November 18, 2022

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Petition for Stay of Action
21 C.F.R. § 10.35

The undersigned submits this petition requesting that the Commissioner of Food and Drugs stay the effective date of the following matter.

A. Decision Involved

On November 1, 2022, FDA issued a Refuse to Accept order to Local Vape Enterprises, Inc. for its ENDS products in the bundled PMTAs assigned STNs: PM0005294. Therefore, this petition is timely.

B. Action Requested

A stay for an indefinite period of time due to the indeterminable timeframe for the Center for Tobacco Products to complete a review under 21 CFR §10.75 (currently administrative appeals with CTP exceed 14 months).

C. Statement of Grounds

NATURE OF THE REQUEST

1. Through this action, Petitioner seeks an Administrative Stay because FDA has violated the Administrative Procedure Act by issuing a Refuse to Accept ("RTA") order for 330 bundled Premarket Tobacco Product Applications ("PMTAs") that Local Vape Enterprises, Inc. submitted for various electronic nicotine delivery system e-liquids it markets.

2. Petitioner contends that FDA acted arbitrarily, capriciously, and otherwise not in accordance with applicable law in issuing the RTA order because the agency (i)

ignored information submitted in the initial PMTA, (ii) failed to consider timely amendments containing required content that LVEI properly submitted, (iii) failed to communicate with LVEI or provide any opportunity to clarify and/or correct its submission, and (iv) invoked regulations governing PMTA acceptance that do not apply to LVEI's PMTA.

3. Petitioner further contends that a stay is in the public interest to help reduce public confusion about the status of the RTA order during the delayed and prolong appeal pursuant to 21 C.F.R § 10.75.

FACTS

A. ENDS Products are "Tobacco Products" under the Tobacco Control Act

4. Electronic nicotine delivery system ("ENDS") products are regulated by FDA as "tobacco products" under the Tobacco Control Act ("TCA"), 21 U.S.C. §§ 387, *et seq.*, because they "contain[] nicotine from any source" and are "intended for human consumption." 21 U.S.C. § 321(rr)(1). As such, they are subject to the requirements of Subchapter IX of the Federal Food, Drug and Cosmetic Act ("FDCA").

5. Section 910 of the FDCA, 21 U.S.C. § 387j, requires that any tobacco product that was not commercially marketed as of February 15, 2007, receive a marketing order from FDA prior to being commercially marketed in the United States.

6. Prior to April 15, 2022, ENDS products containing nicotine that was synthetically manufactured or otherwise not derived from tobacco plants did not qualify as "tobacco products" and were not subject to Section 910's premarket authorization

requirements because the statutory definition of a "tobacco product" extended only to products "made or derived from tobacco that [are] intended for human consumption, including any component, part, or accessory of a tobacco product." 21 U.S.C. § 321(rr) (2009). However, the Consolidated Appropriations Act, 2022, Pub. L. 117-103, 136 Stat. 49, Division P, Title I, Subtitle B, §111(a) expanded the statutory definition to include products containing nicotine "from any source" effective April 15, 2022.

7. As a result, manufacturers and distributors of ENDS products were required to submit premarket tobacco applications for these synthetic nicotine products. If they submitted PMTAs by May 14, 2022, they would not be in violation of the Section 910's marketing authorization requirement during the 60-day period up through July 13, 2022. *See id.* at § 111(d).

B. FDA has Historically Extended Enforcement Discretion to ENDS Products with Timely Submitted and Pending PMTAs

8. May 14, 2022, was not the first time that manufacturers and distributors of ENDS products were required to submit PMTAs for their products in order to keep them on the market.

9. When the Tobacco Control Act was first enacted in 2009, its requirements originally applied only to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. 21 U.S.C. § 387a(b). The TCA's requirements would only apply to other products meeting the statutory definition of a "tobacco product" if FDA "by regulation deems" such products to be "tobacco products." *Id.*

10. Through its so-called "Deeming Rule," 81 Fed. Reg. 28974 (May 10, 2016)

(codified at 21 C.F.R. § 1143.1), FDA deemed ENDS products containing nicotine derived from tobacco plants to be tobacco products.

11. However, because countless ENDS products were already commercially marketed in the United States, in the Deeming Rule's preamble, FDA introduced a discretionary enforcement policy that allowed for delayed compliance periods for ENDS products. *See* 81 Fed. Reg. at 29009-15.

