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Memorandum

To:	File
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Through:	Matthew Holman, Ph.D. Director Office of Science <div style="text-align: right;"> Digitally signed by Matthew R. Holman -S Date: 2021.08.18 14:29:22 -04'00' </div>
Subject:	Addendum to Approach to PMTAs ¹ for Non-Tobacco Flavored ENDS ² 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. On July 9, 2021 (and July 28, 2021 addendum), OS established a plan to effectively manage flavored³ ENDS PMTAs not in Phase III, substantive scientific review, by applying a standard for evidence necessary to demonstrate a potential benefit to adult smokers of flavored ENDS. This addendum addresses the approach used to identify ENDS to undergo this review.

Discussion

FDA review of flavored ENDS as described in PMTA Review: Evidence to Demonstrate Benefit of Flavored ENDS to Adult Smokers memo (signed August 17, 2021) excludes tobacco and menthol. For Appendix A, tobacco-flavored ENDS, and Appendix B, menthol-flavored ENDS, we evaluated the list of all characterizing flavors provided by ENDS e-liquid manufacturers⁴ and identified those characterizing flavors that we considered to be solely tobacco or menthol. Flavor combinations were omitted. For example, in Appendix A, Kentucky Tobacco flavor was interpreted as tobacco only, considering this is a blend type not a flavor. Any characterizing flavor that implied addition of flavors other than tobacco (e.g., Tropical Tobacco) was not included in this appendix. For Appendix B, we used a similar approach, we looked at all the

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 Throughout this memo, and solely as a matter of shorthand to aid in the drafting of this document, the term *flavored ENDS* refers to any ENDS other than tobacco-flavored and menthol-flavored ENDS.

⁴ An archive query was used to identify all the flavors captured in the characterizing flavor field.

flavors listed in the characterizing flavors field and identified any flavor we considered to be menthol only, meaning that if a product listed a characterizing flavor such as “tropical menthol”, this product was not included in Appendix B. Because of spelling variability and the use of different languages, we expanded the list to also include products for which tobacco or menthol was misspelled or used other descriptors such as smooth to describe the flavor. Other menthol variants such as wintergreen and frost were not included in Appendix B. Given the limitations of the archive data quality and sole use of a single field to determine the characterizing flavor, both Appendix A and B may not be an exhaustive list. The remaining flavored ENDS in PMTA bundles received by September 9, 2020, that have not started substantive scientific review, are subject to a streamlined review for evidence to demonstrate benefit to adult smokers.

Appendix A: Characterizing Flavors Determined to be Tobacco

Natural	Latakia	Turkish Bold
Tobacco	Latakia – Flavor	Turkish Flavor
7 Leaf	Latakia tobacco	Turkish Oriental Flavor
7 Leaf Tobacco	Latakia Tobacco	Turkish, Smooth
7 Tobacco	Mild Tobacco	Turkish Tob
American Blend	Mild tobacco flavor	Turkish tobacco
American Blend Tobacco	Native Tobacco	Turkish Tobacco
American tobacco	Oriental Tobacco	Turkish TOBACCO
American Tobacco	Original	TURKISH TOBACCO
American tobacco flavor	Pipe tobacco	Turkish Type
American tobacco flavor	Pipe Tobacco	usa blend
American Tobacco-USA Blend	Pipe Tobcco	USA Blend
American USA Blend	Pureleaf Tobacco	USA Blend Tobacco
American Virginian Flavor	Pure Tobacco	USA Blend Tobacco E Juice
Americna Blend	Regular	USA Blend Tobacco Flavor
Blended Tob	REGULAR TOBACCO	USA Blend Tobacco Flavor.
Blended Tobacco	REGULAR TOBACCO MAX	USA Tobacco
Cigar tobacco	Smooth	VirginaTobacco
Cigar Tobacco	SMOOTH	Virgina Tobacco
Classic	Smooth Tob	Virginia
Classic American tobacco	Smooth Tobacco	Virg inia
Classic Tobacco	Toacco	Virginia Blend
Cuban Cigar	tobacco	Virginia fire cured
CUBAN CIGAR	Tobacco	Virginia Fire Cured
CUBAN CIGAR MAX	Tobacco	Virginia Fire Cured ...
Cubano	TOBACCO	Virginia Fire Cured Tobacco
CUBANO	Tobacco 1	Virginia Fire Cured Tobacco
Cubano Cigar	Tobacco Flav	Virginia Flavor
CUBANO MAX	Tobacco Flavor	Virginia Flue Cured
Cuban Tobac	Tobacco Flavoring	Virginia Flue Cured Type A
Cuban tobacco	Tobacco Pouch	Virginia Long Cut
Cuban Tobacco	Tobacco Pouch Full	Virginia Slim
Dark Mild Tobacco	Tobacco USA Blend	Virginia tobacco
Dry-aged Middle Eastern tobacco	Tobacco Virginia	Virginia Tobacco
Dryleaf Tobacco	Tobacco Virginia Flue Cured	VIRGINIA TOBACCO
Dry Tobacco	Tobacco Western Cigarette	VIRGINIA TOBACCO MAX
Flue Cured Flavor	Top Leaf Tobacco	Western
Flue Cured Tobacco	Traditional tobacco	Western Blend
Full Tobacco	Traditional Tobacco	Western Blend tobacco
Havanah Tobacco	Turkish	Western Flavor
Havana Leaf	TURKISH	Western, Smooth
Havana tobacco	Turkish Blend	Western Tobacco
Havana Tobacco	TURKISH BLENDED	

