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 which 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*.

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

HPV vaccines to section 4132(a)(1) of the Internal Revenue Code of 1986, as amended, which defines all taxable vaccines.

Under the regulations governing the VICP, Category XIV of the Table specifies that ''[a]ny new vaccine recommended by the [CDC] for routine administration to children, after publication by the Secretary of a notice of coverage'' is a covered vaccine under the Table (42 CFR 100.3(a), Item XIV). As explained above, the CDC issued its recommendation. This notice serves to satisfy the regulation's publication requirement. Through this notice, meningococcal and HPV vaccines are included as covered vaccines under Category XIV of the Table.

Under section 2114(e) of the PHS Act, as amended by section 13632(a) of the Omnibus Budget Reconciliation Act of 1993, coverage for a vaccine recommended by the CDC for routine administration to children shall take effect upon the effective date of the tax enacted to provide funds for compensation with respect to the vaccine included as a covered vaccine in the Table. Under section 408 of the Tax Relief and Health Care Act of 2006, the effective date for the excise taxes enacted for meningococcal vaccines against meningococcal disease and the HPV vaccine against HPV disease and infection applies to sale and uses on or after ''the first day of the first month which begins more than 4 weeks after the date of the enactment of this Act.'' It further provides that if the vaccines were sold on or before the effective date of the excise tax, but delivered after this date, the delivery date of such vaccines shall be considered the sale date.

Under this authorizing statutory language, the effective date for coverage of the meningococcal and HPV vaccines under the VICP is February 1, 2007. Thus, meningococcal and HPV vaccines are included as covered vaccines under Category XIV of the Table as of February 1, 2007. Petitioners may file petitions related to meningococcal and HPV vaccines as of February 1, 2007.

Petitions filed concerning vaccine-related injuries or deaths associated with meningococcal and HPV vaccines must be filed within the applicable statute of limitations. The filing limitations applicable to petitions filed with the VICP are set out in section 2116(a) of the PHS Act (42 U.S.C. 300aa–16(a)). Persons who may be eligible must file petitions within: three (3) years from the first symptom or manifestation of onset of an injury or of the significant aggravation of the injury; or two (2) years from the date of a vaccine-related death and four (4) years after the start of the first symptom of the vaccine-related injury from which the death occurred.

In addition, section 2116(b) of the PHS Act lays out specific exceptions to these statutes of limitations that apply when the effect of a revision to the Table makes a previously ineligible person eligible to receive compensation or when an eligible person's likelihood of obtaining compensation significantly increases. Under this provision, persons who may be eligible to file petitions based on the addition of a new vaccine under Category XIV of the Table may file a petition for compensation not later than 2 years after the effective date of the revision if the injury or death occurred not more than 8 years before the effective date of the revision of the Table (42 U.S.C. 300aa–16(b)). Thus, persons whose petitions may not be timely under the limitations periods described in section 2116(a) of the PHS Act, may still file petitions concerning vaccine-related injuries or deaths associated with meningococcal and HPV vaccines until February 2, 2009, as long as the vaccine-related injury or death occurred on or after February 1, 1999 (8 years prior to the effective date of the addition that included meningococcal vaccines and HPV as covered vaccines). Although two years from the date of February 1, 2007, would be February 1, 2009, under the current Rules of the United States Court of Federal Claims, the deadline under section 2116(b) of the PHS Act would be February 2, 2009, because February 1, 2009, falls on a Sunday.

The Secretary plans to amend the Table through the rulemaking process by including meningococcal and HPV vaccines as separate categories of vaccines in the Table. February 1, 2007, will remain the applicable effective date when the Secretary makes a corresponding amendment to add meningococcal and HPV vaccines as separate categories on the Table through rulemaking.

Dated: April 16, 2007.

Elizabeth M. Duke,

Administrator.

[FR Doc. E7–7591 Filed 4–19–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Advisory Council.

Date: June 5, 2007.

Open: 8:30 a.m. to 12 p.m.

Agenda: To discuss program policies and issues.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Closed: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Contact Person: Stephen Mockrin, PhD., Director, Division of Extramural Research Activities, National Institutes of Health, 6701 Rockledge Drive, Room 7100, Bethesda, MD 20892, (301) 435–0260, *mockrins@nhlbi.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.nhlbi.nih.gov/meetings/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for