

number: (770) 488-4538, Internet address: jsb1@cdc.gov.

Dated: May 24, 1999.

**John L. Williams,**

*Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 99-13606 Filed 5-27-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Subcommittee on Vaccine Safety of the National Vaccine Advisory Committee: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following subcommittee meeting.

*Name:* Subcommittee on Vaccine Safety.  
*Time and Date:* 9 a.m.-5 p.m., June 18, 1999.

*Place:* Hubert H. Humphrey Building, Room 305A, 200 Independence Avenue, SW, Washington, DC 20201.

*Status:* Open to the public, limited only by the space available.

*Notice:* In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey Building by non-government employees. Thus, persons without a government identification card should plan to arrive at the building on June 18th either between 8:30 and 9 a.m. or 12:30 and 1 p.m. so they can be escorted to the meeting. Entrance to the meeting at other times during the day cannot be assured.

*Purpose:* This subcommittee will review issues relevant to vaccine safety and adverse reactions to vaccines.

*Matters To Be Discussed:* This subcommittee will discuss the mission of the Vaccine Safety Subcommittee; focus on developing priorities for U.S. vaccine safety and communication activities; and develop draft integral to ensuring the optimal safety of vaccines.

Agenda items are subject to change as priorities dictate.

**CONTACT PERSON FOR MORE INFORMATION:** Gloria Sagar, Committee Management Specialist, NVPO, CDC, 1600 Clifton Road, NE, M/S A11, Atlanta, Georgia 30333, telephone 404/639-4450.

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 CDC and ATSDR.

Dated: May 24, 1999.

**Carolyn J. Russell,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 99-13603 Filed 5-27-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Citizens Advisory Committee on Public Health Service Activities and Research at Department of Energy (DOE) Sites: Fernald Health Effects Subcommittee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

*Name:* Citizens Advisory Committee on Public Health Service Activities and Research at DOE Sites: Fernald Health Effects Subcommittee.

*Times and Dates:* 1 p.m.-9 p.m., June 23, 1999; 8:30 a.m.-5 p.m., June 24, 1999.

*Place:* The Plantation, 9660 Dry Fork Road, Harrison, Ohio 45020, telephone 513/367-5610.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

*Background:* Under a Memorandum of Understanding (MOU) signed in December 1990 with DOE and replaced by an MOU signed in 1996, the Department of Health and Human Services (HHS) was given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS delegated program responsibility to CDC.

In addition, a memo was signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or "Superfund"). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

*Purpose:* This subcommittee is charged with providing advice and recommendations

to the Director, CDC and the Administrator, ATSDR, regarding community, American Indian Tribes, and labor concerns pertaining to CDC's and ATSDR's public health activities and research at this DOE site. The purpose of this meeting is to provide a forum for community, American Indian Tribal, and labor interaction and serve as a vehicle for community concern to be expressed as advice and recommendations to CDC and ATSDR.

*Matters To Be Discussed:* Agenda items include presentations from the National Center for Environmental Health (NCEH), the National Institute for Occupational Safety and Health (NIOSH) and ATSDR on updates regarding progress of current studies. There will also be a presentation from the University of Cincinnati on findings of Fernald Residents Medical Monitoring Program.

Agenda items are subject to change as priorities dictate.

#### CONTACT PERSONS FOR MORE

**INFORMATION:** David Pedersen, Ph.D., Health-Related Energy Research Branch, Division of Surveillance, Hazard Evaluations and Field Studies, NIOSH, CDC, Robert A. Taft Laboratory, 4676 Columbia Parkway, M/S R-44, Cincinnati, Ohio 45226, telephone 513/841-4400, fax 513/841-4470.

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.

Dated: May 24, 1999.

**Carolyn J. Russell,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 99-13604 Filed 5-27-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for OMB Review; Comment Request

*Title:* (1) TANF High Performance Bonus Report and (2) Emergency TANF Public Law Data Report.

*OMB No.:* 0970-0180.

*Description:* 104-193 (the personal Responsibility and Work Opportunity Reconciliation Act of 1996) established the Temporary Assistance for Needy Families (TANF) Program. It also included provisions for rewarding States that attain the highest levels of success in achieving the legislative goals

of that program. The purpose of this collection is to obtain data upon which to base the computations for measuring

State performance in meeting those goals and for allocating the bonus grant funds appropriated under the law.

*Respondents:* State, Local or Tribal Government.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
TANF quarterly Data Report, fy 1999 High Performance Bonus Awards .....	54	4	40	8,640
Emergency TAF Data Report .....	8	4	1218.5	6,992

*Estimated Total Annual Burden Hours:* 15,632.

**Additional Information:** Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

**OMB Comment:** OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Washington, DC 20503, Attn: Ms. Lori Schack.

Dated: May 24, 1999.

**Bob Sargis,**

*Acting Reports Clearance Officer.*

[FR Doc. 99-13569 Filed 5-27-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 97P-0354]

#### Orthopedic Devices; Reclassification of the Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis

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

**ACTION:** Notice of panel recommendation.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing for public comment a recommendation of the Orthopedic and Rehabilitation Devices Panel (the Panel) to reclassify the shoulder joint metal/polymer/metal

nonconstrained or semi-constrained porous-coated uncemented prosthesis from class III into class II. The Panel made this recommendation after reviewing the reclassification petition submitted by the Orthopedic Surgical Manufacturers Association (OSMA) and other publicly available information. FDA is also announcing for public comment its tentative findings on the Panel's recommendations. After considering any public comments on the Panel's recommendations and FDA's tentative findings, FDA will approve or deny the reclassification petition by order in the form of a letter to the petitioner. FDA's decision on the reclassification petition will be announced in the **Federal Register**.

**DATES:** Written comments by August 26, 1999.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Theodore R. Stevens, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036.

#### SUPPLEMENTARY INFORMATION:

##### I. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295), the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101-629), and the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified postamendments devices is governed by section 513(f)(2) of the act. This section provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary of the Department of Health and Human