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Memorandum

To: File

From: Anne Radway, M.S.
Associate Director
Division of Regulatory Project Management
Office of Science

Digitally signed by Anne M. Radway -S
Date: 2023.04.18 13:39:44 -04'00'

Through: Todd Cecil, Ph.D.
Deputy Director
Office of Science

Todd L. Cecil - Digitally signed by Todd L.
Cecil -S
Date: 2023.04.27 10:36:10
-04'00'

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

Background

In the summer of 2021⁴, OS established a process to review non-tobacco flavored 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 (i.e., "FE Review"). On December 7, 2022, OS commenced FE Review on a subset of applications⁵ and created two queues, one for bundles for which only some flavored ENDS products underwent FE Review and the second for those that were never processed for FE Review. This addendum seeks to address the change in FE Review team structure and set review order for pending ENDS PMTAs.

Discussion

In the December 2022 Memo, OS identified two types of teams assigned to respective FE Review queue. These two teams were to apply updated FE Review process as described in the November 22, 2022, addendum to specified PMTAs:

- Teams for Queue A: For ENDS PMTA bundles received by September 9, 2020, in which some flavored ENDS products underwent FE Review, teams consisted of one scientific reviewer, an RHPM, and a TPL.
- Teams for Queue B: For ENDS PMTA bundles in which no products within the submission underwent FE Review and were received prior to the effective date of the Premarket Tobacco Product Applications and Recordkeeping Requirements rule (PMTA rule, November 4, 2021), teams consisted of two scientific reviewers, an RHPM, and a TPL.

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, August 18, 2021, and November 22, 2022, 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 December 7, 2022 (abbreviated as December 2022 Memo).

OS initiated a pilot to test the new FE Review team structure outlined in the December 2022 memo. Based on feedback from the pilot, OS determined it was preferable for two scientific reviewers perform a thorough review of all Flavored ENDS PMTAs. Therefore, OS abandoned the Queue A team structure and decided to move forward with Queue B structure for applications pending FE Reviews. All teams performing FE Review will now be comprised of two scientific reviewers, an RHPM and a TPL.

OS intends to commence FE Review during the second quarter of 2023 for Filed ENDS PMTAs received prior to November 4, 2021. Because many of these applications were submitted on the same day, a “first in, first reviewed” approach would not work. Thus, to maintain a fair order for review, a single listing of Filed ENDS PMTAs were randomized using a randomization function within Microsoft Excel, sorted from high to low, then assigned a ranking number, see Appendix A. Review teams will conduct FE Review in order of the ranking number. If additional applications received prior to November 4, 2021, are identified and subsequently Filed, they will be added to the end of the list. There could be exceptions to this plan if upon review, we determined that FDA inadvertently did not consider all amendments during the initial FE Review. OS will move those bundles up in priority and review the amendment(s) to determine if the original decision still stands or should be rescinded. For example, (b) (4) , (b) (4) , has been moved to the top of this priority list because as it falls into this category of exceptions.

Conclusion

For flavored ENDS³ applications received prior to November 4, 2021, FE Review will be prioritized as outlined in Appendix A by a review team consisting of two scientific reviewers, an RHPM and a TPL.

Appendix A

Randomization Number	Ranking Order	Applicant
	0	(b) (4)
0.987992361	1	Synergy Mixing Labs LLC
0.984328089	2	JD Nova Group LLC
0.983390156	3	Pop Vapor Co. LLC
0.977484812	4	Vapor Ventures Inc dba Innovated Vapors
0.970512620	5	Gundo Distro
0.970285677	6	(b) (4)
0.963463464	7	Vapors of Ohio Inc. dba Nostalgic Vapes
0.962923599	8	(b) (4)
0.950882021	9	Soft Vape Inc
0.949524641	10	(b) (4)
0.942253430	11	(b) (4)
0.926941306	12	Southwest Smokeless
0.921295283	13	(b) (4)
0.917106844	14	Vapor Depot LLC
0.914965205	15	Osment Enterprises LLC dba The Vapor Apothecary
0.914118573	16	BLB7 LLC dbaThe Vape Mall
0.912975467	17	(b) (4)
0.902202968	18	Custom Vapor Blends LLC
0.900234323	19	(b) (4)
0.900132541	20	eCig Source
0.899313209	21	(b) (4)
0.896788878	22	Stark Vapor LLC
0.885455284	23	(b) (4)
0.883798463	24	That 1 Vape
0.883755408	25	(b) (4)
0.881808713	26	(b) (4)
0.880265142	27	UIS Manufacturing, LLC
0.879703041	28	(b) (4)
0.877178427	29	VR Labs LLC
0.874696402	30	Fumizer LLC
0.867994674	31	(b) (4)
0.867876109	32	Warlock Vapes LLC dba ZuluVape
0.866555022	33	Planet of the Vapes, LLC (MD21122)
0.863117608	34	Drippers Vape Shop LLC
0.857350978	35	(b) (4)
0.857045063	36	Drip More LLC
0.857004755	37	MMWTA, Mothers Milk WTA
0.855695895	38	LDP Designs LLC
0.839702467	39	(b) (4)
0.837419634	40	Heartlandvapes LLC

