

CDC Instructions for the Use of Vaccine Information Statements.

**FOR FURTHER INFORMATION CONTACT:**

Anne Schuchat, M.D., Director, National Immunization Program, Centers for Disease Control and Prevention, Mailstop E-05, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639-8200.

**SUPPLEMENTARY INFORMATION:** The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99-660), as amended by section 708 of Public Law 103-183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa-26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers in the United States, whether public or private, to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program. Development and revision of the vaccine information materials, also known as Vaccine Information Statements (VIS), have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC).

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. Since June 1, 1999, health care providers are also required to provide copies of vaccine information materials for the following vaccines that were added to the National Vaccine Injury Compensation Program: hepatitis B, haemophilus influenzae type b (Hib), and varicella (chickenpox) vaccines. In addition, use of vaccine information materials for pneumococcal conjugate vaccine has been required since December 15, 2002, materials for trivalent influenza vaccines since January 1, 2006 and materials for hepatitis A vaccine since July 1, 2006.

**Updated Influenza Vaccine Information Materials**

*Inactivated Influenza Vaccine Information Statement*

*Live, Intranasal Influenza Vaccine Information Statement*

Initial vaccine information materials developed under 42 U.S.C. 300aa-26 for

trivalent inactivated influenza vaccine and for trivalent live, intranasal influenza vaccine were published in the **Federal Register** on November 10, 2005 (70 FR 68461). The edition date of those materials was October 20, 2005. This notice announces availability of the 2006-07 editions of these influenza vaccine information materials. The only substantive revisions that appear in these updated materials are the addition of the influenza season date of 2006-07, the VIS edition date of 6/30/2006 and an update to note the expanded recommended schedule for administration of inactivated influenza vaccine to all children 6-59 months of age and to the household contacts and out-of-home caregivers of such children (with either inactivated or live, intranasal influenza vaccine as applicable).

*Instructions for the Use of Vaccine Information Statements*

The CDC Instructions for the Use of Vaccine Information Statements have been updated to note the new edition dates of the influenza vaccine information materials. Those updated instructions, dated June 30, 2006, can be downloaded at the CDC Web site at: <http://www.cdc.gov/nip/publications/VIS>.

In addition, copies of the updated influenza materials can be downloaded in PDF format at the same Web site. Alternatively, single camera-ready copies are available from State health departments. A list of State health department contacts for obtaining copies of these materials is included in a December 17, 1999 **Federal Register** notice (64 FR 70914).

Dated: August 16, 2006.

**James D. Seligman,**

*Chief Information Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**President's Committee for People With Intellectual Disabilities; Notice of Meeting**

**AGENCY:** President's Committee for People with Intellectual Disabilities (PCPID), Department of Health And Human Services.

**ACTION:** Notice of quarterly meeting.

**DATES:** Thursday, September 14, 2006, from 9 a.m. to 5:30 p.m., and Friday, September 15, 2006, from 9 a.m. to 5 p.m. The entire meeting of PCPID will be open to the public.

**ADDRESSES:** The meeting will be held in Room 800 of the Hubert H. Humphrey building, 200 Independence Ave., SW., Washington, DC 20201. Individuals who will need accommodations for a disability in order to attend the meeting (e.g., interpreting services, assistive listening devices, materials in alternative format such as large print or Braille) should notify Sally Atwater at 202-619-0634 no later than September 7, 2006. We will attempt to meet requests made after that date, but cannot guarantee availability. All meeting sites are barrier free.

*Agenda:* Day One—The new Committee members will take the oath of office, be sworn in as members of the President's Committee for People with Intellectual Disabilities and receive guidance on ethics regulations and the Federal Advisory Committee Act (FACA). Committee members will also hear from the various ex officio members regarding the programs and services provided by their respective Federal agencies.

*Agenda:* Day Two—The Committee will receive a briefing on the New Freedom Initiative and then begin discussion to set Committee priorities for the coming year.

**FOR FURTHER INFORMATION CONTACT:**

Sally D. Atwater, Executive Director, President's Committee for People with Intellectual Disabilities, The Aerospace Center, Suite 701, 370 L'Enfant Promenade, SW., Washington, DC 20447. Telephone: 202-619-0634, fax: 202-205-9591. E-mail: [satwater@acf.hhs.gov](mailto:satwater@acf.hhs.gov).

**SUPPLEMENTARY INFORMATION:** PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and supports for persons with intellectual disabilities. The Committee, by Executive Order, is responsible for evaluating the adequacy of current practices in programs, services and supports for persons with intellectual disabilities, and for reviewing legislative proposals that impact the quality of life experienced by citizens with intellectual disabilities and their families.

Dated: August 14, 2006.

**Sally D. Atwater,**

*Executive Director, President's Committee for People with Intellectual Disabilities.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0326]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

**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 publication of the criteria FDA intends to use to accredit third parties to conduct inspections of eligible manufacturers of class II or class III medical devices.

**DATES:** Submit written or electronic comments on the collection of information by October 23, 2006.

**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 Management Programs (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.

#### Medical Devices: Inspection by Accredited Persons Program Under MDUFMA (OMB Control Number 0910-0510)—Extension

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250) was signed into law on October 26, 2002. Section 201 of MDUFMA adds a new paragraph "g" to section 704 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons or APs) to conduct inspections of eligible manufacturers of class II or class III devices. This is a voluntary program.

FDA has a guidance document that provides information for those interested in participating in this program. The guidance is entitled "Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria."

*Description of Respondents:* Businesses or other for profit organizations.

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

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

Information Collection:	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Request for Accreditation	3	1	3	80	240
Total Hours					240

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