Appendix B: Characterizing Flavors Determined to be Menthol

100ml Menthol Tobacco .00nic 70/30 PGVG	Menthol Chill
100ml Menthol Tobacco .03nic 70/30 PGVG	Menthol Cigarette
100ml Menthol Tobacco .06nic 70/30 PGVG	Menthol Cool
100ml Menthol Tobacco .09nic 70/30 PGVG	Menthol Drops
100ml Menthol Tobacco .12nic 70/30 PGVG	Menthol Eucalyptus
100ml Menthol Tobacco .15nic 70/30 PGVG	Menthol Extreme
100ml Menthol Tobacco .18nic 70/30 PGVG	Menthol Flavor
100ml Menthol Tobacco .21nic 70/30 PGVG	Menthol Heaven
100ml Menthol Tobacco .24nic 70/30 PGVG	Menthol High- VG
100ml Menthol Tobacco .30nic 70/30 PGVG	Menthol Ice
100ml Menthol Tobacco .35nic 70/30 PGVG	Menthol ICE
100ml Menthol Tobacco .40nic 70/30 PGVG	Menthol Ice Tobacco
100ml Menthol Tobacco .45nic 70/30 PGVG	Menthol Kings
100ml Menthol Tobacco .50nic 70/30 PGVG	Menthol Liquid
15ml Menthol Tobacco .00nic 70/30 PGVG	Menthol Liquid (PG)
15ml Menthol Tobacco .03nic 70/30 PGVG	Menthol Lite
15ml Menthol Tobacco .06nic 70/30 PGVG	Menthol Madness
15ml Menthol Tobacco .09nic 70/30 PGVG	Menthol Max
15ml Menthol Tobacco .12nic 70/30 PGVG	MENTHOL MAX
15ml Menthol Tobacco .15nic 70/30 PGVG	Menthol Mint
15ml Menthol Tobacco .18nic 70/30 PGVG	Menthol Pipe
15ml Menthol Tobacco .21nic 70/30 PGVG	Menthol Solution
15ml Menthol Tobacco .24nic 70/30 PGVG	Menthol Tob
30ml Menthol Tobacco .00nic 70/30 PGVG	Menthol Tobacclo
30ml Menthol Tobacco .03nic 70/30 PGVG	Menthol tobacco
30ml Menthol Tobacco .06nic 70/30 PGVG	Menthol Tobacco
30ml Menthol Tobacco .09nic 70/30 PGVG	Menthol Tobacco Like Flavor
30ml Menthol Tobacco .12nic 70/30 PGVG	Menthol Tobbacco
30ml Menthol Tobacco .15nic 70/30 PGVG	Menthol Type
30ml Menthol Tobacco .18nic 70/30 PGVG	Menthol, 120ml CRC Bottle, 0mg Nic
30ml Menthol Tobacco .21nic 70/30 PGVG	Menthol, 120ml CRC Bottle, 3mg Nic
30ml Menthol Tobacco .24nic 70/30 PGVG	Menthol, 120ml CRC Bottle, 6mg Nic
30ml Menthol Tobacco .30nic 70/30 PGVG	Menthol, 30ml CRC Bottle, 0mg Nic
30ml Menthol Tobacco .35nic 70/30 PGVG	Menthol, 30ml CRC Bottle, 12mg Nic
30ml Menthol Tobacco .40nic 70/30 PGVG	Menthol, 30ml CRC Bottle, 18mg Nic
30ml Menthol Tobacco .45nic 70/30 PGVG	Menthol, 30ml CRC Bottle, 24mg Nic
30ml Menthol Tobacco .50nic 70/30 PGVG	Menthol, 30ml CRC Bottle, 36mg Nic
60ml Menthol Tobacco .00nic 70/30 PGVG	Menthol, 30ml CRC Bottle, 3mg Nic
60ml Menthol Tobacco .03nic 70/30 PGVG	Menthol, 30ml CRC Bottle, 48mg Nic
60ml Menthol Tobacco .06nic 70/30 PGVG	Menthol, 30ml CRC Bottle, 6mg Nic
60ml Menthol Tobacco .09nic 70/30 PGVG	Menthol, 60ml CRC Bottle, 0mg Nic
60ml Menthol Tobacco .15nic 70/30 PGVG	Menthol, 60ml CRC Bottle, 3mg Nic
60ml Menthol Tobacco .18nic 70/30 PGVG	Menthol, 60ml CRC Bottle, 6mg Nic
60ml Menthol Tobacco .21nic 70/30 PGVG	Menthol, Mint and Tobacco

