

13. Endolymphatic Shunt Tube with Valve,  
 14. Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis,  
 15. Apnea Monitors,  
 16. Polymethylmethacrylate (PMMA) Bone Cement,  
 17. Cyclosporine and Tacrolimus Assays,  
 18. Transcutaneous Air Conduction Hearing Aid System (TACHAS),  
 19. Intraoral Devices for Snoring and/or Obstructive Sleep Apnea,  
 20. Cutaneous Carbon Dioxide and Oxygen Monitors,  
 21. Knee Joint Patellofemoral and Femoral Tibial Metal/Polymer Porous-Coated Uncemented Prostheses,  
 22. Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations,  
 23. Resorbable Calcium Salt Bone Void Filler Device,  
 24. Surgical Sutures,  
 25. Breath Nitric Oxide Test,  
 26. Breast Lesion Documentation System,  
 27. Arrhythmia Detector and Alarm,  
 28. Serological Reagents for the Laboratory Diagnosis of West Nile Virus,  
 29. Endotoxin Assay,  
 30. Dental Sonography and Jaw Tracking Devices,  
 31. Human Dura Mater (applicable to dura mater recovered before May 25, 2005),  
 32. Hepatitis A Virus Serological Assays,  
 33. Factor V Leiden DNA Mutation Detection Systems,  
 34. Immunomagnetic Circulating Cancer Cell Selection and Enumeration System,  
 35. Root-form Dental Implants and Endosseous Dental Implant Abutments,  
 36. Dental Base Metal Alloys,  
 37. Dental Noble Metal Alloys,  
 38. Serological Assays for the Detection of Beta-Glucan,  
 39. Sirolimus Test Systems,  
 40. Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry,  
 41. Implantable Radiofrequency Transponder System for Patient Identification and Health Information,  
 42. External Penile Rigidity Devices,  
 43. Assisted Reproduction Laser Systems,  
 44. Vascular and Neurovascular Embolization Devices,  
 45. Drug Metabolizing Enzyme Genotyping System,  
 46. Instrumentation for Clinical Multiplex Test Systems,  
 47. Automated Fluorescence in situ Hybridization (FISH) Enumeration Systems,

48. Dental Bone Grafting Material Devices,  
 49. RNA Preanalytical Systems (RNA Collection, Stabilization and Purification Systems for RT-PCR used in Molecular Diagnostic Testing),  
 50. Oral Rinse to Reduce the Adhesion of Dental Plaque,  
 51. AFP-L3% Immunological Test Systems,  
 52. CFTR Gene Mutation Detection System,  
 53. Low Energy Ultrasound Wound Cleaner,  
 54. Tinnitus Masker Devices,  
 55. Labeling for Male Condoms Made of Natural Rubber Latex,  
 56. Implantable Intra-Aneurysm Pressure Measurement System,  
 57. Reagents for Detection of Specific Novel Influenza A Viruses,  
 58. Topical Oxygen Chamber for Extremities,  
 59. Olfactory Test Device,  
 60. Fecal Calprotectin Immunological Test Systems,  
 61. Absorbable Hemostatic Device,  
 62. Quality Control Material for Cystic Fibrosis Nucleic Acid Assays,  
 63. Oxygen Pressure Regulators and Oxygen Conserving Devices,  
 64. Herpes Simplex Virus Types 1 and 2 Serological Assays,  
 65. Computerized Labor Monitoring Systems,  
 66. Gene Expression Profiling Test System for Breast Cancer Prognosis,  
 67. Intervertebral Body Fusion Device,  
 68. Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies,  
 69. Absorbable Poly(hydroxybutyrate) Surgical Suture Produced by Recombinant DNA Technology,  
 70. In Vitro Human Immunodeficiency Virus (HIV) Drug Resistance Genotype Assay,  
 71. Electrocardiograph Electrodes,  
 72. Remote Medication Management System,  
 73. Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle,  
 74. Plasmodium Species Antigen Detection Assays,  
 75. Full Field Digital Mammography System,  
 76. Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters,  
 77. Tissue Adhesive for the Topical Approximation of Skin,  
 78. Bone Sonometers,  
 79. Tissue Expander,  
 80. Cord Blood Processing System and Storage Container.

## II. Electronic Access

Persons interested in obtaining a copy of any revised special controls guidance

document may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. To receive any affected CDRH guidance you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy.

For CBER guidances, you may send a request to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. In addition, CBER guidance documents are available at <http://www.fda.gov/Biologics/BloodVaccines/GuidanceCompliance/RegulatoryInformation/default.htm>.

## III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**Authority:** 21 U.S.C. 371(h).

**Dated:** March 23, 2011.

**David Dorsey,**

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

[FR Doc. 2011-7211 Filed 3-25-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2010-M-0519, FDA-2010-M-0556, FDA-2010-M-0558, FDA-2010-M-0557, and FDA-2010-M-0591]

### 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) 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](mailto: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](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]

**BILLING CODE 4160-01-P**