EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development	$273,838	$136,919
Data Collection Activities	153,119	76,560
Data Processing and Analysis	171,764	85,882
Publication of Results	14,753	7,377
Project Management	10,032	5,016
Overhead	377,696	188,848
Total	1,001,202	500,601

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques, or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: December 20, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012–31592 Filed 1–4–13; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Office for State, Tribal, Local and Territorial Support (OSTLTS)

In accordance with Presidential Executive Order No. 13175, November 6, 2000, and the Presidential Memorandum of November 5, 2009 and September 23, 2004, Consultation and Coordination with Indian Tribal Governments, CDC/Agency for Toxic Substances and Disease Registry (ATSDR), announces the following meeting and Tribal Consultation Session:

Name: Tribal Advisory Committee (TAC) Meeting and 10th Biannual Tribal Consultation Session.

Times and Dates:

8:00 a.m.–9:30 a.m., February 5, 2013 (TAC Meeting).

8:00 a.m.–5:00 p.m., February 6, 2013 (10th Biannual Tribal Consultation Session).

8:00 a.m.–4:00 p.m., February 7, 2013 (TAC Meeting).

Place: The TAC Meeting and Tribal Consultation Session will be held at CDC Headquarters, 1600 Clifton Road, NE., Global Communications Center, Auditorium B3, Atlanta, Georgia.

Status: All meetings are being hosted by CDC/ATSDR. Meetings on February 5, 6, and 7, 2013, are open to the public.

Purpose: In 2011–2012, CDC began revising its existing Tribal Consultation Policy (issued in 2005) with the primary purpose of providing guidance across the agency to work effectively with American Indian/Alaska Native (AI/AN) tribes, communities, and organizations to enhance AI/AN access to CDC resources and programs. Within the CDC Consultation Policy, it is stated that CDC will conduct government-to-government consultation with elected tribal officials or their authorized representatives before taking actions and/or making decisions that affect them. Consultation is an enhanced form of communication that emphasizes trust, respect, and shared responsibility. It is an open and free exchange of information and opinion among parties that leads to mutual understanding and comprehension. CDC believes that consultation is integral to a deliberative process that results in effective collaboration and informed decision making with the ultimate goal of reaching consensus on issues. Although formal responsibility for the agency's overall government-to-government consultation activities rests within the CDC Office of the Director (OD), other CDC Center, Institute, and Office (CIO) leadership shall actively participate in TAC meetings and HHS-sponsored regional and national tribal consultation sessions as frequently as possible.

Matters To Be Discussed: The TAC will convene their advisory committee meeting with discussions and presentations from various CDC senior leaders on activities and areas identified by TAC members and other tribal leaders as priority public health issues. The following topics are scheduled for presentation and discussion during the TAC Meeting; however, discussion is not limited to these topics: substance abuse/mental health, community based participatory public health, success stories, and grant information and opportunities at CDC for Native participation.

The 10th Biannual Tribal Consultation Session will engage CDC senior leadership from the CDC OD and various CDC CIOs. Sessions that will be held during the Tribal Consultation include the following: a listening session with the director of CDC, roundtable discussions with CDC senior leadership and an opportunity for tribal testimony.

Additional opportunities will be provided during the Consultation Session for tribal testimony. Tribal Leaders are encouraged to submit written testimony by 12:00 a.m., EST on January 25, 2013, to Kimberly Cantrell, Deputy Associate Director for Tribal Support, OSTLTS, via mail to 4770 Buford Highway NE., MS E–70, Atlanta, Georgia 30341 or email to *klw6@cdc.gov.* Depending on the time available, it may be necessary to limit the time of each presenter.

The agenda is subject to change as priorities dictate.

Information about the TAC, CDC's Tribal Consultation Policy, and previous meetings may be referenced on the following web link: *http://www.cdc.gov/tribal.*

Contact Person For More Information: Kimberly Cantrell, Deputy Associate Director for Tribal Support, OSTLTS, via mail to 4770 Buford Highway NE., MS E–70, Atlanta, Georgia 30341 or email to *klw6@cdc.gov.*

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.