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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
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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 December 29, 2023, FDA issued a Marketing Denial Order to Royal Diamond Imports, Inc. for its ENDS products in the bundled PMTAs assigned STN PM0004990. 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 Marketing Denial Order (“MDO”) for a bundled Premarket Tobacco Product Applications (“PMTAs”) that Royal Diamond Imports, Inc. submitted for various electronic nicotine delivery system products it markets.

2. Petitioner contends that FDA acted arbitrarily, capriciously, and otherwise not in accordance with applicable law in issuing the MDO because the agency (i) failed to provide the customary notice scientific review had begun (fair notice doctrine), (ii) failed

to follow the timing requirements set forth in 21 C.F.R. §1114.27(c)(1), (iii) failed to communicate with Petitioner any deficiencies or provide any opportunity to clarify and/or correct its submission prior to the MDO (fair notice doctrine), and (iv) as the Fifth Circuit, where Petitioner resides, recently held “...sent manufacturers of flavored e-cigarette products on a wild goose chase.”¹

3. Petitioner further contends that a stay is in the public interest to help reduce public confusion about the status of the MDO during the delayed and prolonged appeal pursuant to 21 C.F.R. § 10.75. As discussed below, the public interest is further reinforced by the January 3, 2024, Fifth Circuit *En Banc*, *Wages & White Lion* opinion (Petitioner resides in Texas) and the December 19, 2022, release of the Reagan Udall audit, which has been described by AP News as "blistering" in its findings.²

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

¹ *En Banc*, *Wages & White Lion* opinion.

² Panel warns FDA’s beleaguered tobacco unit lacks direction (available at: <https://apnews.com/article/health-vaping-us-food-and-drug-administration-robert-califf-63d2cc590965a6f5f39460e19f2a8607>), AP News, December 19, 2022.

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.

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

6. 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.*

7. 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.

8. 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.

9. 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.*

10. 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,³ 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 pending and FDA had taken no adverse action on the application.⁴

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).

³ See April 22, 2020 Order in *American Academy of Pediatrics v. FDA*, No. 8:18-cv-00883-PWG (D. Md.).

⁴ 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>.

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

16. In June 2019, FDA issued its final guidance on PMTAs for ENDS products. FDA, *Guidance for Industry, Premarket Tobacco Applications for Electronic Nicotine Delivery Systems* (June 2019).

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

18. 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.

19. 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>.

20. 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).

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

22. 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.⁵

D. RDI’s PMTAs

23. On September 7, 2021, RDI, through its regulatory counsel, timely submitted various ENDS products bundled into a PMTA for ENDS products containing tobacco-derived nicotine.

24. The ENDS products are packaged in a design that intentionally omits any elements that would appeal to minors.

25. The submission by RDI, was assigned PM0004990 as the Submission Tracking Number (“STN”).

26. On January 14, 2022, approximately four months after submission RDI received an Acceptance Letter.

27. Approximately three months later, on March 24, 2022, RDI received a Filing Letter.

28. All communication ended for nearly 20 months. Then on December 29, 2023, RDI received a one paragraph MDO, which is identical to other MDOs issued around the same date.⁶

29. FDA’s practice and regulations governing PMTAs allow applicants to submit amendments prior to FDA issuing a Marketing Denial Order. *See* 21 C.F.R. §§ 1114.9.

⁵ See <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications>.

⁶ See e.g., December 13, 2023, MDO issued to PM0004888.

30. After completion of the filing review, FDA “begin[s] substantive review of the application.”⁷ Under the TCA, FDA has 180 days to complete its review of the PMTA and act on the application.”⁸

31. FDA’s practice is to provide the submission Point of Contact e-mail notification that the substantive or scientific review has begun.⁹

32. FDA’s practice¹⁰, regulation, and website¹¹ describe a Deficiency Letter as an output of the scientific review.

E. FDA’s Marketing Denial Order

33. On December 29, 2023, FDA issued a Marketing Denial Order to RDI for its ENDS products in the bundled PMTA.

34. The MDO was the first notice RDI received from FDA regarding any purported deficiency in any of its bundled PMTAs.

35. The MDO itself states in bold that RDI “cannot introduce or deliver for introduction” any of the ENDS products subject to the MDO 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.

36. Penalties for selling unauthorized ENDS products can include both substantial

⁷ Final PMTA Guidance at 10.

⁸ 21 U.S.C. § 387j(c)(1)(A)

⁹ See e.g., August 13, 2021, e-mail notification provided to PM0004888 or the May 26, 2022, e-mail notification provided to PM0001155.

¹⁰ See e.g., Deficiency Letter issued by the FDA on April 29, 2021, for PM0001177.

