

The following memorandum “Addendum to Approach to PMTAs for Non-Tobacco Flavored ENDS not in Substantive Scientific Review (Phase III)”, was finalized on July, 28 2021. This memorandum characterizes a plan to manage review of non-tobacco flavored ENDS products as “fatal flaw review,” which oversimplifies CTP’s process of review for flavored ENDS products. Therefore, this explanatory note clarifies that the term should be “flavored ENDS review.”

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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 <small>Date: 2021.07.28 09:33:09 -04'00'</small> </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, OS developed a plan to effectively manage non-tobacco flavored ENDS PMTAs not in Phase III, substantive scientific review, by applying a standard for evidence necessary to demonstrate an incremental benefit to adult smokers of non-tobacco flavored ENDS products. This addendum seeks to address recent updates to the approach.

Discussion

As previously discussed in the July 9, 2021 memo, for FDA to determine marketing of a product is appropriate for the protection of public health, it is necessary for applicants to provide evidence that can demonstrate whether their new non-tobacco flavored product(s) will provide an incremental benefit to adult smokers relative to the applicant's tobacco-flavored product(s). Absence of this evidence, a randomized controlled trial or a longitudinal cohort of study, is considered a fatal flaw, meaning any application lacking this evidence will likely receive a marketing denial order. On July 12, 2021, OS initiated Fatal Flaw review of the top manufacturers with the largest number of pending PMTAs not in Phase III for non-tobacco flavored ENDS products. For the remaining PMTAs not in Phase III for non-tobacco flavored ENDS products, OS had intended to issue a General Correspondence (GC) letter requesting the applicant to confirm if their PMTA contains evidence and, if so, to direct FDA to the location in

¹ Premarket Tobacco Product Applications

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

the application where the studies can be found. For efficiency, it was determined a GC letter will not be issued, in order to reduce the burden on the applicant to respond to the letter and on OS to review subsequent amendments. Instead, OS will initiate Fatal Flaw review on these PMTAs. OS will prioritize Fatal Flaw review of these PMTAs that have been Filed and then placed in order based on the number of products submitted to FDA (see Table 1). PMTAs that are pending Filing review³ will be added to the bottom of the list identified in Table 1 if Filed.

³ See Addendum to Updated Prioritization of PMTA Filing Reviews memo (signed July 28, 2021)

Table 1. Priority for Fatal Flaw Review

Priority List Rank	Company
1	(b) (4)
2	Vapor Salon
3	Cloud House
4	Dominant Vapor LLC
5	Great American Vapes LLC
6	(b) (4)
7	Securience LLC
8	Mountain Vaporz, LLC
9	(b) (4)
10	(b) (4)
11	(b) (4)
12	(b) (4)
13	The Vaping Tiger LLC
14	(b) (4)
15	Flavor Vapors LLC/ Mob Liquid Labs
16	Vape On LLC dba Imperial Vapor Co.
17	Loveli Design LLC DBA Alice in Vapeland
18	(b) (4)
19	Zen RVA LLC
20	MMWTA, Mothers Milk WTA
21	Osment Enterprises LLC dba The Vapor Apothecary
22	Wyoming Vapor Company
23	J-Vapor LLC dba North Shore Vapor
24	Diamond Vapor LLC
25	(b) (4)
26	Custom Vapor Blends LLC
27	Cig Free Vape Shop
28	(b) (4)
29	(b) (4)
30	Warlock Vapes LLC dba ZuluVape
31	VR Labs LLC
32	Ohm Slaw Juice LLC / Ohm Slaw Vapors dba Justin Parrott
33	Yoshicon LLC dba Vapergate
34	Texas Select Ventures LLC dba Texas Select Vapor
35	Viper Vapor LLC
36	(b) (4)
37	Ludovico, Inc.
38	Mom and Pop Vapor Shop
39	Stark Vapor LLC
40	Mountain Oak Vapors LLC
41	(b) (4)
42	(b) (4)
43	DFW Vapor Holdings Inc.

Priority List Rank	Company
44	(b) (4)
45	Apollo Future Technology Inc.
46	Baker White Inc.
47	UIS Manufacturing, LLC
48	SSY Ejuice Inc.
49	S.S. Vape Brands Inc. dba Monster Vape Labs
50	Wages & White Lion Investments LLC dba Triton Distribution
51	Custom Vapors LLC
52	Trendsetters E-Liquid LLC
53	Texas Tobacco Barn LLC dba Ciggy Shack
54	Millennial One Inc. dba The Finest E-Liquid
55	Vapor Stockroom LLC
56	Pettee & D'Sylva Enterprises
57	(b) (4)
58	(b) (4)
59	Verdict Vapors LLC
60	(b) (4)
61	Planet of the Vapes, LLC (MD21122)
62	Underdog E Liquids LLC
63	CITTG dba Orgnx E Liquids
64	Pop Vapor Co. LLC
65	Bogart Enterprises LLC
66	Johnny Copper LLC
67	(b) (4)
68	American Vapor Group LLC
69	Howard Enterprises Inc.
70	(b) (4)
71	Tasty Cloud Vape Co. LLC
72	NicQuid LLC
73	(b) (4)
74	Vape Craft Inc
75	Juice Roll Upz Inc.
76	LDP Designs LLC
77	The Vape Lounge Inc.
78	(b) (4)
79	Smax International LLC
80	(b) (4)
81	HUMBLE JUICE CO LLC
82	Twelfth State Brands LLC
83	Vapetasia LLC
84	Awesome Sauce Vapor, Inc
85	(b) (4)
86	Midas Vape LLC
87	Mister-E-Liquid LLC

Priority List Rank	Company
88	Shenzhen Innokin Technology Co., Ltd
89	The Vapor Vendor LLC
90	Shenzhen Hanqingda Technology Co. Ltd.
91	7 Daze LLC
92	My Vape Order Inc.
93	Vertigo Vapor Inc.
94	VaperMate
95	(b) (4)
96	Town Vapor Co.
97	Gentleman's Draw LLC
98	Vape Element LLC dba BLVK Unicorn
99	Gundo Distro
100	Liquid Art Inc.
101	Sadboy LLC
102	Midwest Vape Supply, Inc.
103	Fumizer LLC
104	Lady Boss Vapor Inc.
105	Simple Vapor Company
106	Beard Vape Company
107	(b) (4)
108	DS Technology Licensing LLC
109	Turncoat Industries Inc.
110	Axiocore Corporation
111	Maniac Vapor LLC
112	CRFT Labs Tennessee LLC
113	The Schwartz E Liquid dba USA Vape Lab
114	Puff Labs LLC
115	Cosmic Fog Vapors Operating Company LLC
116	Riot Labs Ltd
117	Fontem US LLC
118	Newhere Inc. dba Madhatter Juice
119	Buckshot Vapors Inc
120	Magellan Technology Inc.
121	(b) (4)
122	Fuma International LLC
123	Nasty Worldwide SDN BHD
124	Performance Plus Marketing Inc.
125	Ruthless Vapor Corporation
126	VIM Blends Inc.
127	South Beach Holdings LLC
128	Myle Vape Inc.
129	Element E-Liquid LLC
130	Paradigm Distribution
131	Boulder International Inc.

Priority List Rank	Company
132	JMJL Global Inc.
133	R.J. Reynolds Vapor Company
134	(b) (4)
135	MV Enterprises LLC
136	Nude Nicotine Inc.
137	Bidi Vapor LLC
138	Nicopure Labs LLC
139	Alaska Elixirs Vape LLC
140	Breeze Smoke LLC
141	(b) (4)
142	(b) (4)
143	(b) (4)
144	Feel Life Health Inc.
145	Marina Technology LLC
146	Unique eCigs Inc.
147	(b) (4)
148	American Vapor Inc.
149	Dotmod Inc.
150	Shenzhen Smoore Technology Limited
151	Aspire North America LLC
152	DR Distributors LLC
153	Ripe Vapes Inc.
154	Shenzhen Vaporesso Technology Limited
155	Shenzhen Youme Information Technology Co. Ltd
156	Vapor Trail LLC dba Mig Vapor
157	SV3 LLC