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**)