0002, email: *CTPRegulations@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised).''

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act) into law. The Tobacco Control Act grants FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally 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 to be subject to chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

In accordance with that authority, on May 10, 2016, FDA issued a final rule entitled ''Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act: Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products'' (the final deeming 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 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 (21 U.S.C. 387 through 387u) now apply to deemed tobacco products. This includes section 910 (21 U.S.C. 387j), 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 of the FD&C Act. Deemed new tobacco products that remain on the market without marketing authorization are marketed unlawfully in contravention of the Tobacco Control Act.

On January 2, 2020, FDA issued a final guidance entitled ''Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization'' to communicate its enforcement priorities with respect to ENDS products (January 7, 2020; 85 FR 720) (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market*). It also stated that manufacturers of other deemed tobacco products would be required to submit marketing applications for those products by May 12, 2020.

On April 22, 2020, the court granted a motion for a 120-day extension (until September 9, 2020) in light of the global outbreak of respiratory illness caused by a new coronavirus.[1] Accordingly, FDA is revising the guidance to change the date required to submit premarket authorization applications to the Agency from May 12, 2020, to September 9, 2020.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of the Agency's enforcement priorities with respect to ENDS products and the submission of marketing applications for other deemed tobacco products. 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.

III. Paperwork Reduction Act of 1995

This final guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR 1107.1(b) and (c) have been approved under OMB control number 0910–0684; the collections of information under section 910 of the FD&C Act have been approved under OMB control number 0910–0768. The collections of information in section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) have been approved under OMB control number 0910–0673.

[1] *American Academy of Pediatrics, et al.* v. *Food and Drug Administration, et al.,* Case No. 8:18–cv–883 (PWG), (D. Md. April 22, 2020), Dkt. No. 182.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at either *https://www.regulations.gov* or *https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.*

Dated: April 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Correction to Establishment and Solicitation of Nominations for Tribal Advisory Council

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice; correction.

SUMMARY: HRSA is soliciting comments and recommendations regarding HRSA's intent to establish the HRSA Tribal Advisory Council (TAC) and is seeking nominations of qualified tribal officials as candidates for consideration for appointment as voluntary delegate members of the HRSA TAC. Due to delays caused by the global impact of the Coronavirus Disease 2019 (COVID–19), HRSA is extending the deadline for the submissions of nominations of qualified tribal officials for consideration for appointment as voluntary delegate members of the HRSA TAC. Nominations for membership must now be received on or before July 6, 2020. This 60-day extension will allow tribes and tribal serving organizations the additional time needed to identify qualified tribal officials as candidates and submit comprehensive nomination packages.

FOR FURTHER INFORMATION CONTACT: CAPT Elijah K. Martin, Jr. EdD, MPH, Manager, Tribal Health Affairs, Office of Health Equity, HRSA, 5600 Fishers Lane, Room 13N44, Rockville, Maryland 20857, 301–443–7526, *aianhealth@hrsa.gov*.

Correction—Due to COVID–19, HRSA OHE is extending the deadline for HRSA TAC membership nominations by 60 days from May 7, 2020, to July 6, 2020.

Maria G. Button,

Director, Executive Secretariat.

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