

*Estimated Total Annual Burden Hours:* 880.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*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, Fax: 202-395-6974, Attn: Desk Officer for ACF.

Dated: March 15, 2007.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 07-1976 Filed 4-19-07; 8:45 am]

**BILLING CODE 4184-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Help America Vote Act (HAVA) Voting Access Annual Report.

*OMB No.:* New Collection.

*Description:* An annual report is required by Federal statute (the Help

America Vote Act (HAVA) of 2002, Public Law 107-252, Section 291, Payments for Protection and Advocacy Systems, 42 U.S.C. 15461). Each State or Unit of Local Government must prepare and submit an annual report at the end of every fiscal year. The report addresses the activities conducted with the funds provided during the year. The information collected from the annual report will be aggregated into an annual profile of how States have utilized the funds and establish best practices for election officials. It will also provide an overview of the State election goals and accomplishment and permit the Administration on Developmental Disabilities to track voting progress to monitor grant activities.

*Respondents:* Secretaries of State, Directors, State Election Boards, State Chief Election officials.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Help America Vote Act (HAVA) Voting Access Annual Report .....	55	1	24	1,320

*Estimated Total Annual Burden Hours:* 1,320.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

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Dated: March 15, 2007.

**Robert Sargis,**

*Reports Clearance Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Preparation for International Conference on Harmonization Meetings in Brussels, Belgium; Public Meeting**

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

**ACTION:** Notice of meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting entitled "Preparation for ICH meetings in Brussels, Belgium" to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Brussels, Belgium. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Groups meetings in Brussels, Belgium, May 5 through 10, 2007, at which discussion of the topics underway and the future of ICH will continue.

*Date and Time:* The meeting will be held on Thursday, May 3, 2007, from 11:30 a.m. to 1 p.m.

*Location:* The meeting will be held at 5600 Fishers Lane, 3rd floor, Conference Room D, Rockville, MD 20857. For security reasons, all attendees are asked to arrive no later than 11:20 a.m., as you will be escorted from the front entrance of 5600 Fishers Lane to Conference Room D.

*Contact Person:* All participants must register with Tammie Bell, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, e-mail: [Tammie.Bell2@fda.hhs.gov](mailto:Tammie.Bell2@fda.hhs.gov) or fax: 301-827-0003.

*Registration and Requests for Oral Presentations:* Send registration information (including name, title, firm name, address, telephone, and fax number), written material and requests to make oral presentations, to the contact person by April 20, 2007.

If you need special accommodations due to a disability, please contact Tammie Bell at least 7 days in advance.

*Transcripts:* Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

**SUPPLEMENTARY INFORMATION:** The ICH was established in 1990 as a joint

regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area and the World Health Organization. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

The current ICH process and structure can be found at the following Web site: <http://www.ich.org>.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 4:30 p.m. and 5 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by April 27, 2007, and submit a brief statement of the

general nature of the evidence or arguments they wish to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.

The agenda for the public meeting will be made available via the internet at [http://www.fda.gov/cder/meeting/ICH\\_20060508.htm](http://www.fda.gov/cder/meeting/ICH_20060508.htm).

Dated: April 12, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 07-1952 Filed 4-16-07; 3:25 pm]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Vaccine Injury Compensation Program: Addition of Meningococcal and Human Papillomavirus (HPV) Vaccines to the Vaccine Injury Table

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** Through this notice, the Secretary announces that meningococcal (conjugate and polysaccharide) and human papillomavirus (HPV) vaccines are covered vaccines under the National Vaccine Injury Compensation Program (VICP), which provides a system of no-fault compensation for certain individuals who have been injured by covered childhood vaccines. This notice serves to include meningococcal and HPV vaccines as covered vaccines under Category XIV (new vaccines) of the Vaccine Injury Table (Table), which lists the vaccines covered under the VICP. This notice ensures that petitioners may file petitions relating to meningococcal and HPV vaccines with the VICP even before such vaccines are added as separate and distinct categories to the Table through rulemaking.

**DATES:** This notice is effective on April 20, 2007. As described below, meningococcal and HPV vaccines are covered under the VICP as of February 1, 2007.

**FOR FURTHER INFORMATION CONTACT:** Geoffrey Evans, M.D., Division Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857; telephone number (301) 443-6593.

**SUPPLEMENTARY INFORMATION:** The statute authorizing the VICP provides for the inclusion of additional vaccines in the VICP when they are recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children. See section 2114(e)(2) of the Public Health Service (PHS) Act, 42 U.S.C. 300aa-14(e)(2). Consistent with section 13632(a)(3) of Pub. L. 103-66, the regulations governing the VICP provide that such vaccines will be included as covered vaccines in the Table as of the effective date of an excise tax to provide funds for the payment of compensation with respect to such vaccines (42 CFR 100.3(c)(5)).

The two prerequisites for adding meningococcal (conjugate and polysaccharide) and HPV vaccines to the VICP as covered vaccines as well as to the Table have been satisfied. In its May 27, 2005, issue of the Morbidity and Mortality Weekly Report (MMWR), the CDC published its recommendation that meningococcal conjugate vaccines be routinely administered to young adolescents at the pre-adolescent visit (11-12 years olds). Additionally, for those individuals who have not previously received the meningococcal conjugate vaccine, the CDC has recommended vaccination before high school entry to further reduce the incidence of meningococcal disease in adolescents and young adults. The CDC also recommends routine vaccination for college freshmen who live in dormitories because they are at higher risk for meningococcal disease when compared with same aged cohorts. The use of meningococcal conjugate vaccine is preferred among persons aged 11-55 years. If meningococcal conjugate vaccine is unavailable, meningococcal polysaccharide vaccine is an acceptable alternative for persons aged 11-55 years. Meningococcal polysaccharide vaccine is also recommended for children aged 2-10 years and persons aged 55 years and older who are at increased risk for meningococcal disease.

In its March 23, 2007, issue of the MMWR, the CDC published its recommendation that the HPV vaccine be routinely administered to females aged 11-12 years. The HPV vaccine can be administered to females as young as 9 years. Vaccination is recommended for females aged 13-26 years who have not previously received the vaccine or who have not completed the full series.

On December 20, 2006, the excise tax legislation for meningococcal and HPV vaccines was enacted by Pub. L. 109-432, the "Tax Relief and Health Care Act of 2006 (the Act)." Section 408 of this Act adds all meningococcal and