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.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov.*

Dated: *April 15, 2011.*

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9938 Filed 4–22–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–D–0094]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled, "Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities." This guidance document was developed as a special control to support the reclassification of the topical oxygen chamber for extremities (TOCE) from class III (premarket approval) into class II (special controls). This guidance document describes a means by which manufacturers of TOCE may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying these devices from class III into class II (special controls).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled, "Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities," to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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

FOR FURTHER INFORMATION CONTACT: Charles N. Durfor, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3555.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 6, 2006 (71 FR 17390), FDA's Center for Devices and Radiological Health (CDRH) published a proposed rule to reclassify the TOCE device type from class III (premarket approval) into class II (special controls) after reviewing current technological and scientific developments. To support the reclassification, CDRH issued a draft class II special controls guidance document entitled "Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities" (71 FR 17476). Interested persons were invited to comment on the proposed rule and guidance by July 5, 2006. FDA received 11 comments on the proposed rule. The comments received discussed academic literature, clinical experiences, and patient outcomes that support the proposed reclassification's determinations of the safety and effectiveness of the TOCE device. The comments did not recommend any changes to the proposed regulation.

FDA is now identifying the guidance document entitled "Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities" as the special control for these devices. This guidance document provides a means by which manufacturers of TOCE devices may comply with the requirement of special controls for class II devices. Following the effective date of the final reclassification rule, any manufacturer submitting a premarket notification submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C act) (21 U.S.C. 360(k)) for a TOCE device will need to address the issues covered in the special controls guidance document. However, the manufacturer need only show that its device meets the recommendations in the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

II. Significance of Special Controls Guidance

FDA believes that adherence to the recommendations described in this guidance document, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of TOCE classified under § 878.5650 (21 CFR 878.5650). The final rule establishing this guidance document as a special control will be effective May 25, 2011. Following the effective date of the final rule, TOCE classified under § 878.5650 must comply with the requirement of special controls; manufacturers must address the issues requiring special controls as identified in the guidance, either by following the recommendations in the guidance or by some other means that provides equivalent assurances of safety and effectiveness.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/RegulatoryInformation/Guidances/default.htm* or *http://www.regulation.gov.* Always access an FDA guidance document by using FDA's Web site listed previously to find the most current version of the guidance.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information were subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520).

The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR parts 50 and

56 have been approved under OMB control number 0910–0130.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: *April 19, 2011.*

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9898 Filed 4–22–11; 8:45 am]

BILLING CODE 4160–01–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 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: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Auditory System Study Section.

Date: June 1–2, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Lynn E Luethke, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5166, MSC 7844, Bethesda, MD 20892, (301) 806–3323, *luethkel@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences; Integrated Review Group. Molecular and Cellular Endocrinology Study Section.

Date: June 1, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: John Bleasdale, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170 MSC 7892, Bethesda, MD 20892, 301–435–4514, *bleasdaleje@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Molecular Genetics B Study Section.

Date: June 1–2, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Avenue Crowne Plaza Hotel and Suites, 160 E. Huron Street, Chicago, IL 60611.

Contact Person: Richard A Currie, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892, (301) 435–1219, *currieri@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Cognitive Neuroscience Study Section.

Date: June 1, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: One Washington Circle Hotel, One Washington Circle, NW., Washington, DC 20037.

Contact Person: Kirk Thompson, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, 301–435–1242, *kgt@mail.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function E Study Section.

Date: June 1, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monticello, 1075 Thomas Jefferson Street, NW., Washington, DC 20007.

Contact Person: Nitsa Rosenzweig, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1102, MSC 7760, Bethesda, MD 20892, (301) 435–1747, *rosenzweign@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Synthetic and Biological Chemistry B Study Section.

Date: June 1–2, 2011.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Dupont Hotel, 1500 New Hampshire Avenue, NW., Washington, DC 20036.

Contact Person: Kathryn M Koeller, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4166, MSC 7806, Bethesda, MD 20892, 301–435–2681, *koellerk@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Surgery, Anesthesiology and Trauma Study Section.

Date: June 1–2, 2011.

Time: 9 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: The Allerton Hotel, 701 North Michigan Avenue, Chicago, IL 60611.

Contact Person: Weihua Luo, MD, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892, (301) 435–1170, *luow@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Cellular, Molecular and Integrative Reproduction Study Section.

Date: June 2, 2011.

Time: 7 a.m. to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: The Allerton Hotel, 701 North Michigan Avenue, Chicago, IL 60611.

Contact Person: Gary Hunnicutt, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, 301–435–0229, *gary.hunnicutt@nih.gov.*

Name of Committee: Oncology 1–Basic Translational Integrated Review Group; Cancer Molecular Pathobiology Study Section.

Date: June 2–3, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Manzoor Zarger, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6208, MSC 7804, Bethesda, MD 20892, (301) 435–2477, *zargerma@csr.nih.gov.*