EXHIBIT A

Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*

Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to https://www.regulations.gov. Alternatively, submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with docket number FDA-2019-D-0661.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. ET.

Additional copies are available online at https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

April 2020

* This is a revision to the first edition of this guidance, which issued in January 2020.

For ENDS products marketed without FDA authorization, FDA intends to prioritize enforcement against:

- Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);
- All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
- Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors.[3]

Further, FDA intends to prioritize enforcement of any ENDS product that is offered for sale after September 9, 2020, and for which the manufacturer has not submitted a premarket application (or after a negative action by FDA on a timely submitted application).

This guidance does not in any way alter the fact that it is illegal to market any new tobacco product without premarket authorization. FDA is continuously evaluating new information and adjusting its enforcement priorities in light of the best available data, and it will continue to do so with respect to these products. FDA will take appropriate action regarding tobacco products that are marketed without premarket authorization, including as warranted based on changed circumstances, new information, or to better address minors' use of those products.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Statutory and Regulatory History

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) granted FDA the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors. The Tobacco Control Act also gave FDA the authority to issue regulations deeming other products that meet the statutory definition of a tobacco product[4] to be subject to chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387 through 387u) (section 901(b) of the FD&C Act).

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[3] For purposes of this Final Guidance, FDA's use of the term "minor" refers to individuals under the age of 21. This is consistent with the Further Consolidated Appropriations Act, 2020 (H.R. 1865), signed into law on December 20, 2019, which included a provision amending section 906(d) of the Federal Food, Drug, and Cosmetic Act to increase the federal minimum age to purchase tobacco products from 18 to 21, and adding a provision that it is unlawful for any retailer to sell a tobacco product to any person younger than 21 years of age. In addition, FDA is working to update our regulations within 180 days, consistent with the timeline set forth in the law.

[4] 21 U.S.C 321(rr) (section 201(rr) of the FD&C Act).

In accordance with that authority, on May 10, 2016, FDA issued a final rule deeming all products that meet the statutory definition of a tobacco product, except accessories of deemed tobacco products, to be subject to FDA's tobacco product authority. This included electronic nicotine delivery systems (ENDS), cigars, waterpipe (hookah) tobacco, pipe tobacco, nicotine gels, and dissolvables that were not already subject to the FD&C Act (81 FR 28974 at 28976 (May 10, 2016)).

The requirements in Chapter IX of the FD&C Act now apply to deemed products. Particularly relevant to this guidance is section 910, which imposes certain premarket-review requirements for "new tobacco products"—*i.e.*, those that were not commercially marketed in the United States as of February 15, 2007. Accordingly, after the rule's effective date, deemed new tobacco products were required to obtain premarket authorization under Section 910. Deemed new tobacco products that remain on the market without marketing authorization are marketed unlawfully in contravention of the Tobacco Control Act. Through the premarket review process, FDA conducts a science-based evaluation to determine whether a new tobacco product meets the applicable statutory standard for marketing authorization—for example, whether the product is appropriate for the protection of public health with respect to the risks and benefits to the population as a whole, including users and nonusers, and taking into account, among other things, the likelihood that those who do not use tobacco products will start using them.

The preamble to the May 10, 2016, final deeming rule explained that FDA intended to defer enforcement for failure to have premarket authorization during two compliance periods related to premarket review: one for submission and FDA receipt of applications and one for obtaining premarket authorization. The first compliance period depended on the type of application. The compliance date was 12 months from the effective date of the rule for substantial equivalence exemption requests (EX REQs), 18 months for substantial equivalence reports (SE Reports), and 24 months for premarket tobacco applications (PMTAs). In addition, the preamble explained that under the second compliance period:

> Unless FDA has issued an order denying or refusing to accept the submission, products for which timely premarket submissions have been submitted will be subject to a continued compliance period for 12 months after the initial compliance period described previously. For such products, FDA does not intend to initiate enforcement for failure to have premarket authorization during this continued compliance period.[5]

The preamble further explained that this compliance policy did not apply to any new tobacco product that was not on the market on August 8, 2016. Significantly, this policy did not confer lawful marketing status on new tobacco products being marketed without the necessary premarket authorization.

In May 2017, FDA published a guidance document, *Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule*, under which the Agency, as

[5] 81 FR at 29011.

E-liquids are a type of ENDS product and generally refer to liquid nicotine and nicotine-containing e-liquids (*i.e.*, liquid nicotine combined with colorings, flavorings, and/or other ingredients). Liquids that do not contain nicotine or other material made or derived from tobacco, but that are intended or reasonably expected to be used with or for the human consumption of a tobacco product, may be components or parts and, therefore, subject to FDA's tobacco control authorities.

Label means a display of written, printed, or graphic matter upon the immediate container of any article. Section 201(k) of the FD&C Act.

Labeling means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. Section 201(m) of the FD&C Act.

New tobacco product means (1) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (2) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. Section 910(a) of the FD&C Act.

Tobacco product means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term "tobacco product" does not mean an article that under the FD&C Act is a drug (section 201(g)(1) (21 U.S.C 321(g)(1))), a device (section 201(h)), or a combination product (section 503(g) (21 U.S.C 353(g))). Section 201(rr) of the FD&C Act.

IV. ENFORCEMENT PRIORITIES REGARDING CERTAIN ENDS PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION

A. Overview

The Tobacco Control Act provides that new tobacco products (*i.e.*, non-grandfathered products) may not legally be marketed without premarket authorization. Accordingly, all deemed new tobacco products on the market without authorization are illegally marketed products.

Beginning February 6, 2020, FDA intends to prioritize enforcement of the premarket review requirements for certain ENDS products, including against retailers selling such products. Specifically, FDA intends to prioritize enforcement against:

(1) Flavored, cartridge-based ENDS products (except for tobacco- or menthol-flavored products);
(2) All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and

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