number: 021030004, SWIFT Number: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery.)

It is important that the fee arrives at the bank at least a day or two before the application arrives at FDA's CVM. FDA records the official application receipt date as the later of the following: The date the application was received by FDA's CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Treasury notifies FDA of receipt of an electronic or wire transfer payment. U.S. Bank and the U.S. Treasury are required to notify FDA within 1 working day, using the PIN described previously.

The tax identification number of FDA is 53–0196965. (Note: In no case should the payment for the fee be submitted to FDA with the application.)

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log on to the ADUFA website at *https://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* and, under Tools and Resources, click ''The Animal Drug User Fee Cover Sheet'' and then select ''Create ADUFA User Fee Cover Sheet.'' For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Drug User Fee Cover Sheet. One cover sheet is needed for each animal drug application or supplement. Once you are satisfied that the data on the cover sheet are accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three—Send the payment for your application as described in section IX.A of this document.

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.

C. 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.

Dated: September 20, 2018.

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.gpo.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 increase public 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 FCLAA.

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 from an existing internet panel of more than 1.2 million people and screened for inclusion into the study. Participants who meet the inclusion criteria will be randomized into 1 of 17 conditions. In each condition, respondents will view one cigarette warning. In the 16 treatment conditions, participants will view 1 graphic health warning, containing a warning statement accompanied by a concordant color graphic depicting the negative health consequences of smoking described in the statement. In the control condition, participants will be randomized to view one of the four current Surgeon General's warnings, representing the current state of cigarette warnings in the United States. In all conditions, participants will view their assigned warnings both on a mock cigarette package and a mock cigarette advertisement, presented in a randomized order.

There will be three sessions. During Session 1, participants will complete a baseline assessment about their beliefs about the negative health consequences of cigarette smoking. Next, they will be exposed to the stimuli (*i.e.,* the warning based on condition assignment) and complete a set of items assessing (a) if the information presented in the warning was new; (b) self-reported learning from the warning; (c) if the warning was easy to understand; (d) if the warning was perceived to be a fact or an opinion; (e) if the warning was informative; (f) if the warning grabbed their attention; and (g) if the warning made them think about the health risks of cigarette smoking. During Session 2 (1 to 2 days after Session 1), participants will be exposed to the same stimuli again (*i.e.,* the warning based on condition assignment from Session 1), and complete a set of items assessing beliefs about the negative health consequences caused by cigarette smoking. During Session 3 (approximately 14 days after Session 2), participants will complete a delayed post-test on beliefs about the negative health consequences caused by cigarette smoking and items assessing recall of the warning.

Prior to the main data collection, 2 sequential pretests, each with 50 participants, will take place to ensure correct programming of Session 1 and to identify any issues with the study design and implementation.

Study outcomes include comparisons to assess the extent to which exposure to the graphic health warnings, relative to the text-only Surgeon General's warnings, provide new information, increase self-reported learning, change beliefs about the negative health consequences of cigarette smoking, increase thinking about the risks of smoking, as well as the extent to which the warnings are informative, easy to understand, factual, attention grabbing, and recalled.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
Adult—Screener for pretest	456	1	456	0.03 hours (2 minutes)	14
Adult—Pretest	68	1	68	0.20 hours (12 minutes)	14
Adult—Screener for main data collection.	51,054	1	51,054	0.03 hours (2 minutes)	1,532
Adult—Main data collection (3 sessions).	7,460	1	7,460	0.42 hours (25 minutes)	3,133
Total Adult Hours					4,693
Adolescent—Screener for pretest	410	1	410	0.03 hours (2 minutes)	12
Adolescent—Pretest	32	1	32	0.20 hours (12 minutes)	6
Adolescent—Screener for main data collection.	29,487	1	29,487	0.03 hours (2 minutes)	885
Adolescent—Main data collection (3 sessions).	2,300	1	2,300	0.42 hours (25 minutes)	966
Total Adolescent Hours					1,869
Total Burden Hours					6,562

[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.

FDA's burden estimate is based on prior experience with research that is similar to this proposed study (OMB control number 0910–0848). 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 same internet panel as used for the pretests. 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.*

1. Murphy, S.L., J. Xu, K.D. Kochanek. ''Deaths: Final Data for 2010''. *National Vital Statistics Reports,* 61(4):37–41, 2013.
2. U.S. Department of Health and Human Services. ''The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General.'' Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2014.
3. Jamal, A., E. Phillips, A.S. Gentzke, et al. ''Current Cigarette Smoking Among Adults—United States, 2016''. *MMWR Morbidity and Mortality Weekly Report,* 67:53–59, 2018.
4. Centers for Disease Control and Prevention. ''Cigarette Smoking-Attributable Morbidity—United States, 2000''. *MMWR Morbidity and Mortality Weekly Report,* 52(35):842–844, 2003
5. Substance Abuse and Mental Health Services Administration (SAMHSA). See Table 4.10A in '' 2016 National Survey on Drug Use and Health: Detailed Tables.'' Rockville, MD: U.S. Department of Health and Human Services, SAMHSA, Center for Behavioral Health Statistics and Quality; 2017.

Dated: September 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20913 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–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.

ADDRESSES: The public meeting will be held at the Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852, *https://www3.hilton.com/en/hotels/maryland/hilton-washington-dc-rockville-hotel-and-executive-meeting-ctr-IADMRHF/index.html.*

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'').

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–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