodies would continue to receive leachate, directly and in stormwater runoff, from littered combusted cigarette butts. The leachate concentrations would vary with the littering rate near or upstream of the water body and the characteristics of the water body. The occurrence of impacts would vary with trends in rates of combusted cigarette use.

3.8 Cumulative Impacts

NEPA analysis of cumulative impacts considers the proposed actions' potential impacts together with any impacts from past, present, and reasonably foreseeable future actions regardless of the entity undertaking those actions.

In this PEA, other actions considered for cumulative effects are use and disposal of combusted cigarettes, consumer disposal of other waste including small electronic devices, and GHG emissions from all other sources. Each of these actions was considered throughout the analyses in Sections 3.2 through 3.7 for the resources to which they are relevant. No significant cumulative impacts are expected.

4. List of Agencies and Persons Consulted

No agencies or persons were consulted during preparation of this PEA. All information was obtained from the applicant or publicly available information sources.

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Confidential Appendix: Product and Packaging Waste Impacts Based on Confidential Market Projections

Contents:

1 – Market Projections

STN	Product	First Year		Fifth Year	
		PM0000479 (Holder + Charger)	Heatsticks	PM0000479 (Holder + Charger)	Heatsticks
PM0000424	Marlboro Heatsticks	(b) (4)			
PM0000425	Marlboro Smooth Menthol Heatsticks				
PM0000426	Marlboro Fresh Menthol Heatsticks				
—	No action: representative combusted cigarette*	0	11,700,000,000	0	22,400,000,000

*"Market projections" for no-action alternative are based on the number of combusted cigarettes that the new products would replace.

2 – Packaging and Components

Cardboard and Paper Packaging Weights

STN	Product	Heatstick/Cigarette Pack		Heatstick/Cigarette Carton		Heatstick/Cigarette Shipping Box		PM0000479 System (Holder + Charger) Packaging		PM0000479 System (Holder + Charger) Shipping Box	
		Pack - hinge lid and inner frame (g)	Heatsticks per pack	Carton (g)	Packs per carton	Box (g)	Cartons per box	System outer package (g)	Systems per package	Box (g)	Systems per box
PM0000424	Marlboro Heatsticks	(b) (4)									
PM0000425	Marlboro Smooth Menthol Heatsticks										
PM0000426	Marlboro Fresh Menthol Heatsticks										
—	No action: representative combusted cigarette*	5.65	20	18.96	10	638	60	0	1	0	1

*Packaging assumptions for no-action alternative are based on Marlboro combusted cigarette hard pack packaging.

Plastic Packaging and Components Weights

STN	Product	Pack	Carton	PM0000479 System (Holder + Charger)
		Tear tape + overwrap (g)	Tear tape + overwrap (g)	inner trays + charger overwrap + twist
PM0000424	Marlboro Heatsticks	(b) (4)		
PM0000425	Marlboro Smooth Menthol Heatsticks			
PM0000426	Marlboro Fresh Menthol Heatsticks			
—	No action: representative combusted cigarette*	0.384	0	0

*Packaging assumptions for no-action alternative are based on Marlboro combusted cigarette hard pack packaging.

Metal Packaging Weights

STN	Product	PM0000479 System (Holder + Charger including Accessories)
		Al wrap on swabs (g for 10 per device)
PM0000424	Marlboro Heatsticks	(b) (4)
PM0000425	Marlboro Smooth Menthol Heatsticks	
PM0000426	Marlboro Fresh Menthol Heatsticks	
—	No action: representative combusted cigarette*	0

*Packaging assumptions for no-action alternative are based on Marlboro combusted cigarette hard pack packaging.

Mixed (Metal + Plastic + Paper) or Other Material Weights

STN	Product	Pack	PM0000479 System (Holder + Charger including Accessories)	PM0000479 System Components		
		Inner liner (paper + Al) (g for 2 per pack)	Disposable Polypropylene + Cotton + Alcohol Swabs (g for 10 per	Holder (g)	Charger (g)	Device lifetime: 11 heatsticks/day * 365 days (heatsticks per device)
PM0000424	Marlboro Heatsticks	(b) (4)				
PM0000425	Marlboro Smooth Menthol Heatsticks					
PM0000426	Marlboro Fresh Menthol Heatsticks					
—	No action: representative combusted cigarette*	0.9	0	0	0	NA

*Packaging assumptions for no-action alternative are based on Marlboro combusted cigarette hard pack packaging.

