This document has been posted in compliance with the FOIA Improvement Act of 2016, which requires agencies to make certain records that have been requested three or more times publicly available. It provides a snapshot of CTP's internal thinking on certain aspects of tobacco regulatory science. The information it contains is subject to change, such as based on changes in policy, the regulatory framework, or regulatory science. It is not binding on FDA or the public. It may have been withdrawn or superseded after it was issued or may otherwise be outdated. FDA's review of tobacco product applications is based on the specific facts presented in each application, and is documented in reviews particular to each application.

Given the above, you should not use this document as a tool, guide, or manual for the preparation of applications or submissions to FDA. Instead, all interested persons should refer to the Federal Food, Drug, and Cosmetic Act, and its implementing regulations, as well as guidance documents prepared by FDA, for information on FDA's tobacco authorities and regulatory framework. FDA also regularly posts additional resources for applicants, such as webinars and application tips, on CTP's website and social media.



Memorandum

То:	File	
From:	Rosanna Beltre, M.P.H Deputy Director, DRPM Office of Science	Rosanna Beltre -S Digitally signed by Rosanna Beltre -S Date: 2022.02.25 17:37:38 -05'00'
Through:	Matthew Holman, PhD Office Director Office of Science	Digitally signed by Matthew R. Holman -S Date: 2022.02.28 06:45:32 -05'00'
Subject:	Addendum to Filing Prioritization for PMTAs received between September 10, 2020 to November 3, 2021	

Background

On January 21, 2022 OS drafted a memo outlining how applications submitted after the September 9, 2020 deadline will be prioritized for Phase II Filing review. Specifically, OS conducted an archive search for PMTAs received as of September 10, 2020 and before November 4, 2021, which was the effective date of the PMTA final rule, Premarket Tobacco Applications and Recordkeeping Requirements. This memo amends the January 21, 2022 Filing priority memo.

Discussion

The initial archive search using September 10, 2020 to November 3, 2021 search dates yield a list of applicants that were organized in order of review based on FDA receipt date. However, after a database clean-up a recent archive search we identified the following companies that were missed in the previous search:

Table 1: Omitted Companies	Receipt Date
(b) (4)	9/10/2020
(b) (4)	9/11/2020
(b) (4)	3/13/2021
(b) (4)	12/17/2020
(b) (4)	9/10/2020

Conclusion

The updated priority list in Appendix A includes these newly identified companies and set forth a new priority order that includes companies in Table 1 above.

Appendix A

Priorityy Number	Date Received	Сотрануу
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	Elite Vapor LLC
7	9/10/2020	(b) (4)
8	9/10/2020	Imperial Vapors LLC
9	9/10/2020	(b) (4)
10	9/10/2020	Northwest Freedom Vape LLC
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	9/10/2020	(b) (4)
21	9/10/2020	(b) (4) (b) (4)
22 23	9/11/2020	(b) (4) (b) (4)
24	9/11/2020 9/11/2020	(b) (4)
25	9/11/2020	(b) (4)
26	9/11/2020	(b) (4)
27	9/11/2020	(b) (4)
28	9/12/2020	(b) (4)
29	9/15/2020	(b) (4)
30	9/15/2020	(b) (4)
31	9/15/2020	(b) (4)
32	9/15/2020	(b) (4)
33	9/15/2020	(b) (4)
34	9/18/2020	(b) (4)
35	9/21/2020	(b) (4)
36	9/22/2020	(b) (4)
37	9/29/2020	(b) (4)
38	9/29/2020	(b) (4)
39	9/29/2020	VPR Collection
40	9/30/2020	Breeze Smoke LLC
41	9/30/2020	(b) (4)
42	10/6/2020	(b) (4)
43	10/19/2020	(b) (4)
44	11/6/2020	(b) (4)