12. Under this discretionary enforcement policy, PMTA submissions were originally required to be filed in 24 months, or by August 8, 2018. 81 Fed. Reg. at 28977-78, 29011. Tobacco products, including ENDS products, already on the U.S. market would not be subject to FDA enforcement action in the meantime or while a timely submitted PMTA was pending FDA review. *Id.*

13. FDA's deadline for the filing of PMTAs under its discretionary enforcement policy, however, changed multiple times over the succeeding years, and these changes resulted in significant litigation. *See Vapor Technology Ass'n v. FDA*, 977 F.3d 496, 497-502 (6th Cir. 2020) (summarizing history of litigation surrounding PMTA submission deadline).

14. Ultimately, to comply with an order from the United States District Court for the District of Maryland,[1] FDA specified that ENDS products for which a PMTA was submitted by September 9, 2020, could continue to be commercially marketed for a period of up to one year after September 9, 2020, provided that the PMTA remained

[1] *See* April 22, 2020 Order in *American Academy of Pediatrics v. FDA*, No. 8:18-cv-00883-PWG (D. Md.).

pending and FDA had taken no adverse action on the application.[2]

15. Even after September 9, 2021, however, FDA has continued to exercise enforcement discretion to allow the continued marketing of ENDS products containing tobacco- derived nicotine for which timely submitted PMTAs are still pending or, in certain cases, where FDA originally issued a marketing denial order on the PMTA, but then either administratively stayed or retracted the marketing denial order. *See*, *e.g.*, *Turning Point Brands, Inc. v. FDA*, No. 21-3855, ECF No. 19, p. 9-10 (6th Cir. Oct. 8, 2021); *My Vape Order, Inc. v. FDA*, No. 21-71302, ECF No. 45, p. 2 (9th Cir. Dec. 30, 2021); *Juul Labs, Inc. v. FDA*, No. 22-1123, Doc. # 1953737 (D.C. Cir. July 6, 2022).

16. With respect to ENDS products containing non-tobacco-derived nicotine, prior to July 13, 2022, FDA publicly indicated that it would utilize the same approach, with ENDS products that are the subject of pending applications "subject to enforcement at FDA's discretion." *See* Nicholas Florko, Stat News, *FDA appears to hold off on crackdown on synthetic nicotine products, despite calls from Congress* (July 8, 2022).

17. To date, to the knowledge of Petitioners, FDA has not issued a Warning Letter to any manufacturer or importer of an ENDS product regarding a product for which a timely filed PMTA remains pending.

C. Regulations and Forms Governing FDA's Premarket Tobacco Product Application Requirements

18. In June 2019, FDA issued its final guidance on PMTAs for ENDS products. FDA, Guidance for Industry, *Premarket Tobacco Applications for Electronic Nicotine*

[2] U.S. Food & Drug Admin., Guidance for Industry, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised), at 27-28 (Apr. 2020), https://www.fda.gov/media/133880/download.

Delivery Systems (June 2019).

19. In September 2019, FDA issued a proposed rule governing PMTAs. Premarket Tobacco Product Applications and Recordkeeping Requirements, Proposed Rule, https://bit.ly/2m5c2g8.

20. FDA's proposed rule included a draft grouped submission form. The purpose of the form was for submitting PMTAs that contained multiple ENDS products in a single "bundled" submission.

21. FDA published its final PMTA Rule setting out the requirements for a PMTA and the procedures for FDA's review of such applications in the *Federal Register* on October 4, 2022. Premarket Tobacco Product Applications and Recordkeeping Requirements, Final Rule, 86 Fed. Reg. 55300 (Oct. 4, 2020), https://bit.ly/3Dt3d57.

22. In March 2020, FDA included in the reopening of the comment period on the proposed PMTA rule the potential for adding a new Form 4057b to the PMTA submission requirements. *See* 85 Fed. Reg. 13840, 13840-41 (Mar. 10, 2020).

23. The purpose of the form was for submitting PMTAs that contained multiple ENDS products in a single "bundled" submission. *Id.* at 13841.

24. The Office of Management and Budget ("OMB") granted its approval to FDA's inclusion of the amended Form 4057b in its PMTA forms. Office of Management and Budget, *Premarket Tobacco Product Applications and Recordkeeping Requirements*, ICR 202003-0910- 008; https://bit.ly/3f9qcsv.

25. To the knowledge of Petitioners, the draft form and final Form 4057b are

identical except for minor changes in identification to the header.[3]

26. On April 13, 2022, two days before the expanded definition of "tobacco products" established by the Consolidated Appropriations Act, 2022, took effect, FDA sought emergency authority from OMB to amend Form 4057b, and on April 14, 2022, OMB granted emergency authorization for FDA to use the amended Form 4057b. Office of Management and Budget, *Premarket Tobacco Product Applications and Recordkeeping Requirements*, ICR 202204-0910- 012; https://bit.ly/3sv5YMY.