¹¹ <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications#4>

civil penalties and criminal prosecution. 21 U.S.C. §§ 331, 333.

37. Simply resubmitting the bundled PMTAs would not provide an adequate remedy.

38. The inconsistent patchwork of responses shows there is no policy other than rejection.

F. The MDO Threatens RDI Businesses

39. Absent a stay of the MDO, RDI must stop selling its ENDS products and expects that it may lose those customers' business as a result of the MDO.

40. RDI had already spent significantly on the PMTAs at the time the MDO issued and plans to spend on additional costly testing.

41. RDI's products subject to the MDO 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.

42. The MDO means that RDI thus stands to lose substantial sales to the manufacturers and distributors of these products in the highly competitive ENDS industry.

43. If the MDO is not stayed swiftly, because other ENDS manufacturers and distributors have not received MDOs or other adverse actions and FDA continues to

exercise enforcement discretion as to their products, RDI will lose market share to them, as well as associated customer goodwill.

ARGUMENTS

44. 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.

45. 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.

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

47. The stay is in the public interest in light of the recent Fifth Circuit *en banc* opinion. The Petitioner resides in Texas, which is in the Fifth Circuit. The *en banc* opinion held “FDA’s denials of petitioners’ PMTAs were arbitrary and capricious. The agency did not give manufacturers fair notice of the rules; the agency did not acknowledge or explain its change in position; the agency ignored reasonable and

serious reliance interests that manufacturers had in the pre-MDO guidance.”¹²

48. The Petitioner is raising these very same points in its Administrative Appeal. It would be contrary to the public interests to treat Petitioners differently simply because it elected to exhaust its administrative remedies before bearing the significant costs of pursuing relief in the Fifth Circuit.

49. The issue of public confusion is reinforced in the recent Reagan Udall audit. The report explicitly stated that CTP has “struggled to function as a regulator.” Petitioner further contends that a stay is in the public interest to help reduce public confusion is further reinforced by the December 19, 2022 release of the Reagan Udall audit, which has been described by AP News as “blistering” in its findings. The report explicitly stated that CTP has “struggled to function as a regulator.” The report found, “FDA’s plans and approaches to tobacco regulation changed, such changes were not always announced and communicated clearly to external stakeholders or even to staff.”

50. As the report suggests and as the marketing denial orders further emphasize the public would likely understand CTP has an unspoken goal of ending tobacco and nicotine use.

51. The Fifth Circuit also found the FDA had effectively adopted a flavor ban.¹³

52. This confusion must be corrected since that is not the Center’s Congressional mandate.

53. As a federal agency, FDA is subject to the requirements of the Administrative

¹² *En Banc, Wages & White Lion opinion.*

¹³ “FDA’s categorical ban has other statutory problems. For example, the TCA states that FDA must follow notice-and-comment procedures before adopting a “tobacco product standard.” See 21 U.S.C. § 387g(c)–(d). And Congress specifically called a ban on tobacco flavors a “tobacco product standard”....”

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).

54. FDA’s MDO is a “final agency action” for which there is no other adequate remedy.

55. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law in issuing the MDO to RDI.

56. Specifically, FDA acted arbitrarily, capriciously, and otherwise not in accordance with applicable law in issuing the MDO because the agency (i) failed to provide the customary notice scientific review had begun, (ii) failed to follow the timing requirements set forth in 21 C.F.R. §1114.27(c)(1), (iii) failed to communicate with Petitioner any deficiencies or provide any opportunity to clarify and/or correct its submission prior to the MDO, and (iv) as the Fifth Circuit, where Petitioner resides, recently held “...sent manufacturers of flavored e-cigarette products on a wild goose chase.”¹⁴

57. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law by providing a boilerplate MDO, identical to other MDOs, some 20 months after completing the filing review without the customary notice that scientific review had begun or a Deficiency Letter.

58. FDA acted arbitrarily, capriciously, and otherwise not in accordance with law by failing to abide by the fair notice doctrine, which, as the Fifth Circuit held, “...given the

¹⁴ *En Banc, Wages & White Lion opinion.*

MDOs in this case will unquestionably put petitioners out of business...we take it as undisputed that the fair notice doctrine applies.”¹⁵

59. The FDA’s generalized and arbitrary review process will likely be further demonstrated by the Technical Project Lead review report (“TPL Report”). A Freedom of Information Act request has been submitted requesting the TPL Report, but it was not received by the deadline to submit this Petition. TPL Reports are meant to provide a record of the substantive review of each PMTA submitted, providing specific comments from the technical or scientific review of each product. Since the MDO is boilerplate, as explained above, it is expected the TPL will be cursory boilerplate as well.

CONCLUSION

60. 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.

¹⁵ *Id.*

Respectfully Submitted,



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