(PMAs) 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, 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.* 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 § 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 October 1, 2010, through December 31, 2010, and includes one denial action during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the date of action.

TABLE 1—LIST OF PMA ACTIVITY FROM OCTOBER 1, 2010, THROUGH DECEMBER 31, 2010

| PMA No. | Docket No. | Applicant | Trade name | Date of action |
|---|---|---|---|---|
| P100016 | FDA–2010–M–0556 | Aaren Scientific, Inc | EC–3 intraocular lens (IOL) and EC–3 precision aspheric lens (PAL) IOL. | Approved October 19, 2010. |
| P040005 (S005) | FDA–2010–M–0558 | Dako Denmark A/S | *HER* 2 FISH PharmDx kit | Approved October 20, 2010. |
| P980018 (S010) | FDA–2010–M–0557 | Dako Denmark A/S | HercepTest kit | Approved October 20, 2010. |
| P080009 | | Ethicon Endo-Surgery, Inc. | SEDASYS computer-assisted personalized sedation system. | Denied October 27, 2010. |
| P080018 | FDA–2010–M–0591 | Carestream Health, Inc. | Kodak DirectView CR mammography system. | Approved November 3, 2010. |

## II. Electronic Access

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

Dated: March 23, 2011.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

[FR Doc. 2011–7212 Filed 3–25–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0002]**

### Pregnancy and Prescription Medication Use Symposium

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Pregnancy and Prescription Medication Use Symposium. The topic to be discussed is "Prescription Drug Use in Pregnancy."

*Date and Time:* The meeting will be held on May 17, 2011, from 8 a.m. to 4:30 p.m.

*Location:* The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002.

*Contact:* Monica Yu, Office of Women's Health (OWH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 2313, 301–796–9449, e-mail: *monica.yu@fda.hhs.gov.*

*Registration:* There is no registration fee, but seating is limited to 100. Send registration information (including name, title, firm name, address, telephone number, and e-mail address), to the following registration link by May 10, 2011: *http://www.accessdata.fda.gov/scripts/email/oc/pregnancysymposium.cfm.*

If you need special accommodations due to a disability, please contact Monica Yu at least 7 days in advance.

*Visitor parking:* Please see *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

**SUPPLEMENTARY INFORMATION:**

*Transcripts:* There will not be any transcripts; however, the speakers' Power Point presentations will be posted on the FDA/OWH Web site after the meeting at: *http://www.fda.gov/ForConsumers/byAudience/ForWomen/default.htm.*

Dated: *March 23, 2011.*

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

[FR Doc. 2011–7215 Filed 3–25–11; 8:45 am]

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