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DATES: This notice is withdrawn on January 7, 2013.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