EXHIBIT 7

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.

Table of Contents

Contains Nonbinding Recommendations

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

Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance document describes how we intend to prioritize our enforcement resources with regard to the marketing of certain deemed tobacco products that do not have premarket authorization.[2]

[1] This guidance was prepared by the Office of Compliance and Enforcement, Office of Health Communication and Education, Office of Regulations, and Office of Science in the Center for Tobacco Products at FDA.

[2] As with FDA's prior compliance policies on deemed new tobacco products that do not have premarket authorization, this guidance document does not apply to any deemed product that was not on the market on August 8, 2016.

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).

---

[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).

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.