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.

ANNUAL BURDEN ESTIMATES

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

Estimated Total Annual Burden Hours: 5,000.

Dated: June 16, 2017.

Daniel P. Berger,
Acting Administrator and Assistant Secretary for Aging.

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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 call 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

<table>
<thead>
<tr>
<th>Activity and FDA Form 3779</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting violations of the FD&amp;C Act, as amended by the Tobacco Control Act via telephone, Internet form, mail, smartphone application, or email.</td>
<td>750</td>
<td>2</td>
<td>1,500</td>
<td>0.25 (15 minutes)</td>
<td>375</td>
</tr>
</tbody>
</table>

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.

[FR Doc. 2017–13018 Filed 6–21–17; 8:45 am]

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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: