DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 02M–0083, 02M–0082, 02M–0006, 02M–0128, 02M–0076, 02M–0034, 02M–0030, 02M–0060, 02M–0118, 02M–0121, and 02M–0134]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Dockets Management Branch.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule to revise §§ 814.44(d) and 814.45(d) (21 CFR 814.44(d) and 814.45(d)) to discontinue publication of individual PMA approvals and denials in the **Federal Register**. Instead, revised §§ 814.44(d) and 814.45(d) state that FDA will notify the public of PMA approvals and denials by posting them on FDA's home page on the Internet at http://www.fda.gov, by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch, and by publishing in the **Federal Register** after each quarter a list of available safety and effectiveness summaries of approved PMAs and denials announced in that quarter.

FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure explained previously from January 1, 2002, through March 31, 2002. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE JANUARY 1, 2002, THROUGH MARCH 31, 2002

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P000012/02M–0083	Roche Molecular Systems, Inc.	COBAS AMPLICOR Hepatitis C Virus Test, version 2.0.	July 3, 2001.
P000010/02M–0082	Roche Molecular Systems, Inc.	AMPLICOR Hepatitis C Virus Test, version 2.0.	July 5, 2001.
P000025/02M–0006	Med-El Corp.	MED-EL COMBI 40+ Cochlear Implant System.	August 20, 2001.
P010013/02M–0128	Novacept, Inc.	NOVASURE Impedance Controlled Endometrial Ablation System.	September 28, 2001.
P010022/02M–0076	Cohesion Technologies, Inc.	COSEAL Surgical Sealant.	December 14, 2001.
P000048/02M–0034	Dornier Medical Systems, Inc.	DORNIER EPOS ULTRA.	January 15, 2002.
P010038/02M–0030	Intelligent Systems Software, Inc.	MAMMOREADER (Computer-Aided Detection System For Mammography).	January 15, 2002.
P010034/02M–0060	CADx Medical Systems, Inc.	SECOND LOOK (Computer-Aided Detection System For Mammography).	January 31, 2002.
P010040/02M–0118	Safeguard Medical Devices, Inc.	The DISINTEGRATOR Insulin Needle Destruction Device.	March 15, 2002.
H010005/02M–0121	Ascension Orthopedics, Inc.	ASCENSION PIP.	March 22, 2002.
P010049/02M–0134	SUB–Q, Inc.	QuickSeal Femoral Arterial Closure System.	March 25, 2002.

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]

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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**)