Disease.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment or prevention of CMV disease in patients who have undergone SOT or HSCT. Specifically, this guidance addresses FDA's current thinking regarding the overall development program and clinical trial designs for the development of drugs and biologics to support an indication for the treatment or prevention of CMV disease in post-transplant populations. This guidance does not address drug development for the prevention or treatment of congenital CMV infection or CMV infection in patients other than those undergoing SOT or HSCT.

This guidance also discusses the use of CMV DNAemia (CMV deoxyribonucleic acid in blood determined by polymerase chain reaction, an indirect measure of CMV viremia) as a surrogate endpoint in trials designed to support accelerated approval.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on developing drugs to treat or prevent CMV disease in transplantation. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: May 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10733 Filed 5–18–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0821]

Agency Information Collection Activities; Proposed Collection; Comment Request; Investigation of Consumer Perceptions of Expressed Modified Risk Claims

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 the investigation of consumer perceptions of expressed modified risk claims.

DATES: Submit either electronic or written comments on the collection of information by July 20, 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 July 20, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of July 20, 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–0821 for ''Investigation of Consumer Perceptions of Expressed Modified Risk Claims.'' 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.

Investigation of Consumer Perceptions of Expressed Modified Risk Claims

OMB Control Number 0910—NEW

FDA's Center for Tobacco Products proposes to conduct a study to develop generalizable scientific knowledge to help inform its implementation of section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k), wherein FDA will be evaluating information submitted to the Agency about how consumers understand and perceive modified risk tobacco products (MRTPs). Section 911 of the FD&C Act authorizes FDA to grant orders to persons to allow the marketing of MRTPs. The term ''modified risk tobacco product'' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. FDA can issue a risk modification order under section 911(g)(1) of the FD&C Act authorizing the marketing of a MRTP only if the Agency determines that the product, as it is used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products (section 911(g)(1) of the FD&C Act). Alternatively, with respect to tobacco products that may not be commercially marketed under section 911(g)(1) of the FD&C Act, FDA may issue an exposure modification order under section 911(g)(2) of the FD&C Act authorizing the marketing of a MRTP if, the Agency determines that the standard in section 911(g)(2) of the FD&C Act is met, including, among other requirements, that: Any aspect of the label, labeling, or advertising that would cause the product to be an MRTP is limited to an explicit or implicit representation that the tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke; the order would be appropriate to promote the public health; the issuance of the order is expected to benefit the population as a whole taking into account both users and nonusers of tobacco products; and the existing evidence demonstrates that a measurable and substantial reduction in morbidity and mortality among individual tobacco users is reasonably likely to be shown in subsequent studies (section 911(g)(2) of the FD&C Act). In addition, section 911 of the FD&C Act requires that any advertising or labeling concerning modified risk products enable the public to comprehend the information concerning modified risk and to understand the relative significance of such information in the context of total health and in relation to all the diseases and health-related conditions associated with the use of tobacco products (section 911(h)(1) of the FD&C Act). The proposed research will inform the Agency's efforts to implement the provisions of the FD&C Act related to MRTPs.

FDA proposes conducting a study to assist in determining appropriate methods for gathering information about how consumers perceive and understand modified risk information. The study would develop and validate measures of consumer perceptions of health risk from using tobacco products. Moreover, the study would test how participants' responses on these measures are affected by viewing modified risk labeling or advertising, participants' characteristics such as prior beliefs about the harmfulness of tobacco products, current use of tobacco products, and sociodemographic characteristics. Finally, the study would examine factors that may influence the effectiveness of debriefing at the end of a consumer perception study to ensure that people read and recall key information about the study. This research is significant because it will validate methods that can be used in studies of the impact of labels, labeling, and advertising on consumer perceptions and understanding of the risks of product use.

Measures of consumer health risk perception will be developed and validated by conducting a study on two product types: Moist snuff smokeless tobacco products and electronic cigarette (e-cigarette) products. For each product type, we will assess individual-level factors that may moderate the impact of modified risk information on consumer responses. Potential moderating factors under study include: Beliefs (prior to viewing the modified risk information) about the harmfulness of tobacco products, and the strength with which those beliefs are held; current tobacco use behaviors; and sociodemographic characteristics including age and educational attainment. For each product type, participants will be randomized to view one of two conditions: Tobacco product labeling and advertising that either does or does not contain modified risk claims about a product. The labeling will consist of a product package. The

advertising will consist of a print advertisement. The study will assess participants' perceptions of various health risks from using the product, as well as their perceptions of health risk from using the product compared to smoking cigarettes, using nicotine replacement therapies, and quitting all tobacco and nicotine products. The study will also assess participants' intentions to use the product and their level of doubt about whether tobacco products are harmful to users' health. Measures of intentions and doubt will be used to help assess the validity of the measures of health risk perception.

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	Total hours
Invitation: Young Adults (Ages 18–25)	29,000	1	29,000	0.02	580
Invitation: Adults (Ages 26+)	29,000	1	29,000	0.02	580
Consent and Screener: Young Adults (Ages 18–25)	11,000	1	11,000	0.10	1,100
Consent and Screener: Adults (Ages 26+)	16,500	1	16,500	0.10	1,650
Study: Young Adults (Ages 18–25)	3,300	1	3,300	0.33	1,089
Study: Adults (Ages 26+)	3,300	1	3,300	0.33	1,089
Total					6,088

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

FDA's burden estimate is based on prior experience with research that is similar to this proposed study. Approximately 58,000 people will receive a study invitation, estimated to take 1 minute to read (approximately 0.02 hours), for a total of 1,160 hours for invitations. Approximately 27,500 people will complete the informed consent and screener to determine eligibility for participation in the study, estimated to take 6 minutes (0.10 hours), for a total of 2,750 hours for informed consent and screening activities. Approximately 6,600 people will complete the full study, estimated to take 20 minutes (approximately 0.33 hours), for a total of 2,178 hours for study completion activities. The estimated total hour burden of the collection of information is 6,088 hours.

Dated: May 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10723 Filed 5–18–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1708]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Blood Products Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on June 22, 2018, from 11 a.m. to 4:20 p.m.

ADDRESSES: Great Room A, Building 31, FDA White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Bryan Emery or Joanne Lipkind, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, Bldg. 71, Rm. 6132, at 240–402–8054, *bryan.emery@fda.hhs.gov* and Rm. 6270, at 240–402–8106, *joanne.lipkind@fda.hhs.gov,* respectively, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting. For those unable to attend in person, the meeting will also be available via webcast. The webcast will be available at the following link: *https://collaboration.fda.gov/bpac0618/.*

SUPPLEMENTARY INFORMATION:

Agenda: On June 22, 2018, in the morning open session, under Topic 1, the Committee will hear presentations on the research programs in the Laboratory of Emerging Pathogens (LEP), Laboratory of bacterial and TSE Agents (LBTSE), and from the Laboratory of Molecular Virology (LMV) in the Division of Emerging Transfusion-Transmitted Diseases (DETTD), Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER), FDA. After the conclusion of the open session, the meeting will be closed to permit discussion where disclosure would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6).

In the afternoon, in open session, under Topic II, the Committee will hear presentations on the research program in the Hemostasis Branch (HB), in the Division of Plasma Protein Therapeutics (DPPT), Office of Tissues and Advanced Therapies (OTAT), Center for Biologics Evaluation and Research (CBER), FDA. After the open session, the meeting will be closed to the public to permit discussion where disclosure would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552.b(c)(6).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will