CENTER FOR TOBACCO PRODUCTS

Potential Tobacco Product Violations Reporting Form

OMB Control No. 0910-0716

SUPPORTING STATEMENT

Terms of Clearance: None.

Part A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) programs. Tobacco products are generally governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (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): Sales to underage purchasers (persons under 21); Flavored cigarette sales; Illegal marketing and advertising; Distribution of free samples of tobacco products except in limited circumstances; 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 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 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. Instructions on how to report possible tobacco product violations of the FD&C Act can be found at (https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation).

We therefore request extension of OMB approval of information collection provisions as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The Potential Tobacco Product Violations Report, Form FDA 3779, asks for the following information:

- Date potential violation occurred;
- Product type (e.g., cigarette, smokeless, roll-your-own, cigar, e-cigarette, hookah, pipe tobacco);
- Tobacco brand;
- Potential violation type;
- Type of potentially violative promotional materials;
- Who potentially violated;
- Name, address, phone number, and email address of the potential violator (if known);
- Potential violator's website or internet address URL (if available);
- Description of the potential violation; and
- Any additional files or information pertinent to the potential violation.

The information collected will assist FDA in its investigation of violative firms. This collection of information is being collected from the public.

3. Use of Improved Information Technology and Burden Reduction

Information on reported violations may currently be provided to FDA online, via the Tobacco Call Center (toll-free telephone number), email, or by mail by using Form FDA 3779. Instructions on how to report possible tobacco product violations of the FD&C Act can be found at https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation. It is expected that 99 percent of the users of this program will submit their information electronically.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information collection imposes no undue burden on small entities.

6. Consequences of Collecting the Information Less Frequently

FDA will be hindered in its enforcement efforts without the ability to collect information on potential tobacco product violations of the FD&C Act. FDA continues to build its staff, resources, and State/local partnerships needed to enforce the tobacco product provisions of the FD&C Act. Therefore, the assistance of the public in reporting potential violations is an important piece of FDA's enforcement strategy.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This section is not applicable.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the FEDERAL REGISTER of February 02, 2023 (88 FR 7091). One comment that was PRA related was received.

(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.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

Among the laws governing the disclosure of information submitted under section 901 of the FD&C Act are the Freedom of Information Act (FOIA) (5 U.S.C. 552) and FDA's implementing regulations. Under FOIA, the public has broad access to agency records, unless the records (or a part of the records) are protected from disclosure by any of the law's nine exemptions.

CTP also identified privacy compliance requirements and coordinated with FDA's Privacy Officer to ensure responsible offices in CTP satisfy all in accordance with law and policy. FDA's web and privacy policies are provided on all FDA internet (FDA.gov) pages the PIA provides further notice.[1] The Center for Tobacco Products (CTP) Electronic Submissions system (eSub) is a suite of database-supported applications that facilitates the collection, logging, tracking, and retrieval of documents provided to the FDA by the tobacco industry and others (e.g., adverse experience reports from the general public). CTP uses this data to evaluate tobacco products, develop policy, and assess industry compliance with the Family Smoking Prevention and Tobacco Control Act. CTP received HHS approval on the privacy impact assessment for the Electronic Submissions system and was assigned PIA ID: 2060831.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

FDA estimates the number of respondents based on current reporting experience.

FDA estimates the burden for this information collection as follows:

[1] https://www.fda.gov/about-fda/about-website/website-policies#privacy

12a. *Hour Burden Estimate*

In the burden hour table below, we calculate a total of 3,000 respondents.

Table 1.--Estimated Annual Reporting Burden					
Activity and Form FDA 3779	No. of Respondents	Annual Frequency per Response	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

Reporting Burden

FDA estimates that submitting the information (online, telephone, email or mail) will take 0.25 hours (i.e., 15 minutes) per response. Based on the type and rate of reporting that has been submitted through the Potential Tobacco Violation Report Form in the past.

FDA estimates the number of annual respondents to this collection of information will be 3,000, who will each submit 2 reports by online form, telephone, email or mail. 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).

12b. *Reporting Cost Burden Estimate*

FDA estimates the cost burden of this collection of information as follows.

Estimated Annual Reporting Cost			
Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Reporting potential tobacco product violations of the FD&C Act	1,500	$74.72	$112,080
	Annual Responses	Cost of USPS Stamp	
Mailing Cost	60	$0.60	$36.00
		Total	$112,116.00

Because the Tobacco Call Center has a toll-free telephone number and an online form, FDA estimates that there is minimal cost to report a violation. FDA estimates that the average wage for an information worker is approximately $37.36 per hour, based on an estimate of wages retrieved from the Department of Labor's "Economic New Release" (May 2022) located at http://www.bls.gov/news.release/empsit.t24.htm. We double this to account for benefits and overhead, yielding an hourly wage rate of $74.72.

Additional costs associated with this collection pertain to the postage cost for mailing a letter containing the reported violation information. FDA estimates the total cost to submit a report via mail to be $36.00. This estimate is based upon 60 responses (1 percent of 6,000 total responses) being submitted via U.S. first-class mail and the cost of a first-class postage stamp at $0.60.

Therefore, the total cost to respondents is estimated to be $112,116.00.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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

14. Annualized Cost to the Federal Government

FDA's internal assessment estimates that the cost for processing a violation report is $19.00 per report. The total annual responses shown in Table 1 are estimated to be 6,000 responses per year. Thus, $19.00 x 6,000 responses = $114,000 per year.

15. Explanation for Program Changes or Adjustments

We have adjusted our burden estimate, which has resulted in an increase to the currently approved burden. The total estimated burden for this information collection is 1,500 burden hours, and 6,000 annual responses. Our estimated burden for the information collection reflects an overall increase of 157 hours and a corresponding increase of 630 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date Is Inappropriate

FDA is not requesting an exemption for display of the OMB expiration date and is also not seeking OMB approval to exclude the expiration date for this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.