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Timeline of Recent Actions by FDA Center for Tobacco Products; Focus on Addressing Increase in Underage Use of Certain E-Cigarettes

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The U.S. Food and Drug Administration (FDA) is expected to announce today detailed plans to curtail the growing number of youth who are using certain types of e-cigarette products. Below is a summary of the Agency's recent actions and compliance deadlines.

September 12, 2018 Letters to Vuse, Blu, JUUL, MarkTen XL, and Logic

- On September 12, FDA sent letters to the manufacturers of five Electronic Nicotine Delivery System (ENDS) products (Vuse [British America Tobacco], Blu [Imperial Brands], JUUL [JUUL Labs], MarkTen [Altria] and Logic [Japan Tobacco]) "requiring them to submit important documents to better understand the reportedly high rates of youth use and the particular youth appeal of their products." These cartridge-based (closed system) products account for 97% of the closed-system cartridge-based e-cigarette market.

- FDA indicated that it believes e-cigarette use by youth "is reaching epidemic proportions". FDA Commissioner Dr. Scott Gottlieb asked the five manufacturers to "come back to the FDA in 60 days with robust plans on how they'll convincingly address the widespread use of their products by minors, or [FDA will] revisit the FDA's exercise of enforcement discretion for [flavored ENDS] products currently on the market." Dr. Gottlieb continued, "This may require those brands to revise their sales and marketing practices, including online sales; to stop distributing their products to retailers who sell to kids; and to remove some or all of their flavored e-cig products from the market until they receive premarket authorization and otherwise meet applicable requirements."

- In an October 31 Statement, Commissioner Gottlieb announced that he had met with the five manufacturers and heard their comments and proposals on how each company would address sales to minors, and how each company thought FDA should regulate to address the same issue. Altria subsequently announced that it would cease sales of its MarkTen cartridge-based products, as well as its flavored cigalike products other than tobacco and menthol; Fontem Ventures indicated it will tighten its age-verification process and raise the age for online sales to 21; and JUUL has announced that it will only permit the sale of flavored products (e.g., cucumber, mango, crème and fruit) through its age-verified online-

store, while restricting brick-and-mortar retailers to only tobacco, mint and menthol-flavored pods. JUUL further announced it would be increasing retailer compliance efforts, reduce its social media presence, and develop technology to further reduce use of its products by youth.

October 12, 2018 Letters to 21 Manufacturers Regarding Potentially Unauthorized New Tobacco Products

- On October 12, FDA "sent letters to 21 e-cigarette companies . . . seeking information about whether more than 40 products . . . are being illegally marketed and outside the agency's current compliance policy." These letters asked manufacturers to provide documentation within 30 days of receipt demonstrating that the identified products were on the market on August 8, 2016 have not been modified since that date.

- This effort is a clear indication that FDA intends to ramp up its enforcement of the marketing authorization provisions and that ENDS products introduced to the market after August 8, 2016 can expect enforcement.

October 22 – 23, 2018 FDA Public Meeting on Tobacco Product Application Review

- FDA held a meeting (video available) to discuss FDA's review of premarket applications.

- Topics included:

    - Substantial Equivalence (and requests for exemption);
    - Premarket Tobacco Product Applications (PMTAs);
    - Modified Risk Tobacco Product Applications (MRTPAs);
    - Pre-submission meetings;
    - Tobacco Product Master Files (TPMFs);
    - Resources available;
    - Environmental Assessments; and
    - Newly Deemed Tobacco Products

November 8, 2018 Ingredient Listing for Small-Scale Tobacco Product Manufacturers

- Ingredient Listing submissions were due to FDA on November 8 for small-scale manufacturers of Newly Deemed Tobacco Products. Ingredient listing is a requirement for all tobacco products marketed in the United States, regardless of where manufactured.

- For small-scale manufacturers impacted by recent natural disasters, FDA has extended the deadline to submit until May 8, 2019.

- In a revised guidance published in April 2018, FDA clarified that it now intends to enforce the ingredient listing requirement only with respect to those tobacco product components or parts, such as e-liquids, that are made or derived from tobacco, or contain ingredients that are burned, aerosolized or ingested (i.e., consumed) during use.

December 5, 2018 Public Hearing Announced to Discuss FDA's Efforts to Eliminate Youth Electronic Cigarette Use

- As previously reported on Keller and Heckman's Daily Intake blog, On November 2, 2018 FDA announced a public hearing on December 5, 2018 to discuss continued efforts to curb e-cigarette use and to aid cessation amongst youth. Topics of interest noted in Dr. Gottlieb's press release focus on cessation and include:
    - Potential role of drug therapies to support cessation of e-cigarettes and traditional tobacco products use (including cigarettes and smokeless tobacco) amongst youth;
    - Behavioral interventions to aid in cessation;
    - Development of cessation drugs;
    - Development of methods, study designs, and measures for evaluating drugs for use in youth cessation; and
    - Funding opportunities for research on youth use, attitudes, and cessation.

Modification to FDA's Unified Registration and Listing System Tobacco Registration and Listing Module

- In early November, FDA updated its FDA Unified Registration and Listing (FURLS) Tobacco Registration and Listing Module (TRLM) to be more user friendly. The information required for registering a facility and providing product lists does not appear to have changed, but the process should be simpler and more user-friendly.

- As a reminder, facility registrations must be renewed annually by December 31. Changes to product lists to reflect new products being manufactured, products no longer being manufactured, or changes to labeling/packaging, advertising, or consumer information, must be made by June 30 and December 31 every year. This means that any labels that have changed to include FDA's required nicotine warning statement, for example, will need to be updated in FURLS.

Impending FDA Actions

- In recent weeks, FDA has announced through the press that it is considering banning, or otherwise severely limiting, the sales of flavored (except tobacco and menthol), cartridge-based e-liquids in convenience stores and gas stations, and that it is considering proposing a rule to ban menthol in cigarettes as well as characterizing flavors in other combusted tobacco products (e.g., cigars).

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