fully implement the feed standards will vary among States.

Dated: December 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29839 Filed 12–12–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2836]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Donor Risk Assessment Questionnaire for the Food and Drug Administration/National Heart, Lung, and Blood Institute-Sponsored Transfusion-Transmissible Infections Monitoring System—Risk Factor Elicitation

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 12, 2017.

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 ''Donor Risk Assessment Questionnaire for the Food and Drug Administration/National Heart, Lung, and Blood Institute-sponsored Transfusion-Transmissible Infections Monitoring System—Risk Factor Elicitation.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Donor Risk Assessment Questionnaire for FDA/National Heart, Lung, and Blood Institute (NHLBI)-sponsored Transfusion-Transmissible Infections Monitoring System (TTIMS)—Risk Factor Elicitation OMB Control Number—New

FDA intends to interview blood donors to collect risk factor information associated with testing positive for a Transfusion-Transmissible Infection (TTI). This collection of information is part of a larger initiative called TTIMS, which is a collaborative project funded by FDA, the NHLBI of the National Institutes of Health (NIH), and the Department of Health and Human Services (HHS) Office of the Assistant Secretary of Health with input from other Agencies in HHS, including the Centers for Disease Control and Prevention (CDC). FDA will use these scientific data collected through such interview-based risk factor elicitation of blood donors to monitor and help ensure the safety of the U.S. blood supply.

Previous assessments of risk factor profiles among blood donors found to be positive for human immunodeficiency virus (HIV) were funded by CDC for approximately 10 years after implementation of HIV serologic screening of blood donors in the mid-1980s; whereas studies of Hepatitis C virus (HCV) seropositive donors, funded by NIH, were conducted in the early 1990s. Information on current risk factors in blood donors as assessed using analytical study designs was next evaluated by the Transfusion-Transmitted Retrovirus and Hepatitis Virus Rates and Risk Factors Study conducted by the NHLBI Retrovirus Epidemiology Donor Study-II (REDS–II) approved under OMB control number 0925–0630. Through a risk factor questionnaire, this study elicited risk factors in blood donors who tested confirmed positive for one of four transfusion-transmissible infections: HIV, HCV, Hepatitis B virus (HBV), and Human T-cell Lymphotropic virus. The study also elicited risk factors from donors who did not have any infections (controls) and compared their responses to those of the donors with confirmed infection (cases). Results from the REDS–II study were published in 2015.

FDA issued a document entitled ''Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products, Guidance for Industry'' dated December 2015 (*http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM446580.pdf*) that changed the blood donor criterion for men who have sex with men (MSM) from an indefinite (permanent) deferral to a 12-month deferral since last MSM contact. The impact of this change in the deferral criteria requires a national monitoring effort as part of TTIMS to assess if the relative proportions of risk factors for infection in blood donors have changed following the adoption of the 12-month donor deferral for MSM. TTIMS will use similar procedures as the ones used in the REDS–II study to monitor and evaluate risk factors among HIV-positive donors and recently HCV or HBV infected donors as well as controls.

This study will help identify the specific risk factors for TTI and their prevalence in blood donors, and help inform FDA on the proportion of incident (new) infections among all HIV positive blood donors. Donations with incident infections have the greatest potential transmission risk because they could be missed during routine blood screening. The study will help FDA evaluate the effectiveness of screening strategies in reducing the risk of HIV transmission from at-risk donors and to evaluate if there are unexpected consequences associated with the recent change in donor deferral policy such as an increase in HIV incidence among donors. These data also will inform FDA regarding future blood donor deferral policy options to reduce the risk of HIV transmission, including the feasibility of moving from the existing time-based deferrals related to risk behaviors to alternate deferral options, such as the use of individual risk assessments, and to inform the design of potential studies to evaluate the feasibility and effectiveness of such alternative deferral options.

TTIMS will include a comprehensive interview based epidemiological study of risk factor information for viral infection-positive blood donors at the American Red Cross (ARC), Blood Systems, Inc. (BSI), New York Blood Center (NYBC), and OneBlood that will identify the current predominant risk factors and reasons for virus-positive donations. The TTIMS program establishes a new, ongoing donor hemovigilance capacity that currently does not exist in the United States. Using procedures developed by the REDS–II study, TTIMS will establish this capacity in greater than 50 percent of all blood donations collected in the country.

As part of the TTIMS project, a comprehensive hemovigilance database will be created that integrates the risk

factor information collected through donor interviews of blood donor with the resulting data from disease marker testing and blood components collected by participating organizations into a research database. Following successful initiation of the risk factor interviews, the TTIMS network is poised to be expanded to include additional blood centers and/or re-focused on other safety threats as warranted. In this way, the TTIMS program will maintain standardized, statistically and scientifically robust processes for applying hemovigilance information across blood collection organizations.

The specific objectives are to:

- Determine current behavioral risk factors associated with all HIV infections, incident HBV, and incident HCV infections in blood donors (including parenteral and sexual risks) across the participating blood collection organizations using a case-control study design.
- Determine infectious disease marker prevalence and incidence for HIV, HBV, and HCV overall and by demographic characteristics of donors in the majority of blood donations collected in the country. This will be accomplished by forming epidemiological databases consisting of harmonized operational data from ARC, BSI, NYBC, and OneBlood.
- Analyze integrated risk factor and infectious marker testing data concurrently because when taken together these may suggest that blood centers are not achieving the same degree of success in educational efforts to prevent donation by donors with risk behaviors across all demographic groups.

The respondents will be persons who donated blood in the United States and these participants will be defined as cases and controls. The estimated number of respondents is based on an overall expected participation in the risk factor survey. We estimate a case to control ratio of 1:2 (200 to 400) with a 50 percent case enrollment.

In the **Federal Register** of September 30, 2016 (81 FR 67358), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received a few comments from the public. FDA concurs with one comment that providing more information to the blood center and FDA may aid in prevention of transmission of infectious disease and is critical to the safety of the blood supply. Four comments received were not responsive to the comment request on the four specified aspects of the collection of information. None of the responses specifically commented on any of the proposed questions, nor did they request that FDA make any other changes to the Donor Risk Assessment Questionnaire. Furthermore, the responses did not provide any data or explanation that would support a change regarding the information collection requirements.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Questionnaire/survey	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cases and controls [2]	600	1	600	0.75 (45 minutes)	450

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Cases consist of virus-positive donations, and controls represent uninfected donors.

Dated: December 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0508]

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry entitled ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.'' This guidance is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2009–D–0508 for ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product