1. EXECUTIVE SUMMARY

On December 14, 2020, FDA received a supplemental Premarket Tobacco Product Application (sPMTA) for Marlboro Amber HeatSticks (PM0004691.PD1). The applicant referenced the PMTAs for the Marlboro HeatSticks (PM0000424) and for the IQOS 2.4 Holder and Charger (PM0000479). The products subject to the previous PMTAs were granted marketing authorization April 30, 2019 (hereafter, referred to as "the authorized products").

Scientific review of the application found that the comparisons between the new product and the authorized products are appropriate. The applicant has provided adequate information on the manufacturing process and product quality controls that will help ensure that the new product is manufactured consistently and will meet the applicant's specifications. The aerosols from the new product have been evaluated and found to be comparable to that from use of the authorized products.

The new product is not marketed in the U.S.; however, the applicant has provided user information from the international marketing experience with the new product as well as consumer reports, complaint, published literature and product safety information. There were no new safety concerns or unexpected adverse experiences identified. Currently, there is no evidence the user population for the new product will be different from the population who use the authorized products. Although the marketing information provided is not U.S. data, current use patterns available for the authorized products within the U.S. have not raised concerns regarding product use in youth and young adults. Given the product similarities, there is currently no available evidence of increased risk for youth initiation and use for the new product as compared to the authorized products.

The similarities in the product designs of the new and authorized products make it unlikely there are new concerns related to health effects, product quality, human factors, or product misuse for the new product as compared to the authorized products. As the new and authorized products have similar operating procedures, use similar tobacco sources, and produce comparable aerosols, FDA currently has no reason to believe the new product will result in different nicotine exposure, use patterns, user populations, or abuse liability.

The Agency determined that the environmental impacts of simultaneously marketing the authorized and the new products do not represent a significant environmental impact from the proposed and alternative actions.

In conclusion, none of the grounds specified in Section 910(c)(2) of the FD&C Act apply. Specifically, I find the following:

1. Permitting the marketing of the product is appropriate for the protection of the public health (APPH), as described in Section 910(c)(4) of the FD&C Act (subject to the labeling and advertising changes described below);
2. The methods used in, and the facilities or controls used for, the manufacture, processing, and packing of the product do not fail to conform to the requirements in Section 906(e) of the FD&C Act;
3. Based on a fair evaluation of all material facts, the proposed labeling is not false or misleading in any particular; and
4. The product does not fail to conform to a tobacco product standard in effect under Section 907 of the FD&C Act.

I recommend FDA grant marketing authorization for PM0004691.PD1.

FDA has examined the environmental effects of finding the new product APPH and made a Finding of No Significant Impact (FONSI).

2. BACKGROUND

2.1. NEW PRODUCTS

The applicant submitted information for the new product listed on the cover page and with more detail in the Appendix.

2.2. REGULATORY ACTIVITY

On May 25, 2021, FDA received an sPMTA from Philip Morris Products S.A. FDA issued an Acceptance letter to the applicant on June 1, 2021. FDA issued a Filing letter to the applicant on June 7, 2021. FDA issued a Deficiency letter to the applicant on August 19, 2021.

Refer to the Appendix, Table 3, for a complete list of amendments received by FDA.

2.3. SCOPE OF REVIEW

This review captures all compliance and scientific reviews completed for the new product subject of this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1		Cycle 2	
	Reviewer(s)	Review Date	Reviewer(s)	Review Date
Regulatory	Donna Cheung	6/1/2021	Not assigned	N/A
Engineering	Mary Searing	8/18/2021	Not assigned	N/A
Chemistry	Delauren McCauley	8/19/2021	Delauren McCauley	12/15/2021
Medical	Lester (Jao) Lacorte	7/14/2021	Not assigned	N/A
Environmental Science	Bria Martin	8/18/2021	Bria Martin	4/25/2022

Table 2. Consultations

Discipline or Office	Cycle 1		Cycle 2	
	Reviewer(s)	Review Date	Reviewer(s)	Review Date
Medical	Susan Rudy	6/22/2021	Susan Rudy	12/9/2021
	Lester (Jao) Lacorte	7/14/2021		

3. SCIENTIFIC REVIEW

3.1. COMPARISON PRODUCTS

3.1.1. Discipline key findings

The following discussion is based on key findings provided in the discipline reviews.