to mitigate future outbreaks of TASS. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 16, 2014.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for single copies of the draft guidance document entitled ''Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Michelle Tarver, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2504, Silver Spring, MD 20993–0002, 301–796–5620.

SUPPLEMENTARY INFORMATION:

I. Background

TASS has been increasing in frequency. Some cases of TASS are severe enough to require secondary surgical interventions including glaucoma surgery and corneal transplantation. It is estimated that clusters of 3 to 20 cases of TASS occur several times each year, translating to an estimated incidence of more than 1 in 1,000. The use of inadequately or improperly processed ophthalmic surgical instruments is one of many factors suggested as a potential cause of TASS. In many TASS cases, bacterial endotoxin from medical devices is believed to cause the inflammation.

This guidance document was developed to notify manufacturers and other entities involved in submitting PMAs or 510(k)s for different categories of IODs of the recommended endotoxin limit for the release of IODs and single-use intraocular ophthalmic surgical instruments/accessories in an effort to mitigate future TASS outbreaks.

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 endotoxin testing and limits for single-use IODs. 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 using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.*

To receive ''Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices,'' you may either send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1836 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 814 have been approved under OMB control number 0910–0231.

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: April 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08711 Filed 4–16–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, 102–3.65(a), notice is hereby given that the Charter for the National Science Advisory Board for Biosecurity (NSABB) was renewed for an additional two-year period on April 7, 2014.

It is determined that the NSABB is in the public interest and consistent with the performance of duties imposed on the Department of Health and Human Services by law, and that these duties can best be performed with the advice and counsel of this group.

Inquiries may be directed to Jennifer Spaeth, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496–2123, or *spaethj@od.nih.gov.*

Dated: April 11, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–08677 Filed 4–16–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Vaccine Research Center Board of Scientific Counselors, NIAID.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Allergy and

Infectious Diseases, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Vaccine Research Center Board of Scientific Counselors.

Date: May 12–13, 2014.

Time: 8:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Vaccine Research Center, 40 Convent Drive, Bethesda, MD 20892.

Contact Person: John R. Mascola, MD, Deputy Director, Vaccine Research Center NIAID, NIH, 40 Convent Drive, Bethesda, MD 20892, (301) 496–1852, *jmascola@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: April 11, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–08681 Filed 4–16–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, June 11, 2014, 11:00 a.m. to June 11, 2014, 01:00 p.m., National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 which was published in the **Federal Register** on April 09, 2014, 79 FR 19637.

This meeting will be held on June 4, 2014 from 11:00 a.m. until 01:00 p.m. at the National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892. The meeting is closed to the public.

Dated: April 11, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–08675 Filed 4–16–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Biomedical Imaging and Bioengineering Special Emphasis Panel; K Award & R 13 Conference Grant Review.

Date: May 12, 2014.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Steven J Zullo, Ph.D., Scientific Review Officer, National Institutes of Health/NIBIB, Bethesda, MD 20892, 240–271–9007, *Steven.zullo@nih.gov.*

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; MSM Program Review.

Date: May 28, 2014.

Time: 9:30 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Manana Sukhareva, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Boulevard, Suite 959, Bethesda, MD 20892, (301) 451–3397, *sukharem@mail.nih.gov.*

Dated: April 11, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–08679 Filed 4–16–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Human Insulin Research Network—Consortium on Beta Cell Death and Survival (HIRN–CDBS)–RFA–DK–13–018.

Date: June 17, 2014.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS).

Dated: April 11, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–08676 Filed 4–16–14; 8:45 am]

BILLING CODE 4140–01–P