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