DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–17579–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

ACTION: 30-Day notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act (PRA) of 1995, the Office of the Secretary (OS), Department of Health and Human Services, will submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number 0937–0166, scheduled to expire on December 31, 2012. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

Deadline: Comments on the ICR must be received within 30 days of the issuance of this notice.

ADDRESSES: Submit your comments, including the OMB control number 0937–0166 and document identifier HHS–OS–17579–30D, to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806. Copies of the supporting statement and any related forms may be requested via email to *Information.Collection Clearance@hhs.gov* or by calling (202) 690–6162.

Information Collection Request Title: HHS 42CFR subpart B; Sterilization of Persons in Federally Assisted Family Planning Projects

Abstract: This is a request for extension of a currently approved collection for the disclosure and record-keeping requirements codified at 42 CFR part 50, subpart B (''Sterilization of Persons in Federally Assisted Family Planning Projects''). The consent form solicits information to assure voluntary and informed consent to persons undergoing sterilization in programs of health services which are supported by federal financial assistance administered by the Public Health Service (PHS) Act. It provides additional procedural protection to the individual and the regulation requires that the consent form be a copy of the form that is appended to the PHS regulation. In 2003, the PHS sterilization consent form was revised to conform to OMB government-wide standards for the collection of race/ethnicity data and to incorporate the PRA burden statement as part of the consent form. The current form has been updated to conform to the changed name of a federal entitlement program. The program, Aid to Families with Dependent Children (AFDC), utilized by low-income families with dependent children who need federal assistance, has been replaced by a different program with similar aims, Temporary Assistance for Needy Families (TANF). Consequently, the reference to A.F.D.C. in the first paragraph has been replaced with a reference to T.A.N.F.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Forms (if necessary)	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
100,000	citizen seeking sterilization	100,000	1	15/60	25,000

Keith A. Tucker,

Information Collection Clearance Officer, Department of Health and Human Services.

[FR Doc. 2012–24845 Filed 10–9–12; 8:45 am]

BILLING CODE 4150–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting of the Presidential Commission for the Study of Bioethical Issues

AGENCY: Department of Health and Human Services, Office of the Assistant Secretary for Health, Presidential Commission for the Study of Bioethical Issues.

ACTION: Notice of meeting.

SUMMARY: The Presidential Commission for the Study of Bioethical Issues will conduct its eleventh meeting in November. At this meeting, the Commission will continue discussing topics related to the ethical issues associated with the development of medical countermeasures for children.

DATES: The meeting will take place Monday and Tuesday, November 5–6, 2012.

ADDRESSES: Divinity School of The University of Chicago, 1025 E. 58th Street, Chicago, IL 60637. Telephone (773) 702–8200.

FOR FURTHER INFORMATION CONTACT: Hillary Wicai Viers, Communications Director, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW., Suite C–100, Washington, DC 20005. Telephone: 202–233–3960. Email: *Hillary.Viers@bioethics.gov.* Additional information may be obtained at *www.bioethics.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act of 1972, Public Law 92–463, 5 U.S.C. app. 2, notice is hereby given of the eleventh meeting of the Presidential Commission for the Study of Bioethical Issues (the Commission). The meeting will be held from 9 a.m. to approximately 4:15 p.m. on Monday, November 5, 2012, and from 9 a.m. to approximately 11:30 a.m. on Tuesday, November 6, 2012, in Chicago, Ill. The meeting will be open to the public with attendance limited to space available. The meeting will also be webcast at *www.bioethics.gov.*

Under authority of Executive Order 13521, dated November 24, 2009, the President established the Commission. The Commission is an advisory panel of the nation's leaders in medicine, science, ethics, religion, law, and engineering. The Commission advises

the President on bioethical issues arising from advances in biomedicine and related areas of science and technology. The Commission seeks to identify and promote policies and practices that ensure scientific research, health care delivery, and technological innovation are conducted in a socially and ethically responsible manner.

The main agenda item for the Commission's eleventh meeting is to continue discussing topics related to the ethical issues associated with the development of medical countermeasures for children.

The draft meeting agenda and other information about PCSBI, including information about access to the webcast, will be available at *www.bioethics.gov.*

The Commission welcomes input from anyone wishing to provide public comment on any issue before it. Respectful debate of opposing views and active participation by citizens in public exchange of ideas enhances overall public understanding of the issues at hand and conclusions reached by the Commission. The Commission is particularly interested in receiving comments and questions during the meeting that are responsive to specific sessions. Written comments will be accepted at the registration desk and comment forms will be provided to members of the public in order to write down questions and comments for the Commission as they arise. To accommodate as many individuals as possible, the time for each question or comment may be limited. If the number of individuals wishing to pose a question or make a comment is greater than can reasonably be accommodated during the scheduled meeting, the Commission may make a random selection.

Anyone planning to attend the meeting who needs special assistance, such as sign language interpretation or other reasonable accommodations, should notify Esther Yoo by telephone at (202) 233–3960, or email at *Esther.Yoo@bioethics.gov* in advance of the meeting. The Commission will make every effort to accommodate persons who need special assistance.

Written comments will also be accepted in advance of the meeting and are especially welcome. Please address written comments by email to *info@bioethics.gov,* or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave. NW., Suite C–100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Dated: September 28, 2012.

Lisa M. Lee,

Executive Director, Presidential Commission for the Study of Bioethical Issues.

[FR Doc. 2012–24911 Filed 10–9–12; 8:45 am]

BILLING CODE 4154–06–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No FDA–2012–N–0001]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 8, 2012, from 8 a.m. to 5 p.m.

Location: DoubleTree by Hilton Hotel Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel's telephone number is 301–589–5200.

Contact Person: Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *EMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the safety and efficacy of new drug applications (NDAs) 203313, insulin degludec/insulin aspart [rDNA origin] injection and 203314, insulin degludec [rDNA origin] injection, manufactured by Novo Nordisk Inc. The proposed indication (use) for these applications is for the treatment of Type 1 and Type 2 diabetes mellitus.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 24, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 16, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 17, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Paul Tran at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/*