IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

American Academy of Pediatrics, *et al.*, Plaintiffs, v. **Food and Drug Administration**, *et al.*, Defendants.	Case No. PWG-18-883

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. Under that definition:

a. Covered Applications are limited to applications for "New Products," which are defined in paragraph 1 of the revised remedial order as new tobacco products on the market as of August 8, 2016. To determine whether a product was on the market as of August 8, 2016, the FDA has used information previously reported by manufacturers about whether the product was on the market on that date, but has not independently verified that information.[1]

[1] The FDA identified two applications for products sold under the relevant brand names where the applicant stated that the products were not on the market as of August 8, 2016. The FDA also identified three other applications for products sold under the relevant brand names where the applicant did not state whether the products were on the market as of August 8, 2016. The FDA has not included information about these five applications in this status report.

b. Covered Applications are further limited to applications "filed by" September 9, 2020. For purposes of this status report, the FDA has treated an application as "filed by" September 9, 2020, if the application was submitted to the FDA by 11:59 P.M. EDT on September 9, 2020.

c. Covered Applications are also limited to applications for products that are: "(a) sold under the brand names JUUL, Vuse, NJOY, Logic, Blu, SMOK, Suorin, or Puff Bar, or (b) reach 2% of total 'Retail $ Sales' in Nielsen's 'Total E-Cig Market & Players' or 'Disposable E-Cig Market & Players' reports." Defendants conferred with Plaintiffs, who agreed that only one brand beyond those listed in paragraph 7(a) meets the 2% threshold identified in paragraph 7(b).

To determine which applications are for products sold under these brand names, the FDA used its internal premarket tobacco application database, which organizes applications by manufacturer. The FDA searched its database for these brand names to identify the manufacturers related to each relevant brand name. The FDA then searched its database to identify applications submitted by these manufacturers.

d. To calculate the percentages in this report, the FDA has counted each tobacco product for which a marketing order was sought as a separate application, even if the manufacturer made a single submission for multiple products.

2. **Overall Progress:** The FDA is committed to completing review of the applications it has received as soon as feasible to protect and promote the public health. To date, the FDA has resolved — e.g., issued a refuse-to-accept letter, a refuse-to-file letter, a marketing denial order, or a marketing order for — over 99% of the more than 6.5 million timely applications it received. *See* FDA, *FDA Issues Marketing Denial Orders to Fontem US for myblu*

Products, *available at* https://www.fda.gov/tobacco-products/ctp-newsroom/fda-issues-marketing-denial-orders-fontem-us-myblu-products (Apr. 8, 2022).

Of those applications, based on the criteria described in paragraph 1, the FDA has identified 240 Covered Applications. The following estimates represent the FDA's best forecast based on current information. Overall, the FDA expects to have taken action on:

51% of Covered Applications by June 30, 2022;

52% of Covered Applications by September 30, 2022;

56% of Covered Applications by December 31, 2022;

56% of Covered Applications by March 31, 2023; and

100% of Covered Applications by June 30, 2023.

The FDA's progress largely reflects the review priorities that the agency established in 2020, when review began. Given the large influx of concurrent applications, the FDA prioritized review of applications from manufacturers with the greatest market share at the time because decisions on those applications were expected to have the greatest impact on public health. As a result, the FDA allocated significant resources to review applications from the five companies whose brands represented over 95% of the e-cigarette market at that time: Fontem (blu), JUUL, Logic, NJOY, and R.J. Reynolds (Vuse). The FDA expects to have resolved 63% of the applications in its original priority set by June 30, 2022, and 72% of the applications in its original priority set by the end of this year.

Moreover, not every Covered Application has an equal potential impact on the public health. For example, more than 25% of the Covered Applications are for products not currently on the market. Also, some e-cigarette devices consist of a small number of components, resulting in a small number of individual product applications for the entire system. A disposable pre-filled device, for example, could constitute a single product, with one application. Other e-

cigarette devices, by contrast, consist of many components, with separate tanks, coils, tubes, and pods, resulting in dozens of separate product applications for a single system. Of the Covered Applications that the FDA anticipates will remain to be resolved beyond the end of 2022, more than half are for components of a limited number of e-cigarette device systems representing under 2.5% of the e-cigarette market. The FDA has made and will continue to make significant progress in reviewing and resolving applications for e-cigarette products to achieve the greatest impact on public health.

3. In accordance with the revised remedial order, the FDA will file another status report by July 29, 2022, reporting any revisions to these estimates.

Dated: May 13, 2022

Respectfully submitted,

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