27. FDA did not publish the amended Form 4057b on its website where potential applicants could access it until April 28, 2022. FDA, *Premarket Tobacco Product Applications*, https://bit.ly/3Dapi7h.

28. FDA failed to publish notice of the amendment in the Federal Register until May 16, 2022, two days *after* the PMTA submission deadline for the newly defined "tobacco products." 87 Fed. Reg. 29749 (May 16, 2022).

29. FDA's regulations require that applicants submit their PMTAs electronically. *See* 21 C.F.R. § 1114.49(a). This may be done either through FDA's Center for Tobacco Products electronic submission portal, or "CTP Portal," or FDA's separate agency-wide "Electronic Submissions Gateway," although FDA's website recommends submitting PMTAs through the CTP Portal due to better functionality.[4]

D. LVEI's PMTAs

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[3] This likely explains why, even though the RTA alleges product specifications were omitted, Appendix B of the RTA captures the requested product specification.

[4] *See* https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket- tobacco-product-applications.

30. On May 9, 2022, LVEI, through its regulatory counsel, timely submitted 330 e-liquids bundled into one PMTAs for ENDS products containing non-tobacco-derived nicotine.

31. FDA's practice and regulations governing PMTAs allow applicants to submit amendments prior to FDA issuing a refuse to accept order. *See* 21 C.F.R. §§ 1114.9.

32. On July 20 and 22, 2022, LVEI uploaded supplemental amendments for each of the bundled PMTAs it had originally submitted on May 9, 2022.

33. The amendments submitted by LVEI, contained a completed Form 4057a, as well as a Form 4057. The "Submission Summary" section on page 7 of 14 of these Forms 4057a stated that the purpose of the supplemental submissions was to supply Forms 4057 for each bundled submission.

34. On October 6, 2022, LVEI uploaded supplemental amendments for each of the bundled PMTAs it had originally submitted on May 9, 2022.

E. FDA's Refuse to Accept Order

35. On November 1, 2022, FDA issued a Refuse to Accept order to LVEI for its ENDS products in the bundled PMTA. A copy of the RTA order is attached hereto as **Exhibit A**.

36. The RTA order was the first notice LVEI received from FDA regarding any purported deficiency in any of its bundled PMTAs.

37. For the PMTAs submitted by LVEI, FDA determined that the submissions failed to include FDA Form 4057b–Premarket Tobacco Product Application Product Grouping Spreadsheet as required by 21 C.F.R. § 1105.10(a)(6) and 21 C.F.R. §

1114.7(b).

38. FDA made no mention of the draft form included in the initial submission despite using it to create the appendix to the RTA.

39. FDA also found the LVEI submissions deficient for failing to include a certification statement signed by an authorized representative as required by 21 C.F.R. § 1114.7(a)(11) and 21 C.F.R. § 1114.7(m).

40. The certification statement, however, was found in the Forms 4057 that LVEI uploaded through the CTP Portal as part of the amendments submitted.

41. FDA also found the LVEI submissions deficient for failing to identify all new tobacco products subject of review in the Environmental Assessment.

42. The Environmental Assessment, however, referenced the grouped submission form rather than redundantly listing the 330 products.

43. The RTA order noted that "although you submitted additional submissions which may have been intended to amend your applications," the submissions did not specify the STNs assigned to the original submission and omitted FDA form 4057a in violation of 21 C.F.R. § 1114.9.

44. The RTA order states that "although your submission(s) may include the required content for a PMTA, they lack these necessary elements to accurately identify the purpose of the submission as well as the applications, products, and content which is being amended."

45. A review of Appendix B to the RTA order, listing amendments and additional submissions received by FDA for LVEI, suggests that FDA erroneously found the

supplemental submissions, to be lacking Form 4057a-Premarket Tobacco Product Application Amendment and General Correspondence Submission.

46. Regarding the STNs, the RTA order makes reference to a failure to include the STN in Form 4057a. Not only is there only one STN for LVEI, FDA never issued any correspondence or notice to LVEI providing STNs.

47. The RTA order itself states in bold that LVEI "cannot introduce or deliver for introduction" any of the ENDS products subject to the RTA order "into interstate commerce in the United States" and that doing so would be a violation of the FDCA and could result in enforcement action by FDA.

48. Penalties for selling unauthorized ENDS products can include both substantial civil penalties and criminal prosecution. 21 U.S.C. §§ 331, 333.

