

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Request for CLIA categorization	80	5	400	1	400	\$2,000

¹ There are no capital costs associated with this collection of information.

Based on recent receipt data for requests for CLIA categorization separate from a product application, the number of respondents is approximately 80. On average, each respondent requests such categorizations five times per year.

The cost, not including personnel, is estimated at \$5 per submission (5 × 400), totaling \$2,000. This includes the cost of copying and mailing copies of package inserts and a cover letter. The burden hours are based on FDA familiarity with the types of documentation typically included in a sponsor's categorization requests, and costs for basic office supplies (*e.g.*, paper). Upon review of this information collection, we have adjusted the estimated cost per submission (previously \$52). Because the submissions are typically only a few pages per package insert and copying or printing and postage for a few pages is not expected to be more than \$5, we believe this is a more appropriate cost burden estimate.

Our estimated burden for the information collection reflects an overall decrease of 500 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years. Also, upon review of this information collection, we believe the previous estimate may have included requests for categorization associated with a premarket submission, the burden estimate of which is included under the OMB approval for the applicable premarket submission. We have therefore revised the number of respondents/responses to include only those that are separate from a product application, consistent with the scope of this information collection.

Dated: October 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-23274 Filed 10-24-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0190]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 25, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to aira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0671. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act

OMB Control Number 0910-0671—Extension

The Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act and providing FDA with the authority to regulate tobacco products (Pub. L. 111-31; 123 Stat. 1776). Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (the Smokeless Tobacco Act) (15 U.S.C. 4402), as amended by section 204 of the Tobacco Control Act, requires, among other things, that all smokeless tobacco product packages and advertisements bear one of four required warning statements. Section 3(b)(3)(A) of the Smokeless Tobacco Act requires that the warnings be displayed on packaging and advertising for each brand of smokeless tobacco “in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer” to, and approved by, FDA.

This information collection-the submission to FDA of warning plans for smokeless tobacco products is statutorily mandated. The warning plans will be reviewed by FDA, as required by the Smokeless Tobacco Act, to determine whether the companies' plans for the equal distribution and display of warning statements on packaging and the quarterly rotation of warning statements in advertising for each brand of smokeless tobacco products comply with section 3 of the Smokeless Tobacco Act, as amended. Additionally, FDA considers a submission to be a supplement if the submitter is seeking approval of a change to an FDA-approved warning plan.

Based on FDA's experience over the past several years, FDA believes the estimate of 60 hours to complete an initial rotational plan continues to be accurate. If a supplement to an approved plan is submitted, FDA

estimates it will take half the time per response (30 hours).

In the **Federal Register** of June 13, 2019 (84 FR 27638), FDA published a

60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to

the four collection of information topics solicited.

FDA estimates the burden of this collection of information as follows:

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Activity	Numbers of respondents	Numbers of responses per respondent	Total annual responses	Average burden per response	Total hours	Total capital costs
Submission of Initial rotational plans for health warning statements	4	1	4	60	240	\$48
Supplement to approved plan	10	1	10	30	300	120
Total					540	168

¹ There are no operating and maintenance costs associated with this collection of information.

FDA estimates a total of 4 respondents will submit a new original warning plan and take 60 hours to complete a rotational warning plan for a total of 240 burden hours. In addition, 10 respondents will submit a supplement to an approved warning plan at 30 hours per response for a total of 300 hours. The total burden for this collection is estimated to be 540 hours.

Capital costs are based on 14 respondents mailing in their submission at a postage rate of \$12 for a 5-pound parcel (business parcel post mail delivered from the furthest delivery zone). Therefore, FDA estimates that the total postage cost for mailing the rotational warning plans to FDA to be \$168.

We have adjusted our burden estimate, which has resulted in a decrease of 5,460 hours and 86 respondents to the currently approved burden. We received a total number of 44 original smokeless warning plans, and a total of 17 supplements. After receiving the initial influx of original warnings plans, FDA does not expect to receive as many original warning plans annually. We expect that a few supplements will continue to be received as new products are marketed or as warning plans are revised. We anticipate a total number of 10 supplements submitted annually and 4 original smokeless warning plans.

Dated: October 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23250 Filed 10–24–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2686]

Medical Devices; Exemptions From Premarket Notification: Class II Devices; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing its intent to exempt a list of class II devices from premarket notification requirements, subject to certain limitations. The Agency has determined that, based on established factors, these devices no longer require premarket notification to provide reasonable assurance of safety and effectiveness. FDA is publishing this notice to obtain comments regarding the proposed exemptions, in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the notice by December 24, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 24, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 24, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–N–2686 for “Medical Devices; Exemptions from Premarket Notification: Class II Devices; Request for Comments.” Received comments, those filed in a timely manner (see