Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: December 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–27655 Filed 12–20–18; 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; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Cigarette Warnings

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 January 22, 2019.

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–NEW and title ''Experimental Study of Cigarette Warnings.'' 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, 10A–12M, 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.

Experimental Study of Cigarette Warnings

OMB Control Number 0910–NEW

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 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 health 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 health 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 color graphics to accompany health warning label statements as required by section 4 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 cigarette health warning, containing a textual 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 in 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 new cigarette 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, and the extent to which the warnings are informative, easy to understand, factual, attention grabbing, and recalled.

In the **Federal Register** of September 26, 2018 (83 FR 48625), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received six unique comment submissions. Four submissions were PRA related, and some included multiple comments.

(Comment) One commenter stated that it's important to educate and reinforce the facts surrounding the dangers of smoking.

(Response) FDA agrees that it is important to provide the public with accurate information about the risks associated with the use of tobacco products. The purpose of this study is to assess whether new cigarette warnings increase public understanding of the negative health consequences of smoking.

(Comment) One comment urged FDA to move forward to complete the proposed consumer research study as soon as possible to facilitate the prompt promulgation of a rule to require new warnings on cigarette packages and in cigarette advertisements. The comment also stated that FDA must take every available opportunity to minimize delays that may be attributable to the Paperwork Reduction Act.

(Response) FDA agrees that it is important to complete this study and promulgate a rule in accordance with the statutory mandate laid out by Congress. FDA is following the requirements of the Paperwork Reduction Act and its associated timelines.

(Comment) One comment stated that, as designed, the proposed study does not help FDA satisfy the requirements of the First Amendment because FDA has failed to consider less-burdensome alternatives and because FDA has not identified a ''substantial'' interest that this current iteration of a cigarette health warnings rule serves.

(Response) As stated previously, the purpose of the proposed study is to assess whether new cigarette health warnings increase public understanding of the negative health consequences of smoking. FDA further notes that this notice is respecting a proposed study, the results of which, if used in a future rulemaking, would be provided along with other evidence in a future notice of proposed rulemaking and subject to public comment at that time.

(Comment) FDA received two comments that asked FDA to provide more detail about the design of the proposed study to allow for meaningful public comments. One commenter also stated that FDA must provide additional information for public comment, including details of the protocol, inclusion criteria for screening study participants, questionnaire, and the text and color graphics the agency proposes to test.

(Response) FDA notes in response to this comment that the proposed study and copies of the instruments used to collect this information are described in detail as part of the overall information collection request submitted to OMB for review.

(Comment) One comment provided a published scientific study and suggested that focusing on the presence of certain features of the warnings might provide more robust evidence about the effectiveness of warning labels rather than a comparison of a single pictorial message to a text-only message.

(Response) FDA appreciates the submission of the published study; however, it focuses on outcomes not relevant to the study FDA proposes here. The proposed study examines how new cigarette health warnings provide new information, increase self-reported learning, change beliefs about the negative health consequences of cigarette smoking, and increase thinking about the risks of smoking.

(Comment) One comment stated that the cigarette health warnings should be compared relative to the new text-only warning statements rather than the current, familiar text-only Surgeon General's warnings.

(Response) FDA disagrees. First, Section 201 of the Tobacco Control Act amends section 4 of FCLAA to require FDA to issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the textual label statements. Second, FDA believes that the comparison to the current Surgeon General's warnings is the most appropriate comparison for the purposes of this proposed study. This comparison will allow for investigation of the potential effect of implementing new cigarette health warnings compared to the current state of warnings for cigarette packages and advertisements, which the commenter recognizes are ''familiar.''

(Comment) One comment recommended that certain demographic (*e.g.,* age, socioeconomic status) and other (*e.g.,* nicotine dependence among smokers) factors should be evaluated during the course of this study.

(Response) FDA disagrees. The purpose of this proposed study is to assess whether new cigarette health warnings increase public understanding of the negative health consequences of smoking, not the mechanisms for such changes. Some basic sub-group analyses will be performed by age group; however, the primary analyses will focus on whether new cigarette health warnings increase public understanding

of the negative health consequences of smoking in the sample overall.

(Comment) One comment urged FDA to consider previous research that has shown that use of ''graphical'' warnings can produce an opposite effect to the desired outcome.

(Response) In our research to develop, test, and revise the content of new cigarette health warnings, we considered communication best practices, including minimizing unintended consequences and potential reactance to the warnings. Additionally, given the purpose and design of the proposed study, unintended consequences would be evident if the control warnings showed greater gains on outcomes compared to the warnings in the treatment conditions.

(Comment) One comment recommended that the study design include pre/post measures of risk perceptions to evaluate whether the cigarette health warnings meaningfully increase likely pre-existing high levels of incoming risk perceptions.

(Response) FDA declines to make such a change. The purpose of this proposed study is to assess whether new cigarette warnings increase public understanding of the negative health consequences of smoking, not whether such warnings increase risk perceptions. The focus of the study is on the specific health conditions that are the focus of the warning statements and their accompanying color graphics depicting the negative health consequences of smoking, not on the perception of overall risks of smoking.

(Comment) One comment indicated that the sample size for each condition appears to be small.

(Response) FDA disagrees. The sample size for this study was determined by a comprehensive statistical power analysis, taking into account the study design, planned analyses to be conducted, and potential study attrition. Based on its statistical power analysis, FDA is confident that the study will have sufficient sample sizes to detect meaningful effects.

