DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting of the President's Council on Bioethics

AGENCY: Department of Health and Human Services, Office of Public Health and Science, The President's Council on Bioethics.

ACTION: Notice.

SUMMARY: The President's Council on Bioethics (Edmund D. Pellegrino, MD, Chairman) will hold its thirty-third meeting, at which it will discuss its projected White Paper on newborn screening and hear and discuss presentations on the ethics of health care reform. Subjects discussed at past Council meetings (although not on the agenda for the June 2008 meeting) include: therapeutic and reproductive cloning, assisted reproduction, reproductive genetics, neuroscience, aging retardation, organ transplantation, personalized medicine, and lifespan extension. Publications issued by the Council to date include: *Human Cloning and Human Dignity: An Ethical Inquiry* (July 2002); *Beyond Therapy: Biotechnology and the Pursuit of Happiness* (October 2003); *Being Human: Readings from the President's Council on Bioethics* (December 2003); *Monitoring Stem Cell Research* (January 2004), *Reproduction and Responsibility: The Regulation of New Biotechnologies* (March 2004), *Alternative Sources of Human Pluripotent Stem Cells: A White Paper* (May 2005), *Taking Care: Ethical Caregiving in Our Aging Society* (September 2005), and *Human Dignity and Bioethics: Essays Commissioned by the President's Council on Bioethics* (March 2008). Reports on controversies in the determination of death and on organ donation, procurement, allocation, and transplantation are forthcoming.

DATES: The meeting will take place Thursday, June 26, 2008, from 9 a.m. to 5 p.m. (CT); and Friday, June 27, 2008, from 9 a.m. to 11:15 a.m. (CT).

ADDRESSES: Courtyard Marriott Magnificent Mile, 165 East Ontario Street, Chicago, IL 60611. Phone 312–573–0800.

FOR FURTHER INFORMATION CONTACT: Ms. Diane M. Gianelli, Director of Communications, The President's Council on Bioethics, 1425 New York Avenue, NW., Suite C100, Washington, DC 20005. Telephone: 202/296–4669; e-mail: *info@bioethics.gov*; Web site: *http://www.bioethics.gov*.

SUPPLEMENTARY INFORMATION: The meeting agenda will be posted at *http://www.bioethics.gov*. The Council encourages public input, either in person or in writing. At this meeting, interested members of the public may address the Council, beginning at 11 a.m. (CT), on Friday, June 27. Comments are limited to no more than five minutes per speaker or organization. As a courtesy, please inform Ms. Diane M. Gianelli, Director of Communications, in advance of your intention to make a public statement, and give your name and affiliation. To submit a written statement, mail or e-mail it to Ms. Gianelli at one of her contact addresses given above.

Dated: May 22, 2008.

F. Daniel Davis,

Executive Director, The President's Council on Bioethics.

[FR Doc. E8–12344 Filed 6–2–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0313]

Agency Information Collection Activities; Proposed Collection; Comment Request; Requests for Inspection Under the Inspection by Accredited Persons Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the eligibility criteria and the process to be followed by establishments when requesting FDA's approval to have an accredited third party conduct a quality systems regulation inspection of their establishment instead of FDA, under the new inspections by the Accredited Persons Program.

DATES: Submit written or electronic comments on the collection of information by August 4, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, M20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301 827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Requests for Inspection Under the Inspection by Accredited Persons Program—21 U.S.C. 374(g) (OMB Control Number 0910–0569)—Extension

Section 201 of the Medical Device User Fee and Modernization Act of 2002, (Public Law 107–250), amended section 704 of the Federal Food, Drug,

and Cosmetic Act by adding subsection (g) (21 U.S.C. 374 (g)). This amendment authorized FDA to establish a voluntary third party inspection program applicable to manufacturers of class II or class III medical devices who meet certain eligibility criteria. On September 15, 2005, FDA issued a guidance entitled, ''Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act 2002,'' *http://www.fda.gov/cdrh/comp/guidance/1532.html*. This guidance describes the eligibility criteria and the process for establishments to follow when requesting FDA's approval to have an accredited person (AP) conduct a quality system regulation inspection of their establishment under the new inspection by the Accredited Persons Program (AP program) instead of FDA.

The AP program applies to manufacturers who currently market their medical devices in the United States and who also market or plan to market their devices in foreign countries. Such manufacturers may need current inspections of their establishments to operate in global commerce.

In order to meet the eligibility criteria for requesting FDA approval to have an AP conduct a quality system regulations inspection of their establishment instead of FDA, applicants must submit a request with certain information. The following information must be submitted, which shows that the applicant:

(1) ''Manufactures, prepares, propagates, compounds, or processes'' class II or class III medical devices,

(2) Markets at least one of the devices in the United States,

(3) Markets or intends to market at least one of the devices in one or more foreign countries when one or both of the following two conditions are met:

(a) One of the foreign countries certifies, accredits, or otherwise recognizes the selected AP applicant as a person authorized to conduct inspections of device establishments, or

(b) A statement that the law of a country where the applicant markets or intends to market the device recognizes an inspection conducted by FDA or an AP.

(4) Provided the most recent inspection performed by FDA, or by an AP under the AP program and inspection was classified by FDA as either ''No Action Indicated'' or ''Voluntary Action Indicated'' and,

(5) Provided notice advising FDA of their intent to use an AP, and identifying the AP applicant selected.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 U.S.C. Section:	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
374(g)	100	1	100	15	1,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

There are approximately 8,000 foreign and 10,000 domestic manufacturers of medical devices. Approximately 5,000 of these firms only manufacture class I devices and are, therefore, not eligible for the AP program. In addition, 40 percent of the domestic firms do not export devices and therefore are not eligible to participate in the AP program. Further, 10 to 15 percent of the firms are not eligible due to the results of their previous inspection. FDA estimates there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion under the AP program. Based on communications with industry, FDA estimates that on an annual basis approximately 100 of these manufacturers may submit a request to use an AP in any given year.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: May 27, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–12297 Filed 6–2–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0312]

Agency Information Collection Activities; Proposed Collection; Comment Request; Extralabel Drug Use in Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements associated with extralabel drug use in animals.

DATES: Submit written or electronic comments on the collection of information by August 4, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR