

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

AMERICAN ACADEMY OF
PEDIATRICS, *et al.*,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG
ADMINISTRATION, *et al.*,

Defendants.

Civil Action No. 8:18-cv-883-DLB

STATUS REPORT

In accordance with the Court’s revised remedial order (ECF No. 202), Defendants respectfully report as follows:

1. Covered Applications: This report includes information about “Covered Applications” as defined in paragraph 7 of the Court’s revised remedial order. The FDA has used the same method for determining which applications constitute Covered Applications as it did in its most recent status report (ECF No. 216). Before filing this status report, Defendants conferred with Plaintiffs, who agreed that the set of brands covered by paragraph 7 of the revised remedial order is the same as in that status report.

2. Overall Progress: The FDA remains committed to completing review of the applications it has received as soon as feasible to protect and promote the public health. As of December 31, 2023, the FDA had taken action on 72% of Covered Applications. Although the FDA did not take action on the percentage of Covered Applications it had expected to take action on by December 31, 2023, it took action on 91% of the Covered Applications by the time of this report.

In its prior status reports, the FDA estimated that it would take action on 100% of Covered Applications by December 31, 2023, but also noted that that estimate “may change as the agency

considers the D.C. Circuit’s opinion” in *Fontem US, LLC v. FDA*, 82 F.4th 1207 (D.C. Cir. 2023) (affirming in part and vacating and remanding in part Marketing Denial Orders for certain e-cigarette products). ECF No. 216, at 2. There are several reasons why the FDA has now revised its estimated completion date of December 31, 2023, which was first articulated in a status report filed by the FDA a year ago. ECF No. 211.

First, the FDA received late amendments¹ from the majority of entities covered by this Court’s revised remedial order. ECF No. 202. Many of these amendments contain substantial data and scientific explanation. The amendments range from a few pages to hundreds of pages and were received on a rolling basis, with the most recent 2023 amendment being filed in December 2023.

Second, more generally, during the course of 2023, the FDA has navigated many other challenges related to review of the Covered Applications. In total, including applications that the FDA resolved prior to the reporting requirement, as well as the applications that the FDA resolved in the past two years, the FDA has taken action on more than 100 Covered Applications. Those actions, however, have resulted in numerous legal challenges to the FDA’s marketing orders, both in the courts of appeals and through the FDA’s administrative review process. In the past year, the Second, Third, Fifth, Ninth, and D.C. Circuits have each issued significant decisions regarding the FDA’s marketing denial orders. *See, e.g., R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182 (5th Cir. 2023); *Fontem US, LLC v. FDA*, 82 F.4th 1207 (D.C. Cir. 2023); *Logic Tech. Dev. LLC v. FDA*, 84 F.4th 537 (3d Cir. 2023); *see also Magellan Tech., Inc. v. FDA*, 70 F.4th 622 (2d Cir. 2023); *Lotus Vaping Tech., LLC v. FDA*, 73 F.4th 657 (9th Cir. 2023); *Wages and White Lion Invs. LLC v. FDA*, No. 21-60766, --- F.4th ---, 2024 WL 30287 (5th Cir. Jan. 3, 2024) (hereinafter “*Triton*”).² By necessity, the FDA has carefully reviewed each decision and in some cases has

¹ The FDA can send a deficiency letter to an applicant requesting additional information needed to complete scientific review. In such a letter, the FDA will specify the number of days an applicant has to respond. A late amendment is an amendment received after that deadline.

² The applications at issue in *Magellan*, *Lotus*, and *Triton* were not Covered Applications.

adjusted its approach to ensure that it continues to issue orders that are appropriate on both the facts and the law. Those legal reviews often take significant time.

Despite these complexities, the FDA has now taken action on over 99% of the nearly 26 million deemed products for which applications were submitted. This includes determinations on applications for nearly 6.7 million products received by the Court's September 9, 2020 deadline, more than 18 million products received after the September 9 deadline, and applications for nearly 1 million non-tobacco nicotine products submitted by May 14, 2022.³ In addition, for Covered Applications, the FDA has taken action on 97% of non-tobacco flavored, non-menthol flavored e-cigarette products which have been of particular interest to Plaintiffs. *See American Academy of Pediatrics, Flavored E-Cigarette and Tobacco Products, available at <https://www.aap.org/en/advocacy/state-advocacy/flavored-e-cigarette-and-tobacco-products/>* (accessed January 22, 2024).

The FDA now expects to take action on 94% of Covered Applications by March 31, 2024, and on all remaining Covered Applications by June 30, 2024. This revised estimate is necessary for the reasons above. In particular, several of the applicants in question have recently filed amendments—including some after the FDA's most recent status report, with the most recent amendment being filed on Saturday, January 13, 2024. Additionally, continued review is necessary in light of recent judicial decisions in relevant litigation, including (as previewed in the FDA's most recent status report) the D.C. Circuit's decision in *Fontem*. Further, several of these remaining applications present complex scientific issues that require careful review and consideration.

³ Non-tobacco nicotine ("NTN") describes nicotine that does not come from a tobacco plant. Congress passed a federal law which went into effect on April 14, 2022, clarifying that the FDA has the authority to regulate tobacco products containing NTN. More than 200 companies submitted nearly 1,000,000 applications for NTN products, and as of October 2023, the FDA has made determinations on over 98% of the applications received. *See FDA, Regulation and Enforcement of Non-Tobacco Nicotine (NTN) Products, available at <https://www.fda.gov/tobacco-products/products-ingredients-components/regulation-and-enforcement-non-tobacco-nicotine-ntn-products>* (accessed Jan. 22, 2024).

3. In accordance with the revised remedial order, ECF No. 202, the FDA will file another status report on or before April 22, 2024.

DATE: January 22, 2024

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