(Comment) One comment stated that the proposed study's methodology suffers from selection bias. Specifically, the commenter stated that the proposed study is a voluntary online experiment, uses sampling methodology that may limit generalizability of outcomes to the broader U.S. population, and appears to lack corrective measures such as the ability to identify factors that contribute to participant drop out.

(Response) Although the large sample for this study is not truly nationally representative, FDA has made efforts to ensure that the demographics of participants in the study population closely mirror those of national estimates to ensure a better representation. Additionally, the sample size calculation and study analysis account for the potential of attrition over the multiple time points (*i.e.,* study sessions).

(Comment) One comment asserted that the study questions create a serious risk of bias. Specifically, the commenter stated that FDA's broad description of the questions to be asked in the study suggests that they are deliberately crafted to support a ''pre-ordained'' result, namely, that the warnings would increase public understanding of the negative health consequences of cigarette smoking.

(Response) FDA disagrees. There is no pre-ordained result. The questions used in this study were selected from prior studies on similar topics, including cigarette warnings. Some questions have been slightly edited to fit the specific content of the warnings to be tested, but the question instructions and question stems have not changed. The study questions are face valid (*i.e.,* it is clear they measure what they are intended to measure). Additionally, the study questions have previously been shown to produce a range of responses, indicating that they do not produce demand characteristics (*i.e.,* study participants do not respond to the items with what they think the researchers want to hear).

(Comment) One comment stated that FDA will need to avoid question-order bias.

(Response) FDA agrees that it is important to avoid question-order bias in this proposed study. In many sections of the study instrument, the order of questions is randomized specifically to avoid question-order bias. In other sections of the study instrument, the order was determined by starting with more general and then moving on to more specific items to avoid bias. In designing the survey, FDA ensured that the item order follows established models of information processing and attention.

(Comment) One comment raised a number of concerns that the study protocols do not appear to adequately mimic real-world conditions because cigarette smokers would not be exposed to only a single warning (but rather they would be exposed to all of them over time); the study asks participants to specifically focus on the warnings, which will likely overestimate their effects; in the real world, consumers would rarely view both cigarette packaging and advertisements at the same time; the study does not measure whether consumers would get used to the warnings after viewing them repeatedly over a long period of time; and the study's 14-day gap between Sessions 2 and 3 gives participants time to do their own research about the risks of cigarettes, which could overstate any effects that cigarette health warnings might have.

(Response) FDA disagrees with these assertions. The procedures proposed for the current study provide a greater number of exposures (and thus closer to real-world conditions) and use a longer follow-up time than many similar studies (Ref. 6).

The Tobacco Control Act requires that the cigarette health warning label statements with accompanying color graphics be displayed both on cigarette packages and in cigarette advertisements; therefore, exposure to the warnings on both formats provides an appropriate assessment of the impact of the warnings.

Finally, if warnings in certain conditions prompt study participants to seek health information in the 14-day follow-up period, thus resulting in greater understanding of the negative health consequences of cigarette smoking, such an effect would only strengthen findings that the warnings are working as intended and provide further evidence that the study mimics real world conditions in which consumers could seek additional information about the negative health consequences of smoking. Participants' health beliefs will be assessed at all three study sessions, thus allowing for comparison of the effect both immediately after exposure as well as after a delay.

(Comment) One comment recommended that FDA consider assessing comprehension of the new warnings objectively (*i.e.,* evaluating recall of specific content, evaluating comprehension of disease risk) rather than participants indicating only that they learned (*i.e.,* ''self-reported learning from the warning'').

(Response) FDA agrees that it is important to assess comprehension of the new warnings objectively. The proposed study contains these items, in addition to other measures.

(Comment) One comment stated that FDA should prioritize measuring the impact of the warnings on behavior (*e.g.,* quit intentions among cigarette smokers, initiation intentions among non-users) over concepts such as whether the warning is informative or grabs attention.

(Response) The purpose of the proposed study is to assess whether new cigarette health warnings increase

public understanding of the negative health consequences of cigarette smoking. The study does not focus on behavior.

(Comment) One comment stated that the study does not appear to include meaningful pretesting.

(Response) FDA disagrees with this assertion. As explained previously, the items in this proposed study were selected from prior studies on similar topics, including cigarette warnings. Additionally, the specific language used in the warning statements has been extensively tested in multiple qualitative studies and a large quantitative study conducted by FDA. The findings from those studies informed the development of warning statements, revisions to those statements, and the questions used to assess participant reactions (*e.g.,* beliefs) about the warnings.

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).

I. 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.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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.

6. Noar, S.M., Hall, M.G., Francis, D.B., et al. ''Pictorial Cigarette Pack Warnings: A Meta-Analysis of Experimental Studies''. *Tobacco Control,* 25:341–354, 2016.

Dated: December 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–27658 Filed 12–20–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4308]

Labeling of Red Blood Cell Units With Historical Antigen Typing Results; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Guidance for Industry.'' The guidance document provides establishments that collect blood and blood components for transfusion with recommendations for labeling Red Blood Cell (RBC) units with non-ABO/Rh(D) antigen typing results obtained from previous donations (historical antigen typing results). The guidance provides recommendations to transfusion services for managing RBC units labeled with historical antigen typing results. The guidance also provides licensed blood establishments that choose to implement labeling of RBC units with historical antigen typing results instructions regarding how to report the manufacturing and labeling changes under the biologics regulations. The guidance does not apply to test results for ABO and Rh(D) antigens. The guidance announced in this notice finalizes the draft guidance of the same title dated January 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on December 21, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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 2016–D–4308 for ''Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Guidance for Industry.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Segal, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: