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Memorandum

To:	File
From:	Rosanna Beltre, M.P.H. Deputy Director Division of Regulatory Project Management Office of Science Rosanna Beltre -S Digitally signed by Rosanna Beltre -S Date: 2022.01.21 14:37:17 -05'00'
Through:	Matthew Holman, PhD Director Office of Science Digitally signed by Matthew R. Holman -S Date: 2022.01.21 15:27:09 -05'00'
Subject:	Filing Prioritization for PMTAs received between September 10, 2020 to November 3, 2021

Background

On July 12, 2019, the U.S. District Court for the District of Maryland ordered FDA to require premarket applications for all new¹ deemed tobacco products on the market as of August 8, 2016. On April 22, 2020, the Court granted a motion for a 120-day extension of the May 12, 2020, deadline (until September 9, 2020) in light of the global coronavirus disease pandemic.² Consistent with the original Court order, tobacco products with timely received applications by September 9, 2020, may remain on the market during the one-year compliance period.

During the compliance period for deemed tobacco products, the Office of Science (OS) invested most review resources on applications that met the September 9, 2020 court ordered deadline. As of the date of this memorandum, OS is nearing completion of processing Premarket Tobacco Application (PMTA) submissions received by September 9, 2020 for Phase I Acceptance and Phase II Filing; in addition to PMTA submissions received between September 9, 2020 and November 4, 2021, for Phase I Acceptance. As OS shifts to allotting review resources to processing Filing for PMTAs received after September 9, 2020, a new prioritization plan for Filing is necessary.

¹ Section 910(a)(1) of the Federal Food, Drug, and Cosmetic Act defines a “new tobacco product” as: (1) Any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

² *American Academy of Pediatrics, et al. v. Food and Drug Administration, et al.*, No. 8:18-cv-883 (PWG), (D. Md. Apr. 22, 2020) (Dkt. No. 182)

Discussion

To determine applications pending Filing review, we conducted an archive search for PMTAs received as of September 10, 2020 and before November 4, 2021, which is the effective date of the PMTA final rule, Premarket Tobacco Applications and Recordkeeping Requirements. The rule sets forth new regulatory requirements that do not apply to applications received prior to the effective date. Appendix A contains a full list of applications that were received between September 10, 2020 and November 3, 2021. OS decided to use receipt order to determine Filing prioritization. For example, in general, applications received on September 10th will be processed for Filing prior to an application received on September 15th. However, we note the following exceptions to the prioritization plan:

- For example, if an applicant submitted applications on September 10, 15, and 20th, for Filing purposes, these applications will be grouped together and processed for Filing using the earliest receipt date.
- If a submission is pending Acceptance for Phase I, the company will be skipped until completion of acceptance review.
- OS identified (b) (4) and Magellan Technology Inc. (Magellan) as two companies that submitted PMTAs within this timeframe that merit further prioritization.

Exceptions made for (b) (4) received on July 21, 2021, and Magellan (b) (4) received on October 28, 2020 are based product information that may have impact regarding public health concerns. The (b) (4) application was prioritized for Filing because it contains purported age-gating technology. FDA was made aware this application contained age-gating because the company submitted a meeting request ((b) (4) received on January 12, 2021. The purpose of the meeting request was to discuss the new technology embedded within their new tobacco products. Based on information contained in the meeting request, the applications were processed for Phase II and were subsequently Filed.

The Magellan applications for their (b) (4) tobacco products were also pending Phase II Filing. (b) (4)

Filing prioritization as outlined in Appendix A are pending PMTAs received between September 10, 2020 and November 3, 2021 based on order of FDA receipt of the submission.

Conclusion

The Filing teams should use order of receipt to prioritize for Filing applications received September 10, 2020 and November 3, 2021 as outlined in Appendix A.

