DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB
1-14-02
1-15-02
D. Hawkins

Food and Drug Administration

[Docket Nos. 01M–0271, 01M–0255, 01M–0210, 01M–0173, 01M–0254, 01M–0227, 01M–0226, and 01M–0270]

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:

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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 April 1, 2001, through June 30, 2001. 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 APRIL 1, 2001, THROUGH JUNE 30, 2001

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P990086/01M–0271	HealthTronics, Inc.	HealthTronics OssaTron®	October 12, 2000
P000023/01M–0255	TMJ Implants, Inc.	TMJ Fossa-Eminence/Condylar Prosthesis System™	January 5, 2001
P000035/01M–0210	TMJ Implants, Inc.	TMJ Fossa-Eminence Prosthesis™	February 27, 2001
P990080/01M–0173	Pharmacia & Upjohn Co.	CeeOn™ Edge Foldable Ultraviolet Light-Absorbing Posterior Chamber Intraocular Lens, Model 911A	April 5, 2001
P980050(S1)/01M–0254	Medtronic, Inc.	Medtronic® Model 7350 Jewel® AF Implantable Cardioverter Defibrillator System, Medtronic Model 9465 InCheck™ Patient Assistant, and Medtronic Transvene® CS/SVC Model 6937A Lead	April 6, 2001
P000046/01M–0227	Anika Therapeutics, Inc.	Staar Surgical Co. STAARVISC™ II Sodium Hyaluronate	April 18, 2001
P000044/01M–0226	Ortho-Clinical Diagnostics, Inc.	Vitros Immunodiagnostic Products HBsAg Reagent Pack, HBsAg Confirmatory Kit, and HBsAg Calibrator	April 27, 2001
P000037/01M–0270	Medical Carbon Research Institute, LLC.	ON–X® Prosthetic Heart Valve, Model ONXA	May 30, 2001

II. Electronic Access

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

Dated: 12/31/01

December 31, 2001.

Linda S. Kahan

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