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Memorandum

To: File

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Subject: Addendum to Approach to PMTAs¹ for Non-Tobacco Flavored ENDS^{2,3} not in Substantive Scientific Review (Phase III)

Background

As of September 9, 2020, FDA commenced review of premarket applications for electronic nicotine delivery systems (ENDS) products on the market as of August 8, 2016; applicants were required by a court order to submit applications to FDA by this date. To more effectively manage the large volume of applications received by this deadline, in the summer of 2021⁴ OS established a plan to review non-tobacco and non-menthol flavored ENDS PMTAs not in Phase III, scientific review. The approach applied a standard for evidence necessary to demonstrate a potential benefit to adult smokers of flavored ENDS (i.e., "FE Review"). On November 22, 2022, based on previous experience OS reevaluated the FE Review process⁵ and made two changes to include menthol-flavored ENDS PMTAs and expand the scope of review to include the applicant's proposed marketing restrictions and mitigation measures. This addendum seeks to address a stepwise approach to implementing the aforementioned updates and marks the continuation of FE Review for all applicable flavored ENDS PMTAs received after September 9, 2020.

Discussion

As of October 2021, OS paused FE review due to pending litigation. In December 2022, OS intends to reinstate the process of FE Review for all pending filed ENDS PMTAs received by OS. Because some bundled submissions already underwent FE Review for some products and others did not, applications will be placed in two queues:

- Queue A: Includes bundled submissions received by September 9, 2020, in which some flavored ENDS products underwent FE review

¹ Premarket Tobacco Product Applications

² Refers to open e-liquids, closed e-liquids, and closed e-cigarettes containing non-tobacco flavored e-liquid

³ The term flavored ENDS refers to any ENDS product with a characterizing flavor other than tobacco, including menthol.

⁴ Memorandum, ENDS Containing Non-Tobacco Flavored E-Liquid: Approach to PMTAs not in Substantive Scientific Review (Phase III), dated July 9, 2021; and addenda dated July 28, 2021, and August 18, 2021, Addendum to Approach to PMTAs for Non-Tobacco Flavored ENDS not in Substantive Scientific Review (Phase III)

⁵ Addendum to Approach to PMTAs for Non-Tobacco Flavored ENDS not in Substantive Scientific Review (Phase III) Memo dated November 22, 2022 (abbreviated as November 2022 Memo).

- Queue B: Includes bundled submissions received by September 9, 2020, for which no products underwent FE Review

For applications in Queue A, the review team will be comprised of one discipline reviewer, a RHPM and a TPL. A limited team has been deemed appropriate as the pending review bundle would consist mainly of menthol-flavored ENDS PMTAs and studies submitted in the bundled submissions were already reviewed as part of the initial FE Review conducted in during the Summer of 2021. For applications in Queue B, the review team (similar to previous FE review) will consist of two discipline reviewers, a RHPM and a TPL.

As described in the November 2022 Memo, the scope of FE review was revised to include menthol-flavored ENDS and evaluation of all applicant-proposed marketing restrictions and mitigation measures. To ensure appropriate implementation of the changes to the FE Review process, OS has decided to implement changes starting with a small pilot, two review teams for Queue A and three teams for Queue B. Currently, OS is undergoing updates to the electronic system expected to be completed at the end of the year. A comprehensive report of Filed ENDS PMTAs could not be generated. Therefore, OS used prior reports to identify the following Filed applications for FE Review:

Table 1

Queue A		Queue B	
STN	Company name	STN	Company name
(b) (4) ^(b)	Big Time Vapes	(b) (4)	Great Lakes Vapor
(b) (4)	Imperial Vapors LLC	(b) (4)	Absolute Vapor Inc.
(b) (4)	[REDACTED]	(b) (4)	(b) (4)
(b) (4)	SWT Global Supply Inc.	(b) (4)	DNA Enterprise LLC dba Mech Sauce
		(b) (4)	Savage Enterprises
		(b) (4)	ECBlend LLC

Conclusion

FE Review will commence in December 2022 with a small pilot of five teams assigned to either Queue A or B using updated templates and approach described above. If there are no concerns identified during the pilot, in January 2023 OS intends to expand the number of review teams for Queue A and Queue B in order to conduct FE Review of ENDS PMTAs in a timely manner.