Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. We note in this regard that FDA extended the compliance date for 21 CFR part 4, subpart B, until July 2020 for most combination products, and until January 2021 for the remainder, in response to stakeholder feedback, to ensure that Combination Product Applicants have sufficient time to update reporting and recordkeeping systems and procedures.[2] Consequently, entities subject to this rule have not yet had to comply with this information request.

Dated: April 23, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–09175 Filed 4–29–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–0661]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry entitled ''Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised).'' This is a revision to the guidance which describes, among other things, how FDA intends to prioritize its enforcement resources with regard to the marketing of ENDS products that do not have premarket authorization. FDA is revising this guidance to change the date required to submit premarket authorization applications to the Agency from May 12, 2020, to September 9, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on April 30, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–0661 for ''Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Gerie Voss, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993–

[2] See Compliance Policy for Combination Product Postmarketing Safety Reporting (April 2019) (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-policy-combination-product-postmarketing-safety-reporting*).

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.

[FR Doc. 2020–09164 Filed 4–29–20; 8:45 am]

BILLING CODE 4164–01–P

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.

[FR Doc. 2020–09229 Filed 4–29–20; 8:45 am]

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