ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Information Collections	2,700	1	2	5,400

Estimated Total Annual Burden Hours: 5,400.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project. *Fax:* 202–395–7285, *Email: OIRA_SUBMISSION@OMB.EOP.GOV.* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–5600 Filed 3–7–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0553]

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 (the PRA).

DATES: Fax written comments on the collection of information by April 9, 2012.

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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Potential Tobacco Product Violations Reporting Form.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@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–NEW)

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321 *et. seq.*) 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 OMB approval for a new collection of information to accept consumer and other stakeholder feedback and notification of potential tobacco violations of the FD&C Act, as amended by the Tobacco Control Act.

As part of its enforcement strategy, FDA created a Tobacco Call Center (with a toll-free number: 1–877–CTP–1373) to accept information from the public about violations of the Tobacco Control Act. Callers are able to report potential violations of the Tobacco Control Act, and FDA may conduct targeted followup investigation based on information received. When callers report a violation, the caller will be asked to provide as much information as they can recall, including: The date the potential violation happened, the product type (e.g., cigarette, smokeless, roll-your-own, etc.), tobacco brand, type of potentially violative promotional materials, potential violation type, who potentially violated, and the name, address, phone number, and email 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 has developed a form that will be used to solicit this information from the caller (Form FDA 3779, Potential Tobacco Product Violations Reporting), which is expected to eventually replace current Form FDA 3734 for Cigarette Flavor Ban Violations. This new form will be posted on FDA's Web site, and information may be submitted by filling out the form online (or the public can request a copy of Form FDA 3779 by contacting the Center for Tobacco Products (CTP)). In addition, FDA has developed a smartphone application for use with mobile devices (i.e., iPhones, Android) to allow consumers to report potential violations to FDA via their smartphone. Others may simply choose to send a letter to FDA with their information. In summary, 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 fill-able form found on FDA's Web site, using FDA's tobacco violation reporting smartphone application, and sending a letter to FDA's Center for Tobacco Products.

In the **Federal Register** of August 22, 2011 (76 FR 52333), FDA published a 60-day notice requesting public comment on this proposed collection of information. FDA received 24 comment submissions, which included over 60

comments embedded. The comments have been summarized into four PRA-related areas as follows.

(Comment 1) FDA received several comments that said the Tobacco Control Act does not include a provision directing FDA to request or accept information on potential tobacco product violations from the public and other stakeholder groups. The comments stated that the public and other stakeholder groups have not been trained to inspect retail tobacco operations, have not been trained to recognize or report tobacco product violations, and are not able to verify what does or does not constitute compliance with the Tobacco Control Act. Commenters also stated that a retailer of tobacco products could be targeted by overzealous stakeholders and unfairly earmarked by FDA for future inspections.

(Response) FDA disagrees with this comment. The Tobacco Control Act amended the 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 public health generally and to reduce tobacco use by minors. This includes broad authority to enforce the provisions of the Tobacco Control Act.

FDA is requesting OMB approval for a new 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 (TCA). This collection of information falls under FDA's responsibilities to monitor compliance with and enforce the TCA.

In addition, the proposed tobacco violation form does not require respondents to verify compliance with or violations of the TCA. Instead, the submitted information will be one source of information to help FDA identify potential areas for further Agency inquiry.

(Comment 2) FDA received several comments that stated that the form is contrary to and may violate Executive Order 13563, ''Improving Regulation and Regulatory Review,'' the intent of which is to eliminate unnecessary and wasteful government regulations.

(Response) FDA disagrees with this comment. Executive Order 13563 pertains to unnecessary and wasteful regulations. This form is not a regulation but an extension of the means that the public and stakeholders have to voluntarily report potential tobacco violations and events to FDA. Current methods of reporting are FDA's toll-free hotline number (1–877–CTP–1373), email (*AskCTP@fda.hhs.gov*), and Form FDA 3734. This form is not an inspection reporting form but is another, perhaps easier, way for the public and stakeholders to report information to FDA. No information received from the form will be forwarded to inspectors unless the information is deemed credible by FDA.

(Comment 3) Several comments questioned the burden to complete the form and the methodology used to compute total responses expected through the use of this form. Commenters also stated that the form is overly broad and includes some categories of tobacco products currently not regulated by FDA under the Tobacco Control Act. Commenters also stated that the form was redundant in places, while one commenter liked the form and encouraged FDA to make the public aware that the form exists.

(Response) FDA generally agrees with these comments, except with regard to the redundancy of the form. The time to gather information and complete the form has been tested internally to take no longer than 10 minutes. However, due to the comments received, FDA is revising the burden estimate upward to indicate that the form or mobile application will take 15 minutes to complete.

