

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

[Docket No. 2006D-0112]

### **Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities; Availability**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

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry and FDA entitled “Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities.” It 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). Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify the TOCE device from class III into class II (special controls). This draft guidance is neither final nor is it in effect at this time.

**DATES:** Submit written or electronic comments on this draft guidance by *[insert date 90 days after date of publication in the **Federal Register**]*.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled “Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities to the Division of Small Manufacturers, International,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 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.fda.gov/dockets/ecomments>. 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, 301– 594–3090.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled “Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities.”

Following the effective date of any final reclassification rule based on this proposal, any firm submitting a premarket notification (510(k)) for the TOCE will need to address the issues covered in the special controls guidance document. However, the firm need only show that its device meets the recommendations of the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

**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 the TOCE. 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**

To receive "Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities" by fax, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1582) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** notices, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

### **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 PRA). 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.

**V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are

to be identified 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: March 27, 2006.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

**BILLING CODE 4160-01-S**