and perspective on benefit may provide useful context during this assessment.

FDA believes use of this benefit-risk framework in an IDE application will facilitate the incorporation of evidence and knowledge from different domains—clinical, nonclinical, and patient—to support a comprehensive, balanced decision-making approach. FDA envisions this will facilitate a common understanding between FDA and sponsors/sponsor-investigators by highlighting which factors are critical in the benefit-risk assessment for a specific application, and clearly explaining how these factors influence a regulatory decision. FDA also believes implementation of this guidance document will improve the predictability, consistency, and transparency of the review process for IDE applications.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions (IDEs).'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov* or from CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* Persons unable to download an electronic copy of ''Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1783 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 50.23 (Exception from general requirements for informed consent) have been approved under OMB control number 0910–0586; the collections of information in 21 CFR part 56.115 (IRB records) have been approved under OMB control number 0910–0130; and the collections of information in 21 CFR part 50, subpart B (Informed Consent of Human Subjects) and 56 (Institutional Review Boards) have been approved under OMB control number 0910–0755.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: June 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–14982 Filed 6–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1968]

Non-Microbial Biomarkers of Infection for In Vitro Diagnostic Device Use; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Non-Microbial Biomarkers of Infection for In Vitro Diagnostic Device Use.'' The purpose of this workshop is to receive input from stakeholders and discuss approaches to the study of non-microbial biomarkers for differentiating viral from bacterial infections and for diagnosis and assessment of sepsis. Comments and suggestions generated through this workshop will facilitate further development of regulatory science for establishing appropriate comparator methods and clinically relevant performance standards for non-microbial based in vitro diagnostics for infection.

DATES: The public workshop will be held on October 16, 2015, from 8 a.m. to 5 p.m. Registration to attend the meeting must be made by 4 p.m. on October 6, 2015. Registration from those individuals interested in presenting comments should be received by September 16, 2015. See the **SUPPLEMENTARY INFORMATION** section for instructions on how to register for the meeting. Submit either electronic or written comments by 4 p.m. on November 13, 2015.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. 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 *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Natasha Townsend, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5525, Silver Spring, MD 20993–0002, 301–796–5927, FAX: 301–847–2512, email: *natasha.townsend@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

There has been increasing interest in the development of non-microbiological biomarkers to aid in determining whether patient signs and symptoms consistent with infection are attributable to an infectious or non-infectious cause,

and if infectious, whether of viral or bacterial etiology. Interest has ranged from aiding in the diagnosis of relatively mild outpatient upper respiratory symptoms to the assessment of critically ill patients. Progress in this area has been hindered by a lack of consensus on important issues in clinical trial design for new analytes; these issues include appropriate clinical trial designs (including acceptable comparator methods, *e.g.,* for ascertaining viral or bacterial infections), clinical definitions of different disease states, and acceptable device performance (*i.e.,* benefit/risk in different disease states and target populations). Devices that can differentiate a bacterial etiology from other causes of illness (*e.g.,* viral, fungal, or non-infectious etiologies) can significantly impact antibiotic stewardship and potentially antimicrobial resistance.

II. Purpose and Scope of the Public Workshop

The purpose of the public workshop is to discuss the use of non-microbial biomarkers as indicators of infection, potential clinical trial designs that can be used to establish effectiveness, and benefit/risk considerations for use. Specifically, FDA seeks input from health care practitioners, industry, government, academia, and other stakeholders on these topics. This discussion is viewed as essential for establishing the appropriate methods to study the safety and effectiveness of these analytes for different possible uses.

This public workshop will consist of brief presentations providing information to frame the goals of the workshop and interactive discussions via several panel sessions. The presentations will focus on current and anticipated uses for non-microbial biomarkers of infection and a review of different approaches that have been considered for clinical trials. Following the presentations there will be a moderated discussion where participants and additional panelists will be asked to provide their individual perspectives. Topics to be discussed include: (1) Clinical uses for non-microbial biomarkers of infection, (2) comparator methods for studies differentiating viral from bacterial infection, (3) performance standards, (4) statistical methods appropriate for sepsis biomarker trials, and (5) unique considerations when studying pediatric populations.

In advance of the meeting, FDA will place a summary of the issues it believes need consideration on file in the public docket (docket number found in brackets in the heading of this document) and will post it at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. The deadline for submitting comments on this document for presentation at the public workshop is September 11, 2015, although comments related to this document can be submitted until November 13, 2015.

