ANNUAL BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>HS grant and budget instrument</td>
<td>2,000</td>
<td>1</td>
<td>33</td>
<td>66,000</td>
</tr>
</tbody>
</table>

Estimated Total Annual Burden Hours: 66,000.

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. 2016–04166 Filed 2–25–16; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0350]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Tobacco Retailers on Tobacco Retailer Training Programs

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 information collection provisions of the guidance entitled “Tobacco Retailer Training Programs.”

DATES: Submit either electronic or written comments on the collection of information by April 26, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
• If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

• Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2010–D–0350 for “Guidance for Tobacco Retailers on Tobacco Retailer Training Programs.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.
• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts.
Information Request Regarding
Guidance for Tobacco Retailers on
Tobacco Retailer Training Programs—
OMB Control Number 0910–0745—
Extension

The Family Smoking Prevention and
Tobacco Control Act (Tobacco Control
Act) does not require retailers to
implement retailer training programs.
However, the statute does provide for
lesser civil money penalties for
violations of access, advertising, and
promotion restrictions of regulations
issued under section 906(d) of the
Federal Food, Drug, and Cosmetic Act
(21 U.S.C. 387f(d)), as amended by the
Tobacco Control Act, for retailers who
have implemented a training program
that complies with standards developed
by FDA for such programs. FDA intends
to issue regulations establishing
standards for approved retailer training
programs. In the interim, the guidance
is intended to assist tobacco retailers in
implementing effective training
programs for employees.

The guidance discusses the elements
that should be covered in a training
program, such as: (1) Federal laws
restricting the access to, and
advertising and promotion of, cigarettes
and smokeless tobacco products; (2)
the health and economic effects of tobacco
use, especially when the tobacco use
begins at a young age; (3) written
company policies against sales to
minors; (4) identification of the tobacco
products sold in the retail establishment
that are subject to the Federal laws
prohibiting their sale to persons under
the age of 18; (5) age verification
methods; (6) practical guidelines for
refusing sales; and (7) testing to ensure
that employees have the required
knowledge. The guidance recommends
that retailers require current and new
employees to take a written test prior
to selling tobacco products and that
refresher training be provided at least
annually and more frequently as
needed. The guidance recommends
that retailers maintain certain written
records documenting that all individual
employees have been trained and that
retailers retain these records for 4 years
in order to be able to provide evidence
of a training program during the 48-
month time period covered by the civil
money penalty schedules in section
103(q)(2)(A) of the Tobacco Control Act.

The guidance also recommends that
retailers implement certain hiring and
management practices as part of an
effective retailer training program. The
guidance suggests that applicants and
current employees be notified both
verbally and in writing of the
importance of complying with laws
prohibiting the sales of tobacco products
to persons under the age of 18 and that
they should be required to sign an
acknowledgement stating that they have
read and understand the information. In
addition, FDA recommends that
retailers implement an internal
compliance check program and
document the procedures and corrective
actions for the program.

FDA’s estimate of the number of
respondents in tables 1 and 2 of this
document is based on data reported to
the U.S. Department of Health and
Human Services Substance Abuse and
Mental Health Services Administration
(SAMHSA). According to the fiscal year
2009 Annual Synar Report, there are
372,677 total retail tobacco outlets in
the 50 States, District of Columbia, and
8 U.S. territories that are accessible to
youth (meaning that there is no State
law restricting access to these outlets to
individuals older than age 18). Inflating
this number by about 10 percent to
account for outlets in States that sell
tobacco but are, by law, inaccessible to
minors results in an estimated total
number of tobacco outlets of 410,000.
We assume that 75 percent of tobacco
retailers already have some sort of
training program for age and
identification verification. We expect
that some of those retailer training
programs already meet the elements in
the guidance, some retailers would
update their training program to meet
the elements in the guidance, and other
retailers would develop a training
program for the first time. Thus, we
estimate that two-thirds of tobacco
retailers would develop a training
program that meets the elements in the
guidance (66 percent of 410,000 =
270,600).

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

<table>
<thead>
<tr>
<th>Activity</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>Develop training program</td>
<td>270,600</td>
<td>1</td>
<td>270,600</td>
<td>16</td>
<td>4,329,600</td>
</tr>
<tr>
<td>Develop written policy against sales to minors and employee acknowledgement</td>
<td>270,600</td>
<td>1</td>
<td>270,600</td>
<td>1</td>
<td>270,600</td>
</tr>
</tbody>
</table>
TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN 1—Continued

<table>
<thead>
<tr>
<th>Activity</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>Develop internal compliance check program</td>
<td>270,600</td>
<td>1</td>
<td>270,600</td>
<td>8</td>
<td>2,164,800</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6,765,000</td>
</tr>
</tbody>
</table>

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN 1

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeper</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training program</td>
<td>270,600</td>
<td>4</td>
<td>1,082,400</td>
<td>0.25 (15 minutes)</td>
<td>270,600</td>
</tr>
<tr>
<td>Written policy against sales to minors and employee acknowledgement</td>
<td>270,600</td>
<td>4</td>
<td>1,082,400</td>
<td>0.10 (6 minutes)</td>
<td>108,240</td>
</tr>
<tr>
<td>Internal compliance check program</td>
<td>270,600</td>
<td>2</td>
<td>541,200</td>
<td>0.5 (30 minutes)</td>
<td>270,600</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>649,440</td>
</tr>
</tbody>
</table>

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


Leslie Kux,  
Associate Commissioner for Policy.

[FR Doc. 2016–04176 Filed 2–25–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Advisory Committee; Gastrointestinal Drugs Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Gastrointestinal Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Gastrointestinal Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until March 3, 2018.

DATES: Authority for the Gastrointestinal Drugs Advisory Committee will expire on March 3, 2018, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Cindy Hong, Division of Advisory Committee and Consultant Management, Office of Executive Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, email: gidac@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under 41 CFR 102–3.65 and approval by the Department of Health and Human Services under 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Gastrointestinal Drugs Advisory Committee. The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of gastrointestinal diseases and makes appropriate recommendations to the Commissioner. The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of gastroenterology, endocrinology, surgery, clinical pharmacology, physiology, pathology, liver function, motility, esophagitis, and statistics. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/GastrointestinalDrugsAdvisoryCommittee/default.htm or by contacting the Designated Federal Officer (see FOR FURTHER INFORMATION CONTACT). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at http://www.fda.gov/AdvisoryCommittees/default.htm.


Leslie Kux,  
Associate Commissioner for Policy.

[FR Doc. 2016–04093 Filed 2–25–16; 8:45 am]

BILLING CODE 4164–01–P