

**Food and Drug Administration/Center for Tobacco Products  
Potential Tobacco Product Violations Reporting Form**

**0910-0716**

**SUPPORTING STATEMENT PART A**

**A. Justification**

**1. Circumstances Making the Collection of Information Necessary**

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

FDA is requesting Office of Management and Budget (OMB) approval for an extension of an existing collection of information to accept consumer and other stakeholder feedback and notification of potential violations of the FD&C Act, as amended by the Tobacco Control Act.

As part of its enforcement strategy, FDA created the Tobacco Call Center (with a toll-free number: 1-877-CTP-1373) to accept information from the public regarding potential violations of the Tobacco Control Act. Callers may report potential violations of the Tobacco Control Act, and FDA may conduct follow-up investigations based on information received. When reporting a potential violation, callers will be asked to provide as much information about the violation as they can recall, including: the date the 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, and the name, address, phone number, and e-mail address of the potential violator. The caller will also be asked to list the potential violator's website (if available), describe the potential violation, and provide any additional files or information pertinent to the potential violation.

FDA currently provides a form that may be used to collect this information from the public (Form FDA 3779, Potential Tobacco Product Violations Report), and seeks renewal of Form FDA 3779. The public and interested stakeholders can report possible violations of the Tobacco Control Act by submitting information online, via email or postal mail, or by calling FDA's Tobacco Call Center. Instructions on how to report possible violations of the Tobacco Control Act can be found at (<https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation>).

## **2. Purpose and Use of the Information Collection**

Form FDA 3779 (posted online and used by the Tobacco Call Center to gather information on reported violations) asks for the following information:

1. Date the potential violation happened;
2. Product type (e.g., cigarette, smokeless, roll-your-own);
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;
8. Potential violator's website or internet address URL;
9. Description of the potential violation; and
10. Any additional files or information pertinent to the potential violation.

FDA seeks an extension of this existing collection of information. The information collected from the caller will assist FDA in its investigation of violative firms.

## **3. Use of Improved Information Technology and Burden Reduction**

Information on reported violations may currently be provided to FDA using the Tobacco Call Center (toll-free telephone number), online, via email or by mail by using Form FDA 3779. The public may also choose to mail a letter to FDA with their information. 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**

FDA is the only Federal agency that is soliciting information regarding potential violations of the FD&C Act and the Tobacco Control Act; therefore, no duplication of this collection of information exists. It is conceivable that reported potential violation information could be provided about the same retail outlet/tobacco product on the Federal and State level, and it also could be possible that more than one individual could submit a report against the same retail outlet/same tobacco product. Multiple reported potential violations may be indicative of continued violations and patterns of violation of the FD&C Act and Tobacco Control Act; therefore, information submitted more than once by the reporters of potential violations could be useful in FDA's enforcement efforts.

## **5. Impact on Small Businesses or Other Small Entities**

There is no special burden placed on small businesses by this information collection. The ability to submit a report of potential violation to FDA is open to anyone.

## **6. Consequences of Collecting the Information Less Frequently**

Without the ability to collect information on potential violations of the FD&C Act, as amended by the Tobacco Control Act, FDA will be hindered in its enforcement efforts. FDA continues to build its staff, resources, and State/local partnerships needed to enforce the provisions of the Tobacco Control 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 October 15, 2019 (84 FR 55161). Two PRA related comments were received.

(Comment 1) FDA received a comment urging the Agency to publicize the availability of the Potential Tobacco Product Violations Report (PTVR) form more broadly. The comment further urged that if FDA does not already have a dissemination plan for this information collection actively, it must create one because it is important that consumers, retailers, and other stakeholders are aware of this form in order to be most helpful. The comment indicated that it is important that FDA disseminate the violations reporting form more broadly to the public so people are aware of how they can report the various types of violations.

(Response) There are multiple options available for industry and the public to report potential violations of the Tobacco Control Act, and FDA has publicized the form on multiple occasions, including when the FDA Commissioner issued public statements regarding the youth vaping epidemic and potential electronic nicotine delivery systems-related seizures. FDA's website (<https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation>) has a link to submit the online PTVR form (<https://www.accessdata.fda.gov/scripts/ptvr/index.cfm>).

As referenced previously in this notice, there are many additional options for submission, which can be found at <https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation>.

(Comment 2) FDA received a comment which stated that the original burden of this collection of information of 1,500 hours was too low and that the commenter believes more violations occur than 1,500. The commenter pointed to the number of Warning Letters and Civil Money Penalties FDA issued in 2019 to support this statement.

(Response) After reviewing the PTVR submissions again over the past 5 years we have made an adjustment to our burden estimate. The number of complaints submitted by the public is not reflective of the total number of reported violations of the FD&C Act and implementing regulations. In 2019, FDA received over 3,000 annual PTVR complaint reports and issued over 14,600 Warning Letters, 4,700 Civil Money Penalties, and 17 No-

Tobacco-Sale-Orders. Reports of potential violations from the public are critical in helping FDA enforce tobacco regulations to protect America's youth. The PTVR form was designed to provide the public with a means of reporting violations of the FD&C Act to the Center for Tobacco Products. FDA conducts our own investigations and inspections to follow-up on complaints that may be submitted through PTVR submissions. FDA evaluates each report submitted to determine if the activity is a potential violation of the FD&C Act or related regulations before deciding what follow-up action, if any, is necessary. FDA now estimates we will receive 5,370 reports annually.

## **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**

### **Privacy Analysis & Design**

CTP consulted the agency Privacy Officer to identify potential risks to the privacy of respondents and other individuals whose information may be handled by or on behalf of FDA. FDA designed the system that collects information from Form FDA 3779 to minimize privacy risks in keeping with the Fair Information Practice Principles (FIPPs) and applying controls selected from the National Institute of Standards and Technology (NIST), Special Publication 800-53, *Security and Privacy Controls for Federal Information Systems and Organizations*. CTP also identified privacy compliance requirements and coordinated with FDA's Privacy Officer to ensure responsible offices in the CTP satisfy all in accordance with law and policy. FDA has submitted a Privacy Impact Assessment for this electronic information collection to the privacy office that is currently under review.

### **PII Collection**

CTP may collect and/or maintain personally identifiable information (PII) from respondents reporting about potential violations of the FD&C Act, as amended by the Tobacco Control Act via Form FDA 3779. The PII for Form FDA 3779, is formatted for submission via online, email or postal mail, or by calling FDA's Tobacco Call Center. Collected PII can consist of names, phone numbers, email and mailing addresses and is collected directly from the respondent. The PII is hosted on the Contractor Hosted Data Center (CHDC), a public facing facility contracted from Rackspace, and collected data is submitted to Ashburn Data Center (ADC), an FDA internal facing system.

All data collection activities will be conducted in full compliance with FDA regulations to maintain the privacy of data obtained from respondents.

### **Privacy Act Applicability**

The information collection is not subject to the Privacy Act of 1974. Hence, no Privacy Act Statement is required to be displayed on the form, website, mobile application or other point at which individuals submit their information.

### **Data Minimization**

The PII collected is limited to the minimum necessary to achieve the authorized purpose. The purpose of the system is to collect information regarding potential violations of the FD&C Act from the public. The system is authorized under the under the Family Smoking Prevention and Tobacco Control Act and FD&C Act. The PII is collected to provide a reply that the information was received or to contact the respondent for additional information.

Likewise, the potentially sensitive information gathered from respondents in association with their PII is limited to that which is essential for Form FDA 3779.