Appendix B: Characterizing Flavors Determined to be Menthol (continued)

60ml Menthol Tobacco .24nic 70/30 PGVG	MB Type Blend Menthol
60ml Menthol Tobacco .30nic 70/30 PGVG	Medium Menthol
60ml Menthol Tobacco .35nic 70/30 PGVG	Mega Menthol
60ml Menthol Tobacco .40nic 70/30 PGVG	Megan's Menthol
60ml Menthol Tobacco .45nic 70/30 PGVG	Menthol
60ml Menthol Tobacco .50nic 70/30 PGVG	menthol
American Blend Menthol	Menthol
American Menthol	Menthol
Blue Chip-Pure Menthol-	Menthol (Liquid)
Cigarette Menthol	MENTHOL 50/50
Classic Line/Menthol Tobacco	MENTHOL 60/40
Classic Menthol	Menthol and Tobacco
Clear and Menthol	Menthol Blend
Cloud Walker Menthol	Menthol Bold
Crazy Menthol	Menthol, tobacco
Cream De La Menthe	Menthol, Western
Cream de Menthe	Menthol, Western Tobacco
CREAM DE MENTHE	Menthol/Mint
Cream De Menthol	Mentholated Tobacco
Cream Dementhe	Mentholicious
Creame de Menthe	Mentho-Mint
Creamy Menthol	Methol
Crème de menthe	Mighty Menthol
Creme De Menthe	Mighty Menthol
Creme de Menthe II Flavor	Mild Menthol
Double Menthol	Minty Menthol
Double Menthol Tobacco	Mystic Menthol
Flavor Vapors FV Menthol Lights	Natural Menthol
Flavor Vapors FV Menthol Regular	natural menthol, orbit
Flavor Vapors Menthol Burst (Coiled)	Organic Menthol
Flavor Vapors Menthol Mint Blast	Pure Menthol
Fresh Menthol	Ry and Menthol
Half Menthol	RY and Menthol
Heavy Menthol	Smooth Menthol
House Menthol	Smooth Menthol Tobacco
Just Menthol	Spearmenthol
Kool Menthol	Stormcloud menthol
LIGHT MENTHOL	Tobacco and Menthol
Major Menthol, 120ml CRC Bottle, 0mg Nic	Tobacco menthol
Major Menthol, 120ml CRC Bottle, 3mg Nic	Tobacco Menthol
Major Menthol, 120ml CRC Bottle, 6mg Nic	Tobacco Menthol Cigarette
Major Menthol, 30ml CRC Bottle, 0mg Nic	Tobacco with Heavy Menthol
Major Menthol, 30ml CRC Bottle, 12mg Nic	Tobacco with Medium Menthol
Major Menthol, 30ml CRC Bottle, 18mg Nic	Tobacco with Menthol

Appendix B: Characterizing Flavors Determined to be Menthol (continued)

Major Menthol, 30ml CRC Bottle, 24mg Nic	Tobacco with Mild Menthol
Major Menthol, 30ml CRC Bottle, 36mg Nic	Tobacco, Menthol
Major Menthol, 30ml CRC Bottle, 3mg Nic	Traditional Menthol
Major Menthol, 30ml CRC Bottle, 48mg Nic	Turkish Menthol
Major Menthol, 30ml CRC Bottle, 6mg Nic	USA Blend Tobacco, Menthol
Major Menthol, 60ml CRC Bottle, 0mg Nic	USA Menthol
Major Menthol, 60ml CRC Bottle, 3mg Nic	USA Menthol E Juice
Major Menthol, 60ml CRC Bottle, 6mg Nic	Virginia Slim Menthol
Manthol	Western, Menthol
Marbo Menthol	Western, Menthol Liquid (PG)
Marlboro Menthol	Western, Menthol, Smooth
Menthol, Smooth	