TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Part 14; Subpart E—Members of Advisory Committees	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Advisory Committee Membership Nominations	391	1	391	0.25 (15 minutes)	98
Representative Member Submission of Updated Information.	54	1	54	0.25 (15 minutes)	14
Total			445		112

[1] There are no capital or operating and maintenance costs associated with the information collection.

Based on a review of data, we received 354 nominations for membership to FDA advisory committees in Fiscal Year (FY) 2015; we received 510 nominations in FY 2016; we received 500 nominations in FY 2017; we received 258 nominations in FY 2018; and we received 333 nominations in FY 2019. By averaging the number of nominations received annually over the past 5 years, we estimate there are approximately 391 respondents to the information collection. We estimate it takes respondents 15 minutes to complete an initial nomination, where accompanying documentation is already available or has been prepared in advance by respondents. Multiplying 15 minutes (0.25) by the number of respondents to the information collection (391) equals 97.75 (98 rounded) annual burden hours.

We have also included a burden estimate for members who currently serve on FDA advisory committees who are not Special Government and Regular Government Employees and who must submit an updated CV and an executed/completed consent form annually. Currently there are 54 authorized positions for these Representative members, mostly Industry Representatives. While some positions are vacant, we anticipate the positions will be filled during the year. The request for the updated CV and consent form will be made through email communications by the Designated Federal Officer of the committee. We anticipate that the burden to the respondent will be the same as that for new nominations. We estimate each response will require 15 minutes (0.25) for a total of 13.5 (14 rounded) annual hours.

Dated: January 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00041 Filed 1–6–20; 8:45 am]

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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; 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.'' The guidance 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.

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 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 ''Marketing of Unauthorized Deemed Tobacco Products: Enforcement Priorities for Certain Deemed Products on the Market Without Premarket Authorization.'' 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, Document Control Center, 10903 New Hampshire Ave., 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, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 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.''

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act) granted FDA the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless 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. In addition, the preamble to the final deeming rule explained that, for deemed tobacco products on the market as of August 8, 2016, FDA intended to defer enforcement for failure to have premarket authorization during two compliance periods: One for submission and FDA receipt of applications and one for obtaining premarket authorization (81 FR 28974 at 29011).

In May 2017, FDA published a guidance document entitled ''Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule,'' under which the Agency, as a matter of enforcement discretion, stated its intention to defer enforcement of any future compliance dates for requirements under the final deeming rule for an additional 3 months. In July 2017, FDA announced a new comprehensive plan for tobacco and nicotine regulation that would serve as a multiyear roadmap in an effort to significantly reduce tobacco-related disease and death. One aspect of the plan involved striking a balance between regulation and encouraging development of innovative tobacco products that may be potentially less harmful than cigarettes. The Agency announced that it planned to issue an updated compliance policy further deferring some enforcement timelines described in the final deeming rule. In accordance with this comprehensive plan, in August 2017, FDA stated its intention to further extend the period during which it did not intend to initiate enforcement action for the premarket review requirements under the final deeming rule (''August 2017 Compliance Policy'').

In March 2018, in *American Academy of Pediatrics, et al.* v. *Food and Drug Administration, et al.,* the August 2017 Compliance Policy was challenged in the U.S. District Court for the District of Maryland, and on May 15, 2019, the court issued an order that vacated the guidance.[1] On July 12, 2019, the court issued a further order directing FDA to require that premarket authorization applications for all new deemed tobacco products be submitted to the Agency within 10 months, by May 12, 2020, and providing for a 1-year period during which products with timely applications might remain on the market pending FDA review.[2] As required by the court's order, deemed new tobacco products on the market as of August 8, 2016, for which premarket authorization applications are not filed by May 12, 2020, are subject to FDA enforcement actions, in the Agency's discretion. The court subsequently clarified that its order did not restrict FDA's authority to enforce the premarket review provisions against deemed products, or categories of

[1] *American Academy of Pediatrics, et al.* v. *Food and Drug Administration, et al.,* 379 F. Supp. 3d 461, 496 (D. Md. 2019).

[2] *American Academy of Pediatrics, et al.* v. *Food and Drug Administration, et al.,* No. 8:18–cv–883 (PWG), 2019 WL 3067492, at *7 (D. Md. July 12, 2019) (Dkt. No. 127).

deemed products, prior to May 12, 2020, or during the one-year review period.

Since issuing the August 2017 Compliance Policy, FDA has received information underscoring the problem of youth use of ENDS products, as well as evidence of other new and continued public health concerns related to ENDS products. For example, data from the 2018 National Youth Tobacco Survey (NYTS), as described throughout the guidance, documented a significant increase in youth use of ENDS products and revealed the magnitude of the problem. These data prompted FDA to issue a draft guidance regarding the continued marketing of deemed tobacco products that had not obtained premarket authorization, and to call on industry to do more to keep their products out of the hands of minors. In March 2019, FDA published a draft guidance entitled ''Modifications to Compliance Policy for Certain Deemed Tobacco Products'' (''March 2019 Draft Guidance''), which discussed the Agency's plan to modify the August 2017 Compliance Policy and prioritize enforcement of the premarket authorization requirements for certain deemed tobacco products.

Recent data show a second consecutive year with an alarming increase in youth use of ENDS products. In 2019, two of the largest surveys of tobacco use among youth found that e-cigarette use has reached the highest levels ever recorded. The 2019 Monitoring the Future Study shows that e-cigarette use among 8th, 10th, and 12th graders who had used ENDS products during the previous 12 months and those who had ever used ENDS products significantly increased from 2018 to 2019. Data from the 2019 NYTS also show that 2019 was the second consecutive year in which current (past 30-day) e-cigarette use among youth reached unprecedented levels. Evidence from the 2016–2017 (Wave 4) Population Assessment of Tobacco and Health Study and other studies, as described in the guidance, further confirms these trends, including that youth are particularly attracted to flavored ENDS products.

Moreover, recent data indicate that youth overwhelmingly prefer cartridge-based ENDS products, which FDA has found are easy to conceal, can be used discreetly, may have a high nicotine content, and are manufactured on a large scale. The 2019 NYTS survey instrument included a measure for the ''usual brand'' of e-cigarette used in the past 30 days, and the majority of youth who were current e-cigarette users reported a cartridge-based e-cigarette as their usual brand.

Finally, FDA remains concerned about health and safety issues connected to ENDS products—*e.g.,* cases of lung injuries associated with use of vaping products as well as battery explosions with ENDS products—particularly given that all of these products have been marketed without premarket authorization. These current public health issues affirm the importance of the premarket review process, as contemplated by the Tobacco Control Act, to scientifically evaluate products based on a public health standard. For example, FDA review of premarket tobacco product applications considers the risks and benefits of the product to the population as a whole, including tobacco product users and non-users. In reviewing premarket tobacco product applications, FDA will consider, among other things: The product's components, ingredients, additives, and properties; manufacturing practices; and any studies or investigations into the health risks of the tobacco product.

The Agency views the dramatic increase in youth use of these products as a problem that requires an urgent response. Accordingly, FDA is issuing this final guidance to communicate its enforcement priorities with respect to ENDS products. FDA would adopt these enforcement priorities for ENDS regardless of the decision of the U.S. District Court for the District of Maryland in *American Academy of Pediatrics, et al.* v. *Food and Drug Administration, et al.*[3] Additionally, as described in the guidance, consistent with the court's order, manufacturers of other deemed new tobacco products will be required to submit marketing applications for those products by May 12, 2020.[4]

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 for premarket review requirements for certain deemed tobacco products and describes how the Agency intends to prioritize its enforcement resources with regard to the marketing of certain deemed tobacco products that do not have premarket authorization. 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 collections of information found in FDA regulations. 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.

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/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance.*

Dated: December 31, 2019.

Stephen M. Hahn,

Commissioner of Food and Drugs.

[FR Doc. 2019–28539 Filed 1–3–20; 8:45 am]

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[3] *American Academy of Pediatrics, et al.* v. *Food and Drug Administration, et al.,* 379 F. Supp. 3d 461, 496 (D. Md. 2019).

[4] *American Academy of Pediatrics, et al.* v. *Food and Drug Administration, et al.,* No. 8:18–cv–883 (PWG), 2019 WL 3067492, at *7 (D. Md. July 12, 2019) (Dkt. No. 127).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Update to the Women's Preventive Services Guidelines

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

ACTION: Notice.

SUMMARY: On December 17, 2019, HRSA approved an update to the HRSA-supported Women's Preventive Services Guidelines (Guidelines) that addresses health needs specific to women. The Guidelines are based on clinical recommendations from the Women's Preventive Services Initiative. Preventive care and screenings for women provided for in comprehensive guidelines supported by HRSA are required to be covered without cost-sharing by non-grandfathered group health plans and health insurance