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

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–2019–N–5799 for ''Modernizing FDA's Data Strategy; Public Meeting; Request for Comments.'' 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: Jessica Berrellez, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 2308, Silver Spring, MD 20993, 301–796–0511, *Jessica.Berrellez@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In September 2019, FDA announced its Technology Modernization Action Plan (TMAP; *https://www.fda.gov/about-fda/reports/fdas-technology-modernization-action-plan*). The TMAP describes important near-term actions that FDA is taking to modernize use of technology—computer hardware, software, data, and analytics—to advance FDA's public health mission. The TMAP will provide a foundation for developing a more fluid, agile, and efficient FDA that is responsive to novel technologies and rapidly increasing workloads.

To achieve these goals, FDA intends to develop a modernized Agency-wide, strategic approach not only to technology, but to data itself. Data is at the heart of FDA's work as a science-based Agency, and we anticipate ongoing, rapid increases in the amount and complexity of the data that informs FDA's regulatory decision-making process and how we advance our public health mission. FDA will hold a public meeting on March 27, 2020, from 9 a.m. to 5 p.m., to provide an opportunity to hear from FDA staff and outside experts on topics directly related to modernizing FDA's data strategy, including data quality, data stewardship, data exchange, and data analytics.

II. Topics for Discussion at the Public Meeting

FDA is gathering scientific and technical information to help inform its development of an Agency-wide, strategic approach to modernizing its data strategy, including data quality, data stewardship, data exchange, and data analytics. The Agency has determined that a public meeting and an open public docket will encourage public input and engagement in this important topic.

The Agency welcomes any relevant scientific and technical information related to FDA's consideration of the following topics:

1. Standards and policy, including:

a. How can FDA best use policy and common data standards to help ensure the effective and efficient use of data assets?

b. What are the consequences/issues as we move from ''static point-in-time data sets'' to updating digital data streams for analyses?

c. As we move into increased sharing and integrated data sets, how might FDA manage data in a way that avoids unnecessary duplication?

2. Data security, privacy, and management including:

a. How can FDA modernize its data strategy to continue ensuring privacy and security of data?

b. What should FDA do to promote the management and organization of data assets across the Agency, as the amount and complexity of data (*e.g.,* in regulatory submissions to FDA) is rapidly increasing?

3. Data strategies and data sharing, including:

a. How can FDA's data strategy facilitate broader goals of integration and interoperability of health care data, and scientific data/virtual patient data generated using scientific models?

b. How can FDA design its data strategy to reflect a global marketplace and promote clarity to data providers like regulated industry and other stakeholders?

c. How can FDA design its data strategy and policy development to facilitate appropriate data access, data sharing within the Agency and via data sharing agreements, as well as the appropriate reuse and repurposing of data to advance Agency regulatory science priorities?

d. For stakeholders, including regulated industry, that submit data to FDA, how can FDA enhance the efficiency of the preparation and submission of data to FDA?

III. Participating in the Public Meeting

Registration: If you wish to attend this public meeting in person, please register via *https://fdapublicmeeting modernizingdatastrategy.eventbrite.com* by 11:59 p.m. Eastern Time on March 24, 2020. Those without email access can register to attend in person by contacting Jessica Berrellez at 301–796–0511 by March 24, 2020 (see **FOR**

FURTHER INFORMATION CONTACT). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by 11:59 p.m. Eastern Time on March 24, 2020. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization.

If you need special accommodations due to a disability, please contact *Jessica.Berrellez@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**) no later than 11:59 p.m. Eastern Time on March 20, 2020.

Presenters and Panelists: FDA is interested in gathering scientific and technical information from individuals with a broad range of perspectives on the topics to be discussed at the public meeting. Presenters and panelists will discuss their scientific and/or technical knowledge on the questions and presentations in each session. Presenters and panelists will be responsible for their own travel arrangements.

To be considered to serve as a presenter and/or panelist, please provide the following:

- *Presenters:* A brief abstract for each presentation. The abstract should identify the specific topic(s) to be addressed and the amount of time requested.
- *Presenters and panelists:* A one-page biosketch that describes and supports your scientific or technical expertise on the specific topic(s) being presented, nature of your experience and research in the scientific field, positions held, and any program development activities.

If you are interested in serving as a presenter or a panelist, you must submit the above information, along with the topic(s) on which you would like to speak, to *Jessica.Berrellez@fda.hhs.gov* by January 28, 2020.

We will do our best to accommodate requests to make presentations and serve on the panel. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify presenters and panelists by March 6, 2020. If selected for presentation, any presentation materials must be emailed to *Jessica.Berrellez@fda.hhs.gov* no later than 11:59 p.m. Eastern Time on March 20, 2020. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Please register for the streaming webcast of the workshop via *https://fdapublicmeetingmodernizingdatastrategy.eventbrite.com* by 11:59 p.m. Eastern Time on March 24, 2020. Pre-registration for the webcast is recommended, but not required. The webcast will be available and active during the public meeting at *https://collaboration.fda.gov/fdadmpm/.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

An agenda for the public meeting and any other background materials will be made available 5 days before the public meeting at *https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/modernizing-fdas-data-strategy-03272020-03272020.*

Persons attending FDA's meetings are advised that the Agency is not responsible for providing access to electrical outlets.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/modernizing-fdas-data-strategy-03272020-03272020.*

Dated: January 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00071 Filed 1–7–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Refinement and Testing of Interventions to Sustain ADHD Treatment Effects (R34).

Date: February 10, 2020.

Time: 12:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Marcy Ellen Burstein, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6143, MSC 9606, Bethesda, MD 20892–9606, 301–443–9699, *bursteinme@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Mental Health Services: Member Conflict.

Date: February 25, 2020.

Time: 12:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Mental Health, NSC, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Marcy Ellen Burstein, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6143, MSC 9606, Bethesda, MD 20892–9606, 301–443–9699, *bursteinme@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: January 3, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–00111 Filed 1–7–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as