DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–M–0726, FDA–2011–M–0919, FDA–2012–M–0024, FDA–2012–M–0056, FDA–2012–M–0074, FDA–2012–M–0075, FDA–2012–M–0082, FDA–2012–M–0112, FDA–2012–M–0172, FDA–2012–M–0173, FDA–2012–M–0177, FDA–2012–M–0180, FDA–2012–M–0181, FDA–2012–M–0207, FDA–2012–M–0208, FDA–2012–M–0209, FDA–2012–M–0210, FDA–2012–M–0221, and FDA–2012–M–0250]

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 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 § 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 January 1, 2012, through March 31, 2012. 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 JANUARY 1, 2012, THROUGH MARCH 31, 2012

PMA No., Docket No.	Applicant	Trade name	Approval date
P090012, FDA–2012–M–0074	Mela Sciences, Inc	MelaFind	November 1, 2011.
H100008, FDA–2011–M–0726	TriVascular, Inc	OVATION Abdominal Stent Graft System.	November 1, 2011.
H090002, FDA–2011–M–0848	BSD Medical Corporation	BSD–2000 Hyperthermia System	November 18, 2011.
H100004, FDA–2011–M–0919	Berlin Heart, Inc	Berlin Heart EXCOR Pediatric Ventricular Assist Device.	December 16, 2011.
P110031, FDA–2012–M–0024	Roche Diagnostics Corp	Elecsys Anti-HBc IgM Immunoassay and Elecsys PreciControl Anti-HBc IgM.	January 3, 2012.
P040043.S040, FDA–2012–M–0056	W.L. Gore & Associates, Inc	Gore TAG Thoracic Endoprosthesis	January 13, 2012.
P100039, FDA–2012–M–0075	Siemens Healthcare Diagnostics Inc	ADVIA Centaur Anti-HBs2 Assay and Quality Control Material.	January 20, 2012.
P100005, FDA–2012–M–0082	Vucomp, Inc	M–Vu Algorithm Engine	January 23, 2012.
P110016, FDA–2012–M–0112	St. Jude Medical, Inc. (parent company for Irvine Biomedical, Inc.).	Therapy Cool Path Duo/Safire BLU Duo Ablation Catheter and IBI 1500T9–CP V1.6 Cardiac Ablation Generator.	January 25, 2012.
P080012, FDA–2012–M–0180	Flowonix Medical, Inc. (approved under Medasys, Inc.).	Prometra Programmable Infusion Pump System.	February 7, 2012.
P100007, FDA–2012–M–0172	Almen Laboratories, Inc	Breast Companion Software System	February 10, 2012.
P100033, FDA–2012–M–0173	Gen-Probe Inc	PROGENSA PCA3 Assay	February 13, 2012.
P110013, FDA–2012–M–0177	Medtronic Vascular	Resolute MicroTrac/Resolute Integrity Zotarolimus-Eluting Coronary Stent System.	February 17, 2012.
P110028, FDA–2012–M–0181	Abbott Vascular Inc	Absolute Pro Vascular Self-Expanding Stent System.	February 22, 2012.
P100025, FDA–2012–M–0207	Otsuka America Pharmaceutical, Inc	BreathTek UBT *H. pylori* Kit and Pediatric Urea Hydrolysis Rate Calculation Application (PUHR–CA), Version 1.0.	February 22, 2012.
P100023.S015, FDA–2012–M–0208	Boston Scientific Corp	ION Paclitaxel-Eluting Coronary Stent System (Monorail and Over-The-Wire Delivery Systems).	February 22, 2012.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2012, THROUGH MARCH 31, 2012—Continued

PMA No., Docket No.	Applicant	Trade name	Approval date
P060008.S046, FDA–2012–M–0210 ...	Boston Scientific Corp	TAXUS Liberté Paclitaxel-Eluting Coronary Stent System (Monorail and Over-The-Wire Delivery Systems).	February 22, 2012.
P030025.S086, FDA–2012–M–0209 ...	Boston Scientific Corp	TAXUS Express2 Paclitaxel-Eluting Coronary Stent System (Monorail and Over-The-Wire Delivery Systems).	February 22, 2012.
P110023, FDA–2012–M–0221	ev3, Inc	Everflex Self-Expanding Peripheral Stent System (Everflex).	March 7, 2012.
P070004, FDA–2012–M–0250	Sientra, Inc	SIENTRA Silicone Gel Breast Implants.	March 9, 2012.

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm* and *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm.*

Dated: June 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14486 Filed 6–13–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Update to Electronic Common Technical Document Module 1

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Update to Electronic Common Technical Document Module 1. The topic to be discussed is final documentation of the Electronic Common Technical Document (eCTD) Module 1, which is used for electronic submission of administrative and prescribing information by industry. The purpose of the meeting is to provide clarification and answer questions from industry and software vendors regarding the changes being made to this module. Registration is required in advance and participation will be limited.

DATES: *Date and Time:* The meeting will be held on Tuesday, September 18, 2012, from 8 a.m. to 11:30 a.m.

LOCATION: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Great Room 1503, Silver Spring, MD 20993. The following link contains public meeting attendee information as well as frequently asked questions and answers regarding public meetings at White Oak: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

CONTACT: Julie Quinonez, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1135, Silver Spring, MD 20993, 301–796–0282, FAX: 301–796–9876, email: *Julie.Quinonez@fda.hhs.gov.*

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to Julie Quinonez (see *Contact*). Registrations will be accepted in the order that they are received with a limit of 350.

SUPPLEMENTARY INFORMATION: The eCTD is an International Conference on Harmonization (ICH) standard based on specifications developed by ICH and its member parties. The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) have been receiving submissions in the eCTD format since 2003, and the eCTD has been the standard for electronic submissions to CDER and CBER since January 1, 2008. In fact, the majority of new electronic submissions are now received in eCTD format. Since adoption of the eCTD standard, it has become necessary to update the administrative portion of the eCTD Module 1 to reflect regulatory changes; to provide clarification of business rules for submission, processing, and review; to refine the characterization of promotional labeling and advertising material; and to facilitate automated processing of submissions. In the process of considering these changes, FDA has previously made available for comment versions of documents that support making regulatory submissions in electronic format using the (eCTD) specifications. These draft documents represented FDA's major updates to Module 1 of the eCTD based on previous comments. FDA will make available revised versions of these documents in preparation for this meeting. These documents will be posted at: *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm.*

If you need special accommodations due to a disability, please contact Julie Quinonez (see *Contact*) at least 7 days in advance.

Dated: June 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14469 Filed 6–13–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0517]

Notice of Withdrawal of Certain Unapproved Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing its intention to deem to be withdrawn any abbreviated new drug applications (ANDAs) that have been determined to be incomplete and as to which the ANDA applicant has not communicated with FDA since July 8, 1991. Each of these applications will be