0.836853592	41	(b) (4)
0.835942999	42	Walker Enterprises LLC dba MaddCatt Vapors
0.828908020	43	(b) (4)
0.826641652	44	Vapor Salon
0.821764830	45	Central Vapors
0.813001026	46	(b) (4)
0.799847818	47	Vertigo Vapor Inc.
0.793437232	48	(b) (4)
0.782238529	49	(b) (4)
0.779545431	50	Mom and Pop Vapor Shop
0.774401088	51	Electric Smoke Vapor House LLC
0.773869802	52	Innevape LLC
0.769990314	53	Quad City Vapers Club LLC
0.765851775	54	South Coast Vapor Company
0.764689356	55	Feel Life Co Limited
0.764458846	56	Vapor Bank E-Liquid LLC
0.757888924	57	Mountain Vaporz, LLC
0.755873191	58	Elite Brothers, LLC
0.752720892	59	(b) (4)
0.749282280	60	Great American Vapes LLC
0.748342829	61	Parallel Direct LLC dba The Magic Mist
0.746488150	62	Mighty Vapors, LLC
0.737861312	63	JMJL Global Inc.
0.729916568	64	Vapejoose, Inc.
0.728637197	65	Jvapes LLC
0.724612453	66	Gothic Vapor LLC
0.715549538	67	(b) (4)
0.711974588	68	(b) (4)
0.693542978	69	Magellan Technology Inc.
0.688692527	70	Vapor Stockroom LLC
0.688652993	71	Cosmic Fog Vapors Operating Company LLC
0.679566454	72	NicQuid LLC
0.678258697	73	Balboa Vapes LLC
0.674557801	74	Boomtown Vapor LLC
0.659699402	75	Absolute Vapor Lounge LLC
0.656655718	76	(b) (4)
0.654703974	77	(b) (4)
0.644686882	78	Drippers Vape Lounge
0.640507427	79	Breeze Smoke LLC
0.631548337	80	Kloc Vapor LLC (dba "The Vapor Edge")
0.618371166	81	KJJ Enterprises LLC
0.617489661	82	Fuma International LLC
0.617120420	83	Bogart Enterprises LLC
0.616115042	84	Xtreme Vapes LLC
0.615182053	85	Unique eCigs Inc.

0.610987018	86	(b) (4)
0.610955570	87	VPR Collection
0.606689195	88	Jai Mundi Inc. dba Kai's Virgin Vapor
0.605534159	89	American Vapor Company LLC
0.594501553	90	Boulder International Inc.
0.594313788	91	Texas Tobacco Barn LLC dba Ciggy Shack
0.590855525	92	(b) (4)
0.590178571	93	(b) (4)
0.587485015	94	Dominant Vapor LLC
0.586970108	95	GRIPUM LLC
0.582788084	96	(b) (4)
0.582643399	97	(b) (4)
0.579090710	98	(b) (4)
0.578074024	99	(b) (4)
0.576945948	100	J-Vapor LLC dba North Shore Vapor
0.569278282	101	(b) (4)
0.561056080	102	(b) (4)
0.555028747	103	Apollo Future Technology Inc.
0.549397871	104	ECS Global LLC
0.548464550	105	Lead by Sales LLC dba White Cloud Cigarettes
0.543917675	106	Tasty Haze LLC
0.540118002	107	JT Wood Investments LLC dba Vape It
0.538402802	108	(b) (4)
0.538082564	109	CITTG dba Orgnx E Liquids
0.537236155	110	The Vaping Tiger LLC
0.536918863	111	SSY Ejuice Inc.
0.529435685	112	MJ Asset Holdings LLC
0.528748670	113	Performance Plus Marketing Inc.
0.526279617	114	Flavor Vapors LLC/ Mob Liquid Labs
0.520701447	115	(b) (4)
0.504855995	116	Texas Select Ventures LLC dba Texas Select Vapor
0.501158238	117	(b) (4)
0.498395870	118	Vape On LLC dba Imperial Vapor Co.
0.496800454	119	Lotus Vaping Technologies LLC
0.495542533	120	Securience LLC
0.471818140	121	DR Distributors LLC
0.468783223	122	DFW Vapor Holdings Inc.
0.456148567	123	(b) (4)
0.454834234	124	(b) (4)
0.453465971	125	(b) (4)
0.453324779	126	Shop Vapes Inc
0.434263453	127	(b) (4)
0.416487698	128	(b) (4)
0.416245548	129	MH Global LLC dba Streamline Vape Co. LLC
0.416017500	130	Zen RVA LLC

0.412373797	131	Jaded Vapors LLC
0.407992781	132	Vapor Rage LLC
0.397010122	133	Vapor Source Inc.
0.394904650	134	(b) (4)
0.394108586	135	Smokeless Smoking Inc.
0.384683501	136	(b) (4)
0.367263386	137	(b) (4)
0.366588162	138	(b) (4)
0.365344496	139	Feel Life Health Inc.
0.357590615	140	(b) (4)
0.355883191	141	Desert Vapors LLC
0.351547733	142	Northeast Vapor Supplies LLC
0.350827143	143	(b) (4)
0.349968406	144	(b) (4)
0.340775834	145	(b) (4)
0.337117683	146	(b) (4)
0.332525672	147	Vapor Plus Ok
0.326538330	148	Seattle Vapor Co LLC
0.324017403	149	OVapes Ejuice LLC
0.323095834	150	(b) (4)
0.321128263	151	Vaporized Inc.
0.321032312	152	(b) (4)
0.312795283	153	Rock Ridge Vapor LLC
0.293868188	154	Newhere Inc. dba Madhatter Juice
0.284782992	155	Ecig Charleston
0.284735519	156	(b) (4)
0.284301325	157	(b) (4)
0.282858639	158	HMD Investment Group LLC
0.281374675	159	(b) (4)
0.275782081	160	(b) (4)
0.272397083	161	(b) (4)
0.252592504	162	(b) (4)
0.249755204	163	LXJ, LLC
0.247815049	164	The Schwartz E Liquid dba USA Vape Lab
0.246166144	165	Opt2mist Vapor Shop LLC
0.236502686	166	(b) (4)
0.229931862	167	Cloud House LLC
0.229079134	168	Phantasm Vapors LLC
0.228035608	169	RP Vapors, Inc.
0.218966219	170	(b) (4)
0.216777199	171	Vintage & Vapor Marketplace Inc.
0.216352366	172	Licensed E-Liquid Manufacturing
0.215023339	173	(b) (4)
0.211121654	174	(b) (4)
0.205295108	175	(b) (4)

0.200712125	176	(b) (4)
0.200274199	177	Tasty Puff LLC
0.197826124	178	Myle Vape Inc.
0.193485761	179	(b) (4)
0.171330379	180	(b) (4)
0.170041650	181	(b) (4)
0.168578427	182	Element E-Liquid LLC
0.168294805	183	My Vape Order Inc.
0.167216293	184	Midas Vape LLC
0.148523781	185	Tampa Vapor Inc
0.144847110	186	Verdict Vapors LLC
0.140101915	187	(b) (4)
0.133156950	188	(b) (4)
0.132746459	189	Steep Slope Vape Supply
0.131801504	190	Mountain Oak Vapors LLC
0.130961287	191	American Vapor Group LLC
0.122286433	192	(b) (4)
0.117580248	193	(b) (4)
0.113675852	194	Diamond Vapor LLC
0.106398670	195	Cool Breeze Vapor LLC
0.106232710	196	TruVibe Inc. dba Vapor Station FDL
0.098316466	197	Valley Vapors LLC
0.092366808	198	Juicemafia Inc.
0.090621109	199	(b) (4)
0.057044891	200	S.S. Vape Brands Inc. dba Monster Vape Labs
0.056202426	201	HotSpot Cafe LLC dba VV-Juice
0.053622542	202	(b) (4)
0.042476045	203	Juice Roll Upz Inc.
0.039884792	204	(b) (4)
0.024421189	205	Vape Craft Inc
0.017924608	206	(b) (4)
0.008726575	207	Vapor Trail LLC dba Mig Vapor