1. EXECUTIVE SUMMARY

On December 14, 2020, FDA received supplemental Premarket Tobaco Product Applications (sPMTAs) for Marlboro Sienna and Bronze HeatSticks (PM0004337.PD1 and PM0004337.PD2, respectively). The applicant referenced the PMTAs for the Marlboro HeatSticks (PM0000424) 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 applications found that the comparisons between the new products and the authorized products and combusted reference cigarettes are appropriate. The applicant has provided adequate information on the manufacturing process and product quality controls that will help ensure that the new products are manufactured consistently and will meet the applicant's specifications. The aerosols from the new products have been evaluated and found to be comparable to that from use of the authorized products. Both the Marlboro Sienna and Bronze HeatSticks were additionally found to have substantially lower HPHC exposure potential than combusted cigarettes.

The new products are not marketed in the U.S.; however, the applicant has provided user information from the international marketing experience with new products 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 products 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 products 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 products 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 products 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 products 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 products do 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 PM0004337.PD1 – PM0004337.PD2.

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

2. BACKGROUND

2.1. NEW PRODUCTS

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

2.2. REGULATORY ACTIVITY

On December 14, 2020, FDA received two sPMTAs from Philip Morris Products S.A. FDA issued an Acceptance letter to the applicant on May 25, 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 products subject to this review.

Table 1. Disciplines reviewed

Discipline	Cycle 1		Cycle 2	
	Reviewer(s)	Review Date	Reviewer(s)	Review Date
Regulatory	Donna Cheung	5/25/2021	Not Assigned	N/A
Engineering	Mary Searing	8/18/2021	Mary Searing	12/15/2021
Chemistry	Delauren McCauley	8/19/2021	Delauren McCauley	12/15/2021
Toxicology	Not assigned	N/A	Chad Brocker	4/25/2022
Behavioral and Clinical Pharmacology	Katie Hartka	8/18/2021	Not assigned	N/A
Epidemiology	Apostolos Alexandridis & Gabriella Anic	8/18/2021	Not assigned	N/A
Social science	Samantha Stanley	8/18/2021	Not assigned	N/A
Environmental science	Dilip Venugopal	8/18/2021	Dilip Venugopal	4/25/2022