III. Attendance and Registration

Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. on October 6, 2015. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4321, Silver Spring, MD 20993–0002, 301–796–5661, email: *susan.monahan@fda.hhs.gov,* no later than 4 p.m. on October 2, 2015.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

A. Streaming Webcast of the Public Workshop

This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 4 p.m. on October 6, 2015. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after October 8, 2015. 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 *http://www.adobe.com/go/connectpro_overview*. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

B. Requests for Oral Presentations

This public workshop includes a public comment session. During online registration you may indicate if you wish to present during a public comment session, and which topics you wish to address. FDA has included general topics in this document which are addressed in section II. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. All requests to make oral presentations must be received by September 16, 2015. FDA 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 participants by September 22, 2015. If selected for presentation, any presentation materials must be emailed to Yvonne Shea at *yvonne.shea@fda.hhs.gov* no later than 5 p.m. on October 2, 2015. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

IV. Comments

FDA is holding this public workshop to obtain information on approaches for establishing the performance of non-microbial biomarkers of infection for in vitro diagnostic device use. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is 4 p.m. on November 13, 2015.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific topics as

described in section II of this document, please identify the topic you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

V. Transcripts

As soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may also be viewed in person at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. (Select this public workshop from the posted events list.)

Dated: June 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–14983 Filed 6–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Human Immunodeficiency Virus (HIV) Organ Policy Equity (HOPE) Act Safeguards and Research Criteria for Transplantation of Organs Infected With HIV

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice of availability and request for comments.

SUMMARY: The HOPE Act requires the Secretary of Health and Human Services (the Secretary) to develop and publish criteria for research involving transplantation of HIV-infected (HIV+) donor organs in HIV+ recipients. The goals of these criteria are, first, to ensure that research using organs from HIV+ donors is conducted under conditions protecting the safety of research participants and the general public; and second, that the results of this research provide a basis for evaluating the safety of solid organ transplantation (SOT) from HIV+ donors to HIV+ recipients. The National Institutes of Health (NIH), U.S. Department of Health and Human Services, invites the public to submit comments regarding the proposed HOPE Act criteria.

DATES: To ensure that comments will be considered, comments must be received no later than 5:00 p.m. on August 17, 2015.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Email: HOPEAct@mail.nih.gov.*
- *Fax:* 301–451–5671.
- *Regular Mail:* Dr. Jonah Odim, 5601 Fishers Lane, Room 6B21, MSC 9827, Bethesda, MD 20892–9827.
- *Hand Delivery, Overnight Mail, FedEx, and UPS:* Dr. Jonah Odim, 5601 Fishers Lane, Room 6B21, MSC 9827, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Dr. Jonah Odim, 240–627–3540.

SUPPLEMENTARY INFORMATION: There is little evidence base for HIV+ to HIV+ organ transplantation, and it is only in liver and kidney transplantation that there is substantial experience with transplantation of organs from HIV-uninfected (HIV−) donors to HIV+ recipients. The criteria for conducting clinical research in HIV+ to HIV+ organ transplantation are set forth in six broad categories (Donor Eligibility, Recipient Eligibility, Transplant Hospital Criteria, Organ Procurement Organization (OPO) Responsibilities, Prevention of Inadvertent Transmission of HIV, and Study Design/Required Outcome Measures) and are summarized in the table below. These criteria are in addition to current policies and regulations governing organ transplantation and human subjects research. The goals of these criteria are, first, to ensure that research using organs from HIV+ donors is conducted under conditions protecting the safety of research participants and the general public; and second, that the results of this research provide a basis for evaluating the safety of SOT from HIV+ donors to HIV+ recipients.

Category	Criteria
Donor Eligibility:	
Deceased donor with known history of HIV infection.	Cluster of differentiation 4 (CD4)+ T-cell count ≥200/microliter (μL) or ≥14%. HIV–1 ribonucleic acid (RNA) <50 copies/milliliter (mL); No history of viral load >1000 copies/mL in the prior 12 months. No active opportunistic infection (OI).
Deceased donor with newly diagnosed HIV infection.	CD4+ T-cell count ≥200/μL or ≥14%. Viral load: no requirement. No active OI.
Living HIV+ donor	Well-controlled HIV infection. CD4+ T-cell count (lifetime nadir) ≥200/μL. CD4+ T-cell count ≥500/μL for the 6-month period before donation. HIV–1 RNA <50 copies/mL. No OI. Pre-transplant donor allograft biopsy showing no evidence of disease that would increase the risk of post-transplant organ failure or poor graft function.
Recipient (HIV+) Eligibility	CD4+ T-cell count ≥200/μL (kidney). CD4+ T-cell count ≥100μL (liver) within 16 weeks prior to transplant; or ≥200μL with history of OI HIV–1 RNA <50 copies/mL and on a stable antiretroviral regimen. No active OI or neoplasm. No history of chronic cryptosporidiosis, primary central nervous system (CNS) lymphoma, or progressive multifocal leukoencephalopathy (PML).