Step Four—Please submit your application and a copy of the completed Animal Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

G. Product, Establishment, and Sponsor Fees

By December 31, 2018, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2019 using this fee schedule. Payment will be due by January 31, 2019. FDA will issue invoices in November 2019 for any products, establishments, and sponsors subject to fees for FY 2019 that qualify for fees after the December 2018 billing.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–20911 Filed 9–25–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3552]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Cigarette Warnings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on an experimental study of cigarette warnings that is being conducted in support of the graphic label statement provision of the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

DATES: Submit either electronic or written comments on the collection of information by November 26, 2018.

ADDRESSES: 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 November 26, 2018. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 26, 2018. 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:

• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://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 https://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): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

For written/paper comments submitted to the Dockets Management Staff, 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–2018–N–3552 for “Experimental Study of Cigarette Warnings.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the
Dockets Management Staff 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 https://www.regulations.gov. Submit both copies to the Dockets Management Staff. 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: https://www.govinfo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://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 and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, PRAStaff@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 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.

Experimental Study of Cigarette Warnings

OMB Control Number 0910—NEW I. Background

The Tobacco Control Act (Pub. L. 111–31) amends the Federal Food, Drug, and Cosmetic Act to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Section 201 of the Tobacco Control Act amends section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA) (15 U.S.C. 1333) to require FDA to issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection 4(a)(1) of the FCLAA. Section 202(b) of the Tobacco Control Act further amends section 4 of the FCLAA by adding that the Secretary of Health and Human Services (Secretary), through notice and comment rulemaking, may adjust the text of any of the label requirements if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.

In the Federal Register of June 22, 2011 (76 FR 36628), FDA issued a final rule entitled “Required Warnings for Cigarette Packages and Advertisements,” which specified nine images to accompany new textual warning statements for cigarettes. Although the rule was scheduled to become effective 15 months after it was issued, a panel of the U.S. Court of Appeals of the District of Columbia held, on August 24, 2012, that the rule in its current form violated the First Amendment. In a letter to Congress on March 15, 2013, the Attorney General reported FDA’s intention to undertake research to support a new rulemaking consistent with the Tobacco Control Act. Various phases of research have been underway since 2013. The next phase of the research includes the study proposed here, which is an effort by FDA to collect data concerning responses to cigarette warnings placed on cigarette packages and advertisements for cigarettes.

The health risks associated with the use of cigarettes are significant and far-reaching. Cigarette smoking is the leading cause of preventable disease and death in the United States and is responsible for more than 480,000 deaths per year. Smoking causes more deaths each year than human immunodeficiency virus, illegal drug use, alcohol use, motor vehicle injuries, and firearm-related incidents combined (Ref. 1). In addition to lung cancer, heart disease, and chronic obstructive pulmonary disease, smoking also causes numerous other serious health conditions including several types of cancer, premature birth, low birth weight, respiratory illnesses, clogged arteries, reduced blood flow, diabetes, and vision conditions such as age-related macular degeneration and cataracts (Ref. 2).

Approximately 37.8 million U.S. adults smoke cigarettes (Ref. 3) and 8.6 million Americans have at least one serious illness caused by smoking cigarettes (Ref. 4). Results from the 2016 National Survey on Drug Use and Health demonstrate that, each day in the United States, more than 2,300 youth under age 18 smoke their first cigarette, and nearly 400 youth become daily cigarette smokers (Ref. 5). If the current trajectory of smoking rates continues, 5.6 million children alive today will die prematurely as a result of smoking (Ref. 2). Providing the public with accurate information regarding the health consequences of cigarette use is critical in achieving FDA’s mission to protect the public health.

This Experimental Study of Cigarette Warnings is a voluntary online experiment. The purpose of the study is to assess whether new cigarette warnings improve understanding of the negative health consequences of cigarette smoking. The study will collect
data from various groups of consumers, including adolescent current cigarette smokers aged 13 to 17 years, adolescent non-smokers who are susceptible to initiation of cigarette smoking aged 13 to 17 years, young adult current cigarette smokers and non-smokers aged 18 to 24 years, and older adult current cigarette smokers and non-smokers aged 25 years and older. The results will inform the Agency’s efforts to implement the mandatory graphic warning label statements as required by section 4(d) of PCLAA.

Study Overview: In this study, adolescent current cigarette smokers, adolescent non-smokers who are susceptible to initiation of cigarette smoking, young adult current cigarette smokers and non-smokers, and older adult current cigarette smokers and non-smokers will be recruited through the internet screening potential participants for the 2 pretests will occur with 866 respondents (456 adults and 410 adolescents) identified and recruited through the internet panel. Participants will complete the screening questionnaire through an email invitation. This brief screening will take an average of 2 minutes (0.03 hours) per respondent. If, based on this screening, participants qualify for the study, they will be automatically directed to begin the pretest. As previously mentioned, each of the 2 pretests conducted will consist of 50 respondents (34 adults and 16 adolescents in each) (100 total) during a single session and, we estimate an average of 12 minutes (0.20 hours) per respondent. Screening potential participants for the main data collection will occur with 80,541 respondents (51,054 adults and 29,487 adolescents) identified and recruited through the internet.

<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>
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</thead>
<tbody>
<tr>
<td>Adult—Screen for pretest</td>
<td>456</td>
<td>1</td>
<td>456</td>
<td>0.03 hours (2 minutes)</td>
<td>14</td>
</tr>
<tr>
<td>Adult—Pretest</td>
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<td>1</td>
<td>68</td>
<td>0.20 hours (12 minutes)</td>
<td>14</td>
</tr>
<tr>
<td>Adult—Screen for main data collection</td>
<td>51,054</td>
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<td>51,054</td>
<td>0.03 hours (2 minutes)</td>
<td>1,532</td>
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<tr>
<td>Adult—Main data collection (3 sessions)</td>
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<td>1</td>
<td>7,460</td>
<td>0.42 hours (25 minutes)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>4,693</td>
</tr>
<tr>
<td>Adolescent—Screen for pretest</td>
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<td>410</td>
<td>0.03 hours (2 minutes)</td>
<td>12</td>
</tr>
<tr>
<td>Adolescent—Pretest</td>
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<td>1</td>
<td>32</td>
<td>0.20 hours (12 minutes)</td>
<td>6</td>
</tr>
<tr>
<td>Adolescent—Screen for main data collection</td>
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<td>29,487</td>
<td>0.03 hours (2 minutes)</td>
<td>885</td>
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<tr>
<td>Adolescent—Main data collection (3 sessions)</td>
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<td>2,300</td>
<td>0.42 hours (25 minutes)</td>
<td>966</td>
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<tr>
<td>Total Adolescent Hours</td>
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<td></td>
<td></td>
<td></td>
<td>1,869</td>
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<tr>
<td>Total Burden Hours</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6,562</td>
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</tbody>
</table>

1 There are no capital costs or operating and maintenance costs associated with this collection of information.
2 The hours per response are rounded to two decimal places.
recruited through the same internet panel as used for the pretax.

Participants will complete the screener questionnaire through an email invitation. This brief screening will take an average of 2 minutes (0.03 hours) per respondent. If, based on this screening, participants qualify for the study, they will be directed to begin Session 1.

Recent national estimates of the numbers of adolescent current cigarette smokers, adolescents who are susceptible to initiation of cigarette smoking, young adult current cigarette smokers, and older adult current cigarette smokers informed the estimates of 14.6 percent qualification rate for adults and 7.8 percent qualification rate for adolescents. Applying these estimates and other assumptions from previous experience conducting similar studies to the number of adolescents and adults to be screened results in the desired sample size for the main data collection of 9,760 participants, of which 7,460 will be adults and 2,300 will be adolescents. The three sessions of the main data collection will take an average of 12 minutes (0.20 hours) for Session 1, 8 minutes (0.13 hours) for Session 2, and 5 minutes (0.08 hours) for Session 3, for a total of an estimated 25 minutes (0.42 hours) per respondent. The total estimated burden for the data collection is 6,561 hours (4,692 hours for adults + 1,869 hours for adolescents).

II. References

The following references are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at https://www.regulations.gov.


Leslie Kux,
Associate Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA—2018–N–3504]

Tobacco Product Application Review; 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) is announcing a public meeting entitled “Tobacco Product Application Review.” This meeting is intended to improve public understanding and provide FDA feedback on the policies and processes for submitting and reviewing tobacco product marketing applications, including the general scientific principles relevant to various application pathways, to assist those considering submitting marketing applications for tobacco products under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The 2-day public meeting will be held on October 22, 2018, from 8:30 a.m. to 4:30 p.m. and on October 23, 2018, from 8:30 a.m. to 3 p.m. Submit either electronic or written comments on this public meeting by December 7, 2018. See the SUPPLEMENTARY INFORMATION section for registration date and information.


You may submit comments as follows. Please note that late, untimely filed comments may not be considered. The https://www.regulations.gov electronic filing system will accept electronic comments until 11:59 p.m. Eastern Time on December 7, 2018.

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 December 7, 2018.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://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 https://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”).

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- Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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–2018–N–3504 for “Tobacco Product Application Review.” Received comments, filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff 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