4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0086]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Potential Tobacco Product Violations Reporting Form

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0716. 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.

Potential Tobacco Product Violations Reporting Form

OMB Control Number 0910-0716--Extension

This information collection supports the opportunity to accept consumer and other stakeholder feedback and notification of potential violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Tobacco Control Act. Tobacco products are generally governed by chapter IX of the FD&C Act (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t). The FD&C Act provides FDA authority to monitor compliance with Federal tobacco laws and regulations and take corrective action when violations occur.

As part of its enforcement strategy, FDA accepts information from the public regarding potential tobacco product violations of the FD&C Act. Potential tobacco product violations include (but are not limited to): (1) sales to underage purchasers (persons under 21); (2) flavored cigarette sales; (3) illegal marketing and advertising; (4) distribution of free samples of tobacco products except in limited circumstances; (5) placement of cigarette or smokeless tobacco product vending machines in prohibited areas (or providing access to self-service or direct access of tobacco products in prohibited areas); and (6) sale of cigarettes in packages of less than 20.

FDA currently provides a form that may be used to collect this information from the public (Form FDA 3779, Potential Tobacco Product Violations Report). The Potential Tobacco Product Violations Report, Form FDA 3779, asks for the following information: (1) date potential violation occurred; (2) product type (e.g., cigarette, smokeless, roll-your-own, cigar, e-cigarette, hookah, pipe tobacco); (3) tobacco brand; (4) potential violation type; (5) type of potentially violative promotional materials; (6) who potentially violated; (7) name, address, phone number, and email address of the potential violator (if known); (8) potential violator's website or internet address URL (if available); (9) description of the potential violation; and (10) any additional files or information pertinent to the potential violation.

The public and interested stakeholders can report possible tobacco product violations of the FD&C Act by submitting information on Form FDA 3779 online, via email or postal mail, or by calling FDA's Tobacco Call Center. Information on how to submit possible tobacco product

violations using the options above can be found at https://www.accessdata.fda.gov/scripts/ptvr/index.cfm. Further details about reporting possible tobacco product violations of the FD&C Act can also be found at https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation.

In the *Federal Register* of February 2, 2023 (88 FR 7091), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received that was PRA related.

(Comment) The form does not have a specific option under "Potential violation type" for reporting products that have not gone through any of the new pathways to market required by the Tobacco Control Act, including the Premarket Tobacco Product Application (PMTA). The lack of this option may be confusing and make it difficult for members of the public who want to report such violations to determine what sort of violation they are reporting. Thus, we recommend FDA add "Product without a marketing authorization" or a similar category title, as an option under "Potential violation type".

(Response) FDA has reviewed the comment requesting revisions to the Potential Tobacco Product Violations Report, Form FDA 3779 (Potential Tobacco Violation Report Form). The comment correctly points out that the Potential Tobacco Violation Report Form provides the public with a mechanism to report potential violations of the tobacco laws and regulations enforced by the FDA. FDA agrees that a revision to the Potential Tobacco Violation Report Form is warranted and would assist the public in reporting potential violations related to the premarket review and authorization requirements under the law.

The Potential Tobacco Violation Report Form includes some specific options related to potential violation types that are often reported, including, but not limited to, those related to the retail sale of tobacco products to underage purchasers, flavored cigarette sales, the distribution of free samples of tobacco products, and other marketing and advertising requirements. The form

has been updated to include an additional potential violation type: "Unauthorized Tobacco Product."

The Potential Tobacco Violation Report Form is one of many ways the public can report potential tobacco product violations directly to FDA. The public and interested stakeholders can also provide detailed descriptions of potential violations by phone, e-mail, and through the mail.

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

Table 1.--Estimated Annual Reporting Burden[1]

Activity and Form FDA 3779	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Reporting potential tobacco product violations of the FD&C Act	3,000	2	6,000	0.25 (15 minutes)	1,500

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

The burden hour estimates for this collection of information were based on the type and rate of reporting submitted through the Potential Tobacco Violation Report Form and based on a review of the information collection since our last request for OMB approval. FDA estimates that submitting the information (online, telephone, email, or mail) will take 0.25 hours (i.e., 15 minutes) per response.

FDA estimates the number of annual respondents to this collection of information will be 3,000, who will each submit 2 reports. Each report is expected to take 0.25 hours to complete and submit; therefore, total burden hours for this collection of information is estimated to be 1,500 hours (6,000 responses x 0.25 hours per response).

Our estimated burden for the information collection reflects an overall increase of 157 hours and a corresponding increase of 630 responses. FDA attributes this adjustment to an increase in the number of submissions received over the last few years.

Dated: July 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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