

Potential Tobacco Product Violations Reporting Form

0910-0716

SUPPORTING STATEMENT

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 Web site (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 solicit this information from the caller (FDA Form 3779, Potential Tobacco Product Violations Reporting) and seeks renewal of Form 3779. This form is posted on FDA's Web site so the public may submit information by filling out the form online or downloading a PDF version of the form to send via email or mail to FDA. The public can also request a copy of FDA Form 3779 by contacting the Center for Tobacco Products. Others may simply choose to send a letter to FDA with their information. The public and interested stakeholders will be able to report information regarding possible violations of the Tobacco Control Act through the following methods: calling the Tobacco Call Center using CTP's toll-free number; using a fillable form found on FDA's Web site; downloading a PDF version of the form to send via email or mail to FDA; requesting a copy of FDA Form 3779 by contacting the Center for

Tobacco Products and sending by mail to FDA; and sending a letter to FDA's Center for Tobacco Products.

2. Purpose and Use of the Information Collection

FDA's Form 3779 (posted on-line 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 Web site 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 (telephone), on the Internet, via email, or by mail by using Form 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 11/07/2016 (81 FR 78166). FDA received no comments on this notice.

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

The person contacting the Tobacco Call Center by phone or letter is not required to provide his/her name or contact information. Similarly, the form posted on the Internet does not require the name and contact information fields to be completed in order to submit the form electronically. To the extent that 21 CFR 20.64 applies, FDA will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

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 ¹					
Activity and	No. of	Annual	Total Annual	Average	Total Hours

form FDA 3779	Respondents	Frequency per Response	Responses	Burden per Response	
Reporting violations of the FD&C Act, as amended by the Tobacco Control Act via telephone, Internet form, mail, or email.	750	2	1500	0.25 (15 minutes)	375

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

Reporting Burden

FDA estimates that submitting the information (by telephone, Internet form, paper form by 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 Reporting Form in the past, in addition to the increase that FDA has recently experienced in the rate of reporting due to the recently published “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” (Deeming rule), FDA estimates the number of annual respondents to this collection of information will be 750, who will each submit 2 reports by telephone, Internet form, paper form, 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 375 hours (750 responses x 0.25 hours per response). Because of the variety of products regulated by FDA under the authority of the FD&C Act, as amended by the Tobacco Control Act, FDA expects the rate of calls and reports received to remain constant over the next 3 years.

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	375	\$27.90	\$10,463

Because the Tobacco Call Center has a toll-free telephone number and a Web-based form, FDA estimates that there is minimal cost to report a violation. FDA estimates that

the average wage for an information worker is approximately \$27.90 per hour, based on an estimate of wages retrieved from the Department of Labor’s “Economic New Release” located at <http://www.bls.gov/news.release/empsit.t24.htm>. Based on this wage rate, and the estimated hours in table 1 above, the total cost to respondents should be \$10,463 (375 hours multiplied by \$27.90/hour). The postage stamp expense for regular mail delivery is described in item 13 below as a capital cost.

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

The capital costs associated with this collection pertain to the postage cost for mailing a letter containing the reported violation information. FDA estimates the capital cost to submit a report via mail to be \$3.68. This estimate is based upon 8 responses (1 percent of 800 total responses) being submitted via U.S. first class mail and the cost of a first class postage stamp at \$ 0.46.

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 800 responses per year. Thus, \$19.00 x 800 responses = \$15,200.00 per year.

15. Explanation for Program Changes or Adjustments

This is an extension with adjustments based on past submissions to FDA, and in particular, the recent increase in submissions due to the recently finalized Deeming rule. The deeming rule extended FDA’s authority to regulate all products that meet the definition of a tobacco product, including E-Cigarettes and all other Electronic Nicotine Delivery Systems (ENDS), Dissolvable, Pipe Tobacco, Hookah Tobacco, Cigars, as well as, Novel and Future Tobacco Products. The total annual estimated burden hours for this collection are expected to increase by 125 hours, from 250 to 375 hours. This is due to the number of estimated annual respondents increase from 1,000 to 1,500 and the number of estimated responses per respondent increasing from 1 to 2. The estimated number of total annual responses will therefore increase from 1,000 to 1500.

This estimate is based on the actual rate of reporting through Form FDA 3779 over the past 2 years, taking into account the recent increase in reporting, received from FDA’s toll-free telephone number, web portal, and email address, and FDA’s past experience.

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.