

five minutes per speaker or organization. As a courtesy, please inform Ms. Diane 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 to Ms. Gianelli at one of the address given below.

**FOR FURTHER INFORMATION CONTACT:** Ms. Diane Gianelli, Director of Communications, The President's Council on Bioethics, Suite 700, 1801 Pennsylvania Avenue, NW., Washington, DC 20006. Telephone: 202/296-4669. E-mail: [info@bioethics.gov](mailto:info@bioethics.gov). Web site: <http://www.bioethics.gov>.

Dated: October 16, 2006.

**F. Daniel Davis,**

*PhD., Executive Director, The President's Council on Bioethics.*

[FR Doc. 06-8968 Filed 10-30-06; 8:45 am]

**BILLING CODE 4154-07-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the President's Council on Physical Fitness and Sports

**AGENCY:** Office of Public Health and Science, Office of the Secretary, DHHS.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (DHHS) is hereby giving notice that the President's Council on Physical Fitness and Sports will hold a meeting. This meeting is open to the public. A description of the Council's functions is included with this notice.

**DATES:** November 15, 2006, from 8:30 a.m. to 4 p.m.

**ADDRESSES:** Department of Health and Human Services, Hubert H. Humphrey Building, Room 800, 200 Independence Avenue, SW., Washington, DC 20201.

**FOR FURTHER INFORMATION CONTACT:** Melissa Johnson, Executive Director, President's Council on Physical Fitness and Sports, Hubert H. Humphrey Building, Room 738H, 200 Independence Avenue, SW., Washington, DC 20201, (202) 690-5187.

**SUPPLEMENTARY INFORMATION:** The President's Council on Physical Fitness and Sports (PCPFS) was established originally by Executive Order 10673, dated July 16, 1956. PCPFS was established by President Eisenhower after published reports indicated that American boys and girls were unfit compared to the children of Western Europe. The Council has undergone two name changes and several

reorganizations since its inception. Authorization to continue Council operations has been given at appropriate intervals by subsequent Executive Orders. Authority to continue Council operations was most recently directed by Executive Order 13385, dated September 29, 2005. Presently, the PCPFS serves as a program office that is located organizationally in the Office of Public Health and Science within the Office of the Secretary in the U.S. Department of Health and Human Services.

On June 6, 2002, President Bush signed Executive Order 13256 to reestablish the PCPFS. Executive Order 13256 was established to expand the focus of the Council. This directive instructed the Secretary to develop and coordinate a national program to enhance physical activity and sports participation. The Council currently operates under the stipulations of the new directive. The primary functions of the Council include to: (1) Advise the President, through the Secretary, on the progress made in carrying out the provisions of the enacted directive and recommend actions to accelerate progress; (2) advise the Secretary on ways and means to enhance opportunities for participation in physical fitness and sports, and, where possible, to promote and assist in the facilitation and/or implementation of such measures; (3) to advise the Secretary regarding opportunities to extend and improve physical activity/fitness and sports programs and services at the national, State and local levels; and (4) to monitor the need for the enhancement of programs and educational and promotional materials sponsored, overseen, or disseminated by the Council, and advise the Secretary, as necessary, concerning such needs.

The PCPFS holds at a minimum, one meeting in the calendar year to (1) assess ongoing Council activities and (2) discuss and plan future projects and programs.

Public attendance at the meeting is limited to space available. Individuals must provide a photo ID for entry into the meeting. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person.

Dated: October 25, 2006.

**Melissa Johnson,**

*Executive Director, President's Council on Physical Fitness and Sports.*

[FR Doc. E6-18244 Filed 10-30-06; 8:45 am]

**BILLING CODE 4150-35-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0220]

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Detention and Banned Medical Devices

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by November 30, 2006.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

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

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Administrative Detention and Banned Medical Devices—(OMB Control Number 0910-0114)—Extension

FDA has the statutory authority under section 304(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 334(g)), where officers or employees (FDA investigators), duly designated by the Secretary of Health and Human Services, may detain during establishment inspections devices that are believed to be adulterated or misbranded. In the **Federal Register** of March 9, 1979 (44 FR 13234), FDA issued, under § 800.55 (21 CFR 800.55), a final regulation on administrative detention procedures, under section 304(g) of the act, which includes certain reporting requirements (§ 800.55(g)(1) and (g)(2)) and recordkeeping requirements (§ 800.55(k)). Under § 800.55(g), an appellant of a detention order must show documentation of

ownership if devices are detained at a place other than that of the appellant. Under § 800.55(k), the owner or other responsible person must supply records about how the devices may have become adulterated or misbranded, as well as records of distribution of the detained devices. These recordkeeping requirements for administrative detentions allow FDA to trace devices for which the detention period expired

before a seizure is accomplished or injunctive relief is obtained.

FDA also has the statutory authority under section 516 of the act (21 U.S.C. 360f), to ban devices that present substantial deception, or unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals. The final regulation for banned devices (part 895 (21 CFR part 895)), issued in the

**Federal Register** of May 18, 1979 (44 FR 29214), contained certain reporting requirements (§§ 895.21(d) and 895.22(a)).

In the **Federal Register** of June 7, 2006 (71 FR 32987), FDA published a 60-day notice requesting public comments on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
800.55(g)	1	1	1	25	25
895.21(d) and 895.22(a)	26	1	26	16	416
Total					441

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record	Total Hours
800.55(k)	1	1	1	20	20

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the burden under the administrative detention provision is based on FDA's discussion with the last firm whose devices had been detained. Historically, FDA has had very few or no annual responses for this information collection.

Dated: October 24, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-18190 Filed 10-30-06; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0426]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee and Modernization Act Small Business Qualification Certification (Form FDA 3602)

**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 proposed collection of information that will permit an applicant to certify that it qualifies as a "small business" within the meaning of the Medical Device User Fee and Modernization Act (MDUFMA).

**DATES:** Submit written or electronic comments on the collection of information by January 2, 2007.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. 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 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