

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 This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 16, 2014.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 Submit written requests for single copies of the draft guidance document entitled "Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices" to the Office of the Center Director, Guidance and Policy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Submit electronic comments on the draft guidance to 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](mailto: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.*

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**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](mailto:spaethj@od.nih.gov).

Dated: April 11, 2014.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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**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