49. Simply resubmitting the bundled PMTAs would not provide an adequate remedy for LVEI because, to LVEI's understanding, FDA will not consider exercising enforcement discretion as to any non-tobacco-derived nicotine ENDS products unless the corresponding PMTAs were submitted by May 14, 2022, and remain pending.

F. The MDO Threatens LVEI Businesses

50. Absent a stay of the RTA order, LVEI must stop selling its ENDS products and expects that it may lose those customers' business as a result of the RTA order.

51. LVEI had already spent significantly on the PMTAs at the time the RTA order issued and plans to spend on additional costly testing.

52. LVEI's products subject to the RTA order compete with numerous other ENDS products that either have received marketing authorization from FDA or, while they also

lack marketing authorization from FDA, are not subject to FDA enforcement because the PMTAs submitted by the manufacturers of those products are still pending or, if FDA has issued a marketing denial order on the application, the agency has administratively stayed or retracted the marketing denial order and is re-reviewing the application.

53. The RTA order means that LVEI thus stands to lose substantial sales to the manufacturers and distributors of these products in the highly competitive ENDS industry.

54. If the RTA order is not stayed swiftly, because other ENDS manufacturers and distributors have not received RTA orders or other adverse actions and FDA continues to exercise enforcement discretion as to their products, LVEI will lose market share to them, as well as associated customer goodwill.

ARGUMENTS

55. Pursuant to 21 C.F.R. § 10.35 The Commissioner shall grant a stay in any proceeding if all of the following apply: (1) The petitioner will otherwise suffer irreparable injury; (2) The petitioner's case is not frivolous and is being pursued in good faith; (3) The petitioner has demonstrated sound public policy grounds supporting the stay; (4) The delay resulting from the stay is not outweighed by public health or other public interests.

56. The Petitioner has established it meets the criteria in subparagraphs (1), (2), and (4) in the above explanation. Furthermore, the arguments below provide a good faith basis for why there are sound public policy grounds to support the stay.

57. Petitioner contends that a stay is in the public interest to help reduce public

confusion about the status of the RTA order during the delayed and prolong appeal pursuant to 21 C.F.R § 10.75.

58. As a federal agency, FDA is subject to the requirements of the Administrative Procedure Act, including the prohibition against agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2).

59. FDA's RTA order is a "final agency action" for which there is no other adequate remedy.

60. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law in issuing the RTA order to LVEI.

61. Specifically, FDA acted arbitrarily, capriciously, and otherwise not in accordance with applicable law in issuing the RTA order because the agency (i) ignored information submitted in the initial PMTA, (ii) failed to consider timely amendments containing required content that LVEI properly submitted, and (iii) invoked regulations governing PMTA acceptance that do not apply to LVEI's PMTA.

62. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law by failing to provide sufficient public notice of newly required forms prior to the filing deadline.

63. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law by issuing the RTA order on the ground that LVEI's PMTA failed to include FDA Form 4057b—Premarket Tobacco Product Application Product Grouping Spreadsheet as required by 21 C.F.R. § 1105.10(a)(6) and 21 C.F.R. § 1114.7(b) because LVEI, through

its regulatory counsel submitted an identical draft form (accepted prior to post-May 14th deadline publication of the final form), and submitted timely amendments that contained FDA Form 4057b.

64. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law by issuing the RTA order on the ground that LVEI's PMTA failed to include a certification statement signed by an authorized representative as required by 21 C.F.R. § 1114.7(a)(11) and 21 C.F.R. § 1114.7(m) because the certification statements were found in the Forms 4057 that were submitted as timely amendments.

65. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law by failing to consider LVEI's timely amendments submitted on the grounds that the amendments did not include or reference the Submission Tracking Numbers assigned to the original bundled applications to which the amendments related when FDA itself failed to assign the original bundled applications corresponding Submission Tracking Numbers. FDA similarly acted arbitrarily, capriciously, and otherwise not in accordance with law by issuing the RTA order on the basis that LVEI's amendments did not specify the STNs.

66. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law by failing to communicate interactively regarding minor administrative corrections or clarifications regarding what was submitted (LVEI's regulatory counsel sent the RHPM explaining the above upon receipt of the RTA order but to-date there has been no acknowledgment or reply of any kind).

CONCLUSION

67. The Petitioner has demonstrated it meets the criteria for an administrative stay under 21 C.F.R. 10.35(e) and respectfully requests one be GRANTED.

Respectfully Submitted,

Digitally signed by Marc C. Sanchez, Esq.
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