FDA has minimized the risk of unnecessary access, disclosure, use or proliferation PII about respondents. FDA and other parties involved in the collection of information maintain Form FDA 3779 records containing PII only as long as required. Currently there are no record schedules in place to provide guidance on PII gathered and retained by the FDA. Therefore, FDA will archive the data, retained indefinitely, and provide access to approved personnel. FDA records that do not have an approved disposition schedule will be retained until disposition authority is obtained from NARA in accordance with Implementing Schedules under 36 CFR 1226.14. Neither CTP nor the CHDC share PII gathered via this collection with any other individuals or entities.

### **Notice and Transparency**

Form FDA 3779 provides all respondents notice regarding the collection and use of the information they submit. Links to FDA's website privacy policies are provided on all webpages where respondents may submit PII. Form FDA 3779, webpages and other related materials are clearly branded as FDA products.

Privacy compliance documentation materials such as Privacy Impact Assessments are typically posted on HHS.gov and linked on FDA.gov to provide further notice and transparency regarding this collection.

### **Individual Participation and Control**

Respondents provide their PII voluntarily. The respondent is responsible for providing accurate information. Respondents can opt to remain anonymous and no PII will be collected. However, if the Form FDA 3779 is submitted via email, FDA will receive the respondent's email address. FDA will not contact the respondent if they indicate "no" for consent to provide additional information if needed and that they want to remain anonymous. Only those who indicate "yes" for consent to indicate that they agree to be contacted if additional information is needed.

### **Third-Party Accountability**

Contract agreements include clauses that hold prime and subcontractors and their service providers to federal standards and the laws and policies specifically applicable to this study. FDA reviewed the privacy policies of all third parties to confirm that it does not conflict with HHS/FDA and/or is superseded by contract content.

### **Data Security**

FDA information security SMEs have been consulted; formal security assessment conducted; and an authorization to operate (ATO) issued. FDA has reviewed third-party/contractor/subcontractor certifications and standards. In addition, cybersecurity and physical security practices have been put into practice.

**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:

*12a. Hour Burden Estimate*

Table 1.--Estimated Annual Reporting Burden <sup>1</sup>					
Activity and Form FDA 3779	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Average Burden per Response	Total Hours
Reporting violations of the FD&C Act, as amended by the Tobacco Control Act via telephone, online form, mail, or email.	2,685	2	5,370	0.25 (15 minutes)	1,343

*Reporting Burden*

FDA estimates that submitting the information (by telephone, online form, mail or email) 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 2,685, who will each submit 2 reports by telephone, online form, mail or email. 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 1,343 hours (5,370 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 violations of Tobacco Control Act	1,343	\$23.46	\$31,506.78
	Annual Responses	Cost of USPS Stamp	
Mailing Cost	54	\$0.55	\$29.70
		Total	\$31,536.48

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 \$23.46 per hour, based on an estimate of wages retrieved from the Department of Labor's "Economic New Release" (July 2019) located at <http://www.bls.gov/news.release/empsit.t24.htm>

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 \$29.70. This estimate is based upon 54 responses (1 percent of 5,370 total responses) being submitted via U.S. first-class mail and the cost of a first-class postage stamp at \$ 0.55.

Therefore, the total cost to respondents is estimated to be \$31,536.48.

### 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 5,370 responses per year. Thus, \$19.00 x 5,370 responses = \$102,030 per year.

### 15. Explanation for Program Changes or Adjustments

We have adjusted our burden estimate based on the updated number of reports received to approximately 5,370 forms annually, which more accurately reflects the projected number of submissions based on current trends. Using these new figures, our estimated

burden for the information collection signifies an overall increase to reflect 2,685 respondents per year and 1,343 hours.

This estimate is based on the actual rate of reporting violations through Form FDA 3779 over the past 5 years, from FDA's toll-free telephone number, online, email and mailed complaints.

**16. Plans for Tabulation and Publication and Project Time Schedule**

There are no plans to publish data from this information collection.

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

We are not seeking approval to not display the expiration date for OMB approval of the information collection.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

No exceptions to the certification statement were identified.