3 – Tobacco in Litter

Used heatsticks were assumed to weigh the same as un-used heatsticks and contain the same weight of tobacco filler, as measured by FDA (2017).

Cigarette butt weight was estimated as follows:

- Butt length was based on ISO 3308 (draft revisions): (b) (4)
- Length of rod combusted = (b) (4)
- Combusted weight = (b) (4)
- Butt weight = total 3R4F (b) (4)
- Tobacco filler per butt = (b) (4)

The used heatstick and cigarette butt littering rate was assumed to be 34 percent, as discussed in Section 3.6.3.2.

STN	Product	Littered Heatsticks and Butts (short tons)		Tobacco Filler in Littered Heatsticks and Butts (short tons)	
		Year 1	Year 5	Year 1	Year 5
PM0000424	Marlboro Heatsticks	(b) (4)			
PM0000425	Marlboro Smooth Menthol Heatsticks				
PM0000426	Marlboro Fresh Menthol Heatsticks				
	Sum, new products				
—	No action: representative combusted cigarette*	1,697	3,249	482	923

*Litter volumes for no-action alternative are based on the number of combusted cigarettes that the new products would replace and the characteristics of the 3R4F reference cigarette.

4 – MSW Generation

MSW generation was estimated using the following general equation:

Marketing projection x packaging weight x fraction of material not recycled

Recycling rates are 64.7, 9.5, and 34 percent for cardboard/paper, plastic, and metal, respectively (EPA, 2016a).

STN	Product	MSW (short tons)											
		Butts or Used Heatsticks		Paper + Cardboard		Plastic		Metal		Mixed/Other		Total	
		Year 1	Year 5	Year 1	Year 5	Year 1	Year 5	Year 1	Year 5	Year 1	Year 5	Year 1	Year 5
PM0000424 + PM0000479	Marlboro Heatsticks + IQOS System	(b) (4)											
PM0000425 + PM0000479	Marlboro Smooth Menthol Heatsticks + IQOS System												
PM0000426 + PM0000479	Marlboro Fresh Menthol Heatsticks + IQOS System												
	Sum, new products												
—	No action: representative combusted cigarette*	3,294	6,307	1,960	3,752	224	429	0	0	383	733	5,861	11,221

*Assumptions for no-action alternative are based on the number of combusted cigarettes that the new products would replace, characteristics of the 3R4F reference cigarette, and Marlboro combusted cigarette hard pack packaging.

5 – GHG Emissions

GHG emissions from use were calculated by multiplying the market projections (see first page of this appendix) by the CO_2-eq generation rates listed in Section 3.2.2.1.

GHG emissions from disposal were calculated using the estimated MSW (above) and the CO_2-eq generation rates from WARM (EPA, 2016b) for each waste type, as follows:

Waste	Metric tons CO_2-eq generated per short ton		WARM category
	Landfilled MSW	Incinerated MSW	
Cigarette butts	(b) (4)		
Cardboard/paper			
Plastics			
Metals			
Mixed materials			

STN	Product	Greenhouse Gas Emissions, CO_2-eq (metric tons per year)					
		Use		Disposal		Total	
		Year 1	Year 5	Year 1	Year 5	Year 1	Year 5
PM0000424 + PM0000479	Marlboro Heatsticks + IQOS System	(b) (4)					
PM0000425 + PM0000479	Marlboro Smooth Menthol Heatsticks + IQOS System						
PM0000426 + PM0000479	Marlboro Fresh Menthol Heatsticks + IQOS System						
	Sum, new products						
—	No action: representative combusted cigarette*	1,499	2,870	740	1,416	2,238	4,286

*Assumptions for no-action alternative are based on the number of combusted cigarettes that the new products would replace, characteristics of the 3R4F reference cigarette, and Marlboro combusted cigarette hard pack packaging.

6 – References Cited

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