With regard to the form being overly broad, the Potential Tobacco Product Violations Reporting Form has been revised to ensure that it only lists currently regulated tobacco products and possible violations under the TCA for those products. Most notably, the word ''other'' has been removed from some of the questions on the form to reduce confusion about which tobacco products are regulated by FDA. The layout of the form has also been adjusted to make it easier for the public to voluntarily submit information to FDA. The intent of the form is not to gather establishment inspection information like that collected by Federal, State, or local inspectors of tobacco facilities but to offer another means of contacting FDA about tobacco-related events and potential violations, such as that offered by the 1–877–CTP–1373 toll-free hotline and the *AskCTP@fda.hhs.gov* email address. The use of the form is voluntary and is not designed to target specific establishments or deputize the public as inspectors for identifying specific violations of the TCA.

With regard to the comments addressing the methodology for computing the burden, FDA has based this estimate on information received from several flavored cigarette reports, reports currently received from FDA's toll-free hotline and email address, and FDA experience. If the number of actual reports received is either too high or low, FDA will either correct the collection via a revision of the information collection or during its next renewal submission to OMB. Upon receiving OMB approval for the form and the collection of information, FDA will place the form on its complaint Web site and will advertise its location to the public.

With regard to the redundancy of fields of information on the form, FDA has reviewed all aspects of the form and mobile application carefully and has eliminated any redundant fields on the form.

(Comment 4) Several comments indicated that they thought the form is being used by the public and stakeholders as an inspection report to police or target tobacco retailers and the public, and that stakeholders have not been thoroughly or extensively trained with the training provided to FDA's Federal, State, and local inspectors. In addition to the lack of training, commenters also wondered what type of corrective action would or could be taken against a person or entity who files a false or inaccurate report against a retailer.

(Response) FDA's intent in creating this form and mobile application is not to target retailers but to provide the public and stakeholders with another means to report tobacco-related events, concerns, or potential violations, much like the information that is currently collected using the existing Center for Tobacco Products toll-free hotline telephone number, email address, and Form FDA 3774. The Web-based, paper, and mobile application form may allow the Agency to become better informed about certain tobacco-related topics and will provide the public and other stakeholders with an easier and possibly more efficient way to submit potential violation and event information to FDA. Information received by FDA from this form will not be forwarded to an inspector unless FDA deems the information is credible and worth further investigation. The information provided by this form will also help FDA more efficiently use its inspection resources, based on credible information provided by the public and stakeholders on potential events.

With regard to the type of corrective action taken against persons falsifying information submitted on these forms, FDA will scrutinize each submission carefully. Only forms containing information which are determined to be worthy of further investigation will be submitted to investigators for further review. Because this form is voluntary,

submission of the information by the public and stakeholders does not guarantee that an investigation against a retailer will be triggered, and FDA will work to ensure that no specific retailer or supplier is unfairly targeted.

To clarify that Form FDA 3779 is not an inspection report, FDA is amending the title of Form FDA 3779 to ''Potential Tobacco Product Violations Reporting.'' FDA is making this change to reflect that the form is voluntary, that the form is intended to be a means for the public to submit information to FDA regarding possible violations of the laws that it enforces, and that a Form FDA 3779 submission is not, by itself, enough to warrant further FDA action.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity and Form FDA 3779	Number of respondents	Annual frequency per response	Total annual responses	Average burden per response	Total hours
Reporting potential violations of the FD&C Act, as amended by the Tobacco Control Act, by telephone, Internet or paper form, smartphone application or email	1,000	1	1,000	0.25	250

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

FDA estimates that submitting the information (by phone, Internet form, paper form by mail, smartphone application, or email) will take 15 minutes per response. Since a similar type of reporting went into effect for the cigarette flavor ban, FDA has received several reports via the Internet or email. Based on the rate of reporting for the cigarette flavor ban, reports received from FDA's toll-free telephone number and email address, and FDA experience, FDA estimates the number of annual respondents to this collection of information will be 1,000, who will each submit 1 report by phone, Internet form, paper form, smartphone application, or email. Each report is expected to take 15 minutes to complete and submit, therefore, total burden hours for this collection of information is estimated to be 250 hours (1,000 responses × 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.

Dated: March 5, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–5634 Filed 3–7–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0197]

Agency Information Collection Activities; Proposed Collection; Comment Request; Emergency Shortages Data Collection System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Emergency Shortages Data Collection System.

DATES: Submit either electronic or written comments on the collection of information by May 7, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Emergency Shortages Data Collection System—Section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (OMB Control Number 0910–0491)—Extension

Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(d)(2)), the Commissioner of Food and Drugs is authorized to implement general powers (including conducting research) to carry out effectively the mission of FDA. Subsequent to the events of September 11, 2001, and as part of broader