Comments in Response to the 60 Day Federal Register Notice

A 60-Day notice was published in the **Federal Register** in Vol. 82, No. 13457 on March 13, 2017. A Notice of Correction was published in the **Federal Register** in Vol. 82, No. 15062 on March 24, 2017, announcing that ACL was requesting approval of a proposed extension with modifications of a currently approved data collection. A second Notice of Correction was published in the **Federal Register** in Vol. 82, No. 20896 on May 4, 2017, announcing that the web location of the proposed information collection would change due to an update of the *ACL.gov* Web site.

ACL received comments from eighty-nine (89) organizations and just over 13,900 individuals about the National Survey of Older Americans Act Participants (NSOAAP). ACL reviewed all of the comments. Eight (8) of the comments were deemed not relevant because they were: (a) Programmatic in nature and not survey-related; (b) referencing other data collections and not the NSOAAP (*e.g.,* Census); or (c) commentary without reference to the NSOAAP. The majority of the comments that ACL received expressed the need to retain demographic questions on sexual orientation/gender identity. In addition, comments addressed: (a) Methodological, survey design, and sampling considerations; (b) concern about the survey length; and (c) recommendations to modify and/or add clarifying questions throughout the survey. ACL has made minor changes to the survey based on some suggested changes, including retaining the primary question regarding sexual orientation. This survey has remained essentially the same since the last OMB approval on 7/17/2014 (OMB Control Number 0985–0023), and the sampling methodology and the data collection procedures are identical to the previous survey approved in 2014.

Burden Estimates

Descriptions of previous National Surveys of OAA Participants can be found under the section on OAA Performance Information on ACL's Web site at: *https://www.acl.gov/programs/oaa-performance-information.* Copies of the survey instruments and data from previous National Surveys of OAA Participants can be found and queried using the AGing Integrated Database (AGID) at *https://agid.acl.gov/.* The proposed National Survey entitled National Survey of Older Americans Act Participants 2017 Revised may be found on the ACL Web site at: *https://www.acl.gov/about-acl/public-input.* The revisions, including the reinstatement of the primary question on sexual orientation, represent minor changes in terms of data collection burden that do not change the overall estimated burden on respondents.

ANNUAL BURDEN ESTIMATES

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Area Agency on Aging: Respondent selection process	250	1	4.0	1,000
Service Recipients (i.e., Congregate and Home-delivered meal nutrition programs; Case Management, Homemaker, and Transportation Services).	4,000	1	.6667	2,666.80
National Family Caregiver Support Program Clients	2,000	1	.6667	1,333.40
Total	6,250	1	.80 (weighted mean)	5,000

Estimated Total Annual Burden Hours: 5,000.

Dated: June 16, 2017.

Daniel P. Berger,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2017–13030 Filed 6–21–17; 8:45 am]

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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.

DATES: Fax written comments on the collection of information by July 24, 2017.

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 0910–0716. 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, 10A63, 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

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 section 201 *et seq.* of 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 an extension of OMB approval for the 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.

FDA created a Tobacco Call Center (with a toll-free number: 1–877–CTP–1373). Callers are able to report potential violations of the Tobacco Control Act, and FDA may conduct followup investigations based on information received. When callers report a violation, the caller will be asked to provide as much certain information 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 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 currently provides a form that may be used to solicit this information from the caller (Form FDA 3779, Potential Tobacco Product Violations Report), and seeks renewal of Form FDA 3779. This form is posted on FDA's Web site. The public and interested stakeholders are also able to report information regarding possible violations of the Tobacco Control Act through the following methods: Calling the Tobacco Call Center using the Center for Tobacco Products' (CTP) toll-free number; using a fillable Form FDA 3779 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 Form FDA 3779 by contacting CTP and sending by mail to FDA; and sending a letter to FDA's CTP.

In the **Federal Register** of November 7, 2016 (81 FR 78166), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity and FDA Form 3779	Number of respondents	Number of responses per respondent	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, Internet form, mail, smartphone application, or email.	750	2	1,500	0.25 (15 minutes)	375

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

FDA estimates that submitting the information (by telephone, Internet form, paper form by mail, or email) will take 0.25 hour (*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 recent rule, ''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,'' 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 hour to complete and submit; therefore, total burden hours for this collection of information is estimated to be 375 hours (1,500 responses x 0.25 hour per response).

Dated: June 12, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–3615]

Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the following meeting: ''The Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access.'' This public meeting is intended to provide the public an opportunity to submit comments concerning administration of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) to help ensure the intended balance between encouraging innovation in drug development and accelerating the availability to the public of lower cost alternatives to innovator drugs is maintained.

DATES: The meeting will be held on July 18, 2017, from 9 a.m. to 5 p.m. The deadline for submitting comments regarding this meeting is September 18, 2017.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 18, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 18, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way: