www.govinfo.gov/content/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 this guidance to the Office of Policy, Bldg. 32, Rm. 4248, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jarilyn Dupont, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4248, Silver Spring, MD 20993–0002, 301–796–4850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 25, 2019 (84 FR 64906), FDA published a notice with a 45-day comment period to request comments on the draft guidance for industry and staff entitled ''Certificates of Confidentiality; Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff.'' FDA is extending the comment period, in response to a request from a stakeholder, until January 24, 2020. The Agency believes the extension allows adequate time for interested persons to submit comments without significantly delaying publication of the final version of the guidance.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Regulatory Information/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: January 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00070 Filed 1–7–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2836]

Agency Information Collection Activities; Proposed Collection; 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, the Agency, or we) 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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on an information collection request regarding risk factors associated with transfusion-transmissible infections (TTI) in blood donors.

DATES: Submit either electronic or written comments on the collection of information by March 9, 2020.

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 March 9, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 9, 2020. 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–2016–N–2836 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Donor Risk Assessment Questionnaire for FDA/National Heart, Lung, and Blood Institute-Sponsored Transfusion-Transmissible Infections Monitoring System—Risk Factor Elicitation.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in

its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), 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, including each proposed extension of an existing 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.

Donor Risk Assessment Questionnaire for FDA/National Heart, Lung, and Blood Institute (NHLBI)-Sponsored Transfusion-Transmissible Infections Monitoring System (TTIMS)—Risk Factor Elicitation (RFE)

OMB Control Number 0910–0841—Extension

FDA intends to interview blood donors to collect risk factor information associated with testing positive for a 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 (available at: *https://www.fda.gov/media/92490/download*), which 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 refocused 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.

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	0.50 (30 minutes)	300

[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.

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. Based on experience with this survey, we decreased the average burden per response from 45 to 30 minutes, resulting in a change from 450 to 300 total hours.

Dated: January 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00047 Filed 1–7–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5799]

Modernizing the Food and Drug Administration's Data Strategy; 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, the Agency, or we) is announcing the following public meeting entitled ''Modernizing FDA's Data Strategy.'' The purpose of the public meeting and the request for comments is to discuss possible Agency level approaches to modernizing FDA's data strategy, including approaches to data quality, data stewardship, data exchange, and data analytics.

DATES: The public meeting will be held on March 27, 2020, from 9 a.m. to 5 p.m. Eastern time. The public meeting may be extended or may end early. Submit electronic or written comments on this public meeting by April 30, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rooms 1503B/C), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/white-oak-campus-information/public-meetings-fda-white-oak-campus.*

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 April 30, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 30, 2020. 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