Appendix A

Order	FDA Receipt Date	Applicant
1	7/21/2021	(b) (4)
2	10/28/2020	Magellan Technology Inc.
3	9/10/2020	(b) (4)
4	9/10/2020	(b) (4)
5	9/10/2020	Drip More LLC
6	9/10/2020	(b) (4)
7	9/10/2020	(b) (4)
8	9/10/2020	Imperial Vapors LLC
9	9/10/2020	(b) (4)
10	9/10/2020	(b) (4)
11	9/10/2020	(b) (4)
12	9/10/2020	Parallel Direct LLC dba The Magic Mist
13	9/10/2020	(b) (4)
14	9/10/2020	(b) (4)
15	9/10/2020	(b) (4)
16	9/10/2020	(b) (4)
17	9/10/2020	(b) (4)
18	9/10/2020	(b) (4)
19	9/10/2020	(b) (4)
20	9/11/2020	(b) (4)
21	9/11/2020	(b) (4)
22	9/11/2020	(b) (4)
23	9/11/2020	(b) (4)
24	9/11/2020	(b) (4)
25	9/12/2020	(b) (4)
26	9/15/2020	(b) (4)
27	9/15/2020	(b) (4)
28	9/15/2020	(b) (4)
29	9/15/2020	(b) (4)
30	9/15/2020	(b) (4)
31	9/18/2020	(b) (4)
32	9/21/2020	(b) (4)
33	9/22/2020	(b) (4)
34	9/29/2020	(b) (4)
35	9/29/2020	(b) (4)
36	9/29/2020	VPR Collection
37	9/30/2020	Breeze Smoke LLC
38	9/30/2020	(b) (4)
39	10/6/2020	(b) (4)
40	10/19/2020	(b) (4)
41	11/6/2020	(b) (4)

42	11/10/2020	(b) (4)
43	11/18/2020	DS Technology Licensing LLC
44	11/20/2020	(b) (4)
45	12/22/2020	(b) (4)
46	12/23/2020	(b) (4)
47	12/29/2020	(b) (4)
48	12/30/2020	LAS Ventures Ltd
49	1/6/2021	(b) (4)
50	1/10/2021	(b) (4)
51	1/14/2021	Shenzhen Yibo Technology Co. Ltd.
52	1/20/2021	Performance Plus Marketing Inc.
53	1/25/2021	Apollo Future Technology Inc.
54	1/26/2021	(b) (4)
55	2/1/2021	Blue Label Elixir
56	2/15/2021	(b) (4)
57	3/13/2021	(b) (4)
58	3/17/2021	(b) (4)
59	3/26/2021	American Vapor Company LLC
60	3/28/2021	(b) (4)
61	4/5/2021	(b) (4)
62	4/26/2021	(b) (4)
63	5/6/2021	FuZion Vapor LLC
64	5/10/2021	(b) (4)
65	5/12/2021	HMD Investment Group LLC
66	5/18/2021	Mountain Vaporz, LLC
67	5/31/2021	Fuma International LLC
68	5/31/2021	MH Global LLC dba Streamline Vape Co. LLC
69	6/2/2021	(b) (4)
70	6/4/2021	Shenzhen IVPS Technology Co.Ltd.
71	6/10/2021	(b) (4)
72	6/30/2021	(b) (4)
73	7/1/2021	Savage Enterprises
74	7/5/2021	Vapor Ventures Inc dba Innovated Vapors
75	7/6/2021	(b) (4)
76	7/15/2021	Rogue Vapers LLC
77	7/21/2021	(b) (4)
78	7/27/2021	eCig Source
79	7/29/2021	(b) (4)
80	8/8/2021	(b) (4)
81	8/13/2021	Mid Cities Vapor LLC
82	8/31/2021	Fumizer LLC
83	8/31/2021	(b) (4)
84	9/7/2021	(b) (4)
85	9/8/2021	(b) (4)
86	9/9/2021	(b) (4)

87	9/10/2021	BLB7 LLC dbaThe Vape Mall
88	9/13/2021	LoneStar Vapor Shop LLC
89	9/15/2021	(b) (4)
90	9/16/2021	(b) (4)
91	9/16/2021	(b) (4)
92	9/16/2021	(b) (4)
93	9/16/2021	(b) (4)
94	9/16/2021	(b) (4)
95	9/20/2021	(b) (4)
96	9/20/2021	(b) (4)
97	9/23/2021	Vapor Depot LLC
98	9/28/2021	(b) (4)
99	9/28/2021	(b) (4)
100	10/4/2021	(b) (4)
101	10/4/2021	(b) (4)
102	10/9/2021	(b) (4)
103	10/12/2021	(b) (4)
104	10/14/2021	(b) (4)
105	10/20/2021	(b) (4)