The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

**Dana Redford,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2013–00007 Filed 1–4–13; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–D–0530]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Medical Devices: The Pre-Submission Program and Meetings With FDA Staff; Withdrawal

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

**ACTION:** Withdrawal of notice.

**SUMMARY:** This document withdraws a Food and Drug Administration (FDA) notice that published in the **Federal Register** of December 11, 2012 (77 FR 73662).

**DATES:** This notice is withdrawn on January 7, 2013.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** FDA published a notice in the **Federal Register** of December 11, 2012 (77 FR 73662), informing interested parties that the proposed collection of information entitled ''Guidance on Medical Devices: The Pre-Submission Program and Meetings with FDA Staff'' had been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 and inviting the public to submit comments on the proposed study to OMB. As of the date of this notice, FDA has not finalized the policy document underlying this information collection request. Thus, FDA is withdrawing the proposed collection of information published on December 11, 2012, at this time.

Dated: December 31, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–00009 Filed 1–4–13; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–2012–M–0712, FDA–2012–M–0713, FDA–2012–M–0734, FDA–2012–M–0735, FDA–2012–M–0814, FDA–2012–M–0833, FDA–2012–M–0893, FDA–2012–M–0965, FDA–2012–M–0968, FDA–2012–M–1011, and FDA–2012–M–1013]**

### 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 sections 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 July 1, 2012, through September 30, 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 JULY 1, 2012, THROUGH SEPTEMBER 30, 2012

| PMA No., Docket No. | Applicant | Trade name | Approval date |
|---|---|---|---|
| P980022/S010, FDA–2012–M–0965. | Medtronic MiniMed, Inc ..... | Guardian Telemetered Glucose Monitoring System (TGMS). | January 7, 2004. |
| P000008/S017, FDA–2012–M–1013. | Allergan, Inc ..... | LAP–BAND™ Adjustable Gastric Banding System ..... | February 16, 2011. |
| P100049, FDA–2012–M–0893. | Torax Medical, Inc ..... | LINX™ Reflux Management System ..... | March 22, 2012. |
| P010031/S232, FDA–2012–M–0814. | Medtronic, Inc ..... | Concerto/Concerto II; Consulta; Maximo II; and Protecta/Protecta XT Families of CRT–Ds. | April 4, 2012. |

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JULY 1, 2012, THROUGH SEPTEMBER 30, 2012—Continued

| PMA No., Docket No. | Applicant | Trade name | Approval date |
|---|---|---|---|
| P080030, FDA–2012–M–0712. | Glaukos Corp | Glaukos iStent® Trabecular Micro-Bypass Stent and Inserter. | June 25, 2012. |
| P110007, FDA–2012–M–0734. | Abbott Medical Optics, Inc | Healon® EndoCoat OpViscosurgical Ophthalmic Device (OVD) (3% Sodium Hyaluronate). | July 2, 2012. |
| P110037, FDA–2012–M–0713. | Roche Molecular Systems, Inc. | COBAS® AmpliPrep/COBAS® TaqMan® CMV Test | July 5, 2012. |
| P110030, FDA–2012–M–0735. | QIAGEN Manchester, Ltd | *therascreen*® KRAS RGQ PCR Kit | July 6, 2012. |
| P110043, FDA–2012–M–0833. | Abbott Vascular | Omnilink Elite Vascular Balloon-Expandable Stent System. | July 31, 2012. |
| P040024/S056, FDA–2012–M–0968. | Medicis Aesthetics Holdings, Inc. | Restylane L Injectable Gel | August 30, 2012. |
| P110006, FDA–2012–M–1011. | U-Systems, Inc | somo-v® Automated Breast Ultrasound System (ABUS). | September 18, 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.*

Dated: December 31, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–00004 Filed 1–4–13; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2012–N–1205]**

### Accessible Medical Device Labeling in a Standard Content and Format Public Workshop; Request for Comments

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

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Accessible Standardized Medical Device Labeling.'' The purpose of this public workshop is to discuss the growing need for medical device labeling to be delivered in a clear, concise, and readily accessible format so that patients, caregivers, and healthcare providers may access and utilize device labeling as efficiently and effectively as possible. This public workshop aims to engage stakeholders in active discussion with FDA and to encourage public comments regarding standard content and format for medical device labeling and the use of a repository containing medical device labeling.

**DATES:** The public workshop will be held on April 29, 2013, from 8 a.m. to 5 p.m. and April 30, 2013, from 8 a.m. to 4 p.m.

**ADDRESSES:** The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503A), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

**FOR FURTHER INFORMATION CONTACT:** Mary Weick-Brady, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5426, 301–796–6089, FAX: 301–847–8510, email: *Mary.Brady@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

*Registration:* Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by April 5, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Joyce Raines by email: *Joyce.Raines@fda.hhs.gov* or phone: 301–796–5709 at least 7 days prior to the public workshop.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* Select this public workshop from the posted events list. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Mary Weick-Brady to register (see **FOR FURTHER INFORMATION CONTACT**). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

*Streaming Webcast of the Public Workshop:* This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by April 5, 2013, 5 p.m. EST. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after April 5, 2013. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

*Requests for Oral Presentations:* This public workshop includes a public comment session and topic-focused sessions. During online registration, you may indicate if you wish to present during a public comment session and which topics you want to address. All topic-focused sessions will be held