II. Electronic Access

Persons with access to the Internet may obtain the documents at http://www.fda.gov/cdrh/pmapage.html.

Dated: July 5, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–18038 Filed 7–16–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Safety and Efficacy of Methods for Reducing Pathogens in Cellular Blood Products Used in Transfusion; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of Public Workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Safety and Efficacy of Methods for Reducing Pathogens in Cellular Blood Products Used in Transfusion.'' The workshop will provide a forum for discussion of the scientific aspects of using state of the art methods for pathogen reduction in cellular blood products.

Date and Time: The 2-day public workshop will be held on August 7 and 8, 2002, from 8 a.m. to 5 p.m.

Location: The workshop will be held at Jack Masur Auditorium, National Institutes of Health, Bldg. 10, 9000 Rockville Pike, Bethesda, MD 20892.

Contact:

For information about this notice: Michael D. Anderson, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20857, 301–827–6210, FAX 301–594–1944.

For information about the public workshop: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–305), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6129, FAX 301–827–2843, e-mail at wilczek@cber.fda.gov.

Registration: Mail, fax, or e-mail your registration information (including name, professional degree, title, e-mail address, firm name, address, telephone, and fax number) to Joseph Wilczek by July 26, 2002. There is no registration fee for the public workshop. Space is limited, therefore, interested parties are encouraged to register early. There will be onsite registration done on a space available basis on the days of the workshop beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Joseph Wilczek at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is sponsoring a public workshop on evaluating methods for reducing pathogens in cellular blood products. Although there are no currently approved methods on the market today for pathogen reduction in cellular blood products, FDA is sponsoring this workshop for discussion of the scientific aspects of such methodologies. The objectives of the workshop are to discuss the criteria to define the efficacy of such products and appropriate ways to evaluate their toxicities to the transfusion products and to the recipients of these products. A public discussion of these topics will help the transfusion community better understand the development of these methods for cellular blood products intended for transfusion. The workshop will also help FDA prepare for the review of related applications. The public workshop agenda is posted on the FDA Internet at http://www.fda.gov/cber/scireg.htm.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 per page. The public workshop transcript will also be available on the Internet at http://www.fda.gov/cber/minutes/workshop-min.htm.

Dated: July 11, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–18037 Filed 7–16–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0064]

Draft Special Control Guidance Document on Encapsulated Amalgam,Amalgam Alloy, and Dental Mercury Labeling; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 60 days the comment period on the draft guidance entitled ''Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling.'' Elsewhere in this issue of the **Federal Register**, the agency is announcing the extension of the comment period on a proposed rule to classify encapsulated amalgam into class II, to amend the classification regulation for amalgam alloy to provide for special controls, and to reclassify dental mercury into class II. The draft guidance document is intended to serve as a special control for these devices. The agency is taking this action in response to a request for an extension.

DATES: Submit written or electronic comments on the guidance by September 16, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Susan Runner, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200Corporate Blvd., Rockville, MD 20850, 301–827–5283.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 20, 2002 (67 FR 7703), FDA published a notice announcing the availability of a draft guidance entitled ''Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling.'' In the same issue of the **Federal Register** (67 FR 7620), the agency published a proposed rule to classify encapsulated amalgam into class II, to amend the classification regulation for amalgam alloy to provide for special controls, and to reclassify dental mercury into class II. The draft guidance document is intended to serve as a special control for these devices.

FDA received an electronic request dated May 20, 2002, requesting that the agency extend the comment period on the proposed rule for 60 days, noting the importance of public health issues involved and explaining that there were apparently technical difficulties with the submission of electronic comments. FDA has determined that it is appropriate to grant this request, and elsewhere in this issue of the **Federal Register** FDA is announcing the reopening of the comment period on the proposed rule. FDA believes that it is also appropriate to reopen the comment period on the guidance document.

You may submit to the Dockets Management Branch (see **ADDRESSES**)

written or electronic comments on the draft guidance entitled ''Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling'' by September 16, 2002. You must submit two copies of any comments. Individuals may submit one copy. You must identify comments with the docket number found in brackets in the heading of this document. Comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 5, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–17961 Filed 7–16–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1458]

Medical Devices: Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA; 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: Apnea Monitors; Guidance for Industry and FDA.'' This document describes a means by which apnea monitors 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 classifying apnea monitors into class II (special controls).

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

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance entitled ''Class II Special Controls Document: Apnea Monitors; Guidance for Industry and FDA'' 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 two self-addressed labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: William Noe, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 22, 2000 (65 FR 57355), FDA announced the availability of this draft guidance document and invited interested persons to comment on it by December 21, 2000. FDA also announced in that notice its intention to modify the guidance so that it would apply to apnea monitors for patients of all ages. In that same issue of the **Federal Register** (65 FR 57301), FDA proposed to classify the apnea monitor into class II with this guidance document as the special control. This guidance supersedes the draft guidance entitled ''Guidance for Infant/Child Apnea Monitor 510(k) Submissions.''

FDA received comments on the draft guidance from one manufacturer. We considered this manufacturer's comments and included some of its suggestions in our revised guidance. We revised the guidance to make it applicable to devices intended for adults as well as infants and children, added information concerning industry's option to submit an abbreviated 510(k) when relying on a class II special controls guidance document, and retitled the guidance to reflect these changes.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on ''Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA.'' 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

In order to receive the guidance entitled ''Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA'' via your fax machine, call the Center for Devices and Radiological Health (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 (1178) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so 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** reprints, 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 home page 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 at http://www.fda.gov/ohrms/dockets.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 collection of information in the labeling section of this guidance discussing labeling under 21 CFR 807.87(e) was approved under OMB control number 0910–0120. The collection of information in the labeling section of this guidance discussing labeling under 21 CFR 801.109 was approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the