presentations using unapproved or uncleared investigational devices in the United States. This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 16, 2014.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 Submit written requests for a single hard copy of the draft guidance document entitled ''Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials: Draft Guidance for Institutional Review Boards, Industry, Investigators, and Food and Drug Administration Staff'' to the Office of the Center Director, Guidance and Policy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Submit electronic comments on the draft guidance to *http://www.regulations.gov*.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: Sheila Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1651, Silver Spring, MD 20993–0002, 301–796–6563, *sheila.brown@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Requests for live case presentations have been submitted to the Agency as multiple supplements to an approved IDE application as either protocol deviations, changes to the investigational plan, or study expansion requests. Live case presentations have not generally been prospectively identified and described as components of the overall study design in original IDE applications.

Although it is expected that very few investigations conducted under an IDE will have the need for live case presentations, FDA has seen an increase in the number of requests for certain investigations to conduct live case presentations. Live case presentations may increase awareness of the study for potential investigators and facilitate the recruitment of subjects. Increased awareness of the IDE clinical study by other health care professionals resulting from a live case presentation might accelerate enrollment of eligible subjects which, in turn, may lead to new therapies being made available sooner. However, because of concerns related to human subject protection and uncertainty about potential differences between outcomes of subjects participating in live case presentations compared to subjects not participating in live case presentations, this guidance was developed for institutional review boards, review staff, the regulated industry and clinical community.

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 live case presentations during IDE clinical trials. 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*. Persons unable to download an electronic copy of ''Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials: Draft Guidance for Institutional Review Boards, Industry, Investigators, and Food and Drug Administration Staff,'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1736 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.

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. 2014–08710 Filed 4–16–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0332]

Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices.'' National outbreaks of Toxic Anterior Segment Syndrome (TASS) have been associated with single-use intraocular ophthalmic devices (IODs) and single-use intraocular ophthalmic surgical instruments/accessories that are contaminated with endotoxins. These devices can become contaminated as part of the manufacturing, sterilization, or packaging processes. This guidance document provides recommendations for endotoxin limits as well as endotoxin testing to manufacturers and other entities involved in submitting premarket applications (PMAs) or premarket notification submissions (510(k)s) for different categories of IODs

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