Federal Register: Medical Devices: Safety and Effectiveness Summaries for Premarket Approval Applications; Availability(2)

U.S. Food & Drug Administration

[Federal Register: November 26, 2010 (Volume 75, Number 227)] [Notices] [Page 72829-72830] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr26no10-81]

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration [Docket Nos. FDA-2010-M-0402, FDA-2010-M-0361, and FDA-2010-M-0519] 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 Division of Dockets Management. ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (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: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993-0002, 301-796-6570. SUPPLEMENTARY INFORMATION: I. Background In the Federal Register of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the Federal Register. Instead, the Agency now posts this information on the Internet on FDA's home page at http://www.fda.gov [1]. 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 FD&C 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 FD&C Act. The 30-day period for requesting reconsideration of an FDA action under Sec. 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 regulations provide

that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from July 1, 2010, through September 30, 2010. 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 From July 1, 2010, Through September 30, 2010

PMA No. Docket No. Applicant Trade name Approval date

P080027, FDA-2010-M-0402..... OraSure Technologies, ORAQUICK HCV RAPID June 25, 2010. Inc. ANTIBODY TEST. P050034, FDA-2010-M-0361..... Vision Care Ophthalmic IMPLANTABLE MINIATURE July 1, 2010. Technologies, Ltd. TELESCOPE. P080026, FDA-2010-M-0519..... Abbott Molecular, Inc... ABBOTT REALTIME HBV August 13, 2010. ASSAY.

II. Electronic Access Persons with access to the Internet may obtain the documents at http://www.fda.gov/cdrh/pmapage.html [2]. Dated: November 18, 2010. Nancy K. Stade, Deputy Director for Policy, Center for Devices and Radiological Health. [FR Doc. 2010-29731 Filed 11-24-10; 8:45 am] BILLING CODE 4160-01-P

SOURCE [3]

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http://www.mdtmag.com/news/2010/11/federal-register-medical-devices-safety-and-effectiveness-summaries-premarket-approval-applications-availability2?qt-most_popular=0

Links:
[1] http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.fda.gov
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[3] http://edocket.access.gpo.gov/2010/2010-29731.htm