

Place: The DoubleTree Club Hotel, 720 Las Flores Road, Livermore, California 94551, telephone 925/443-4950, fax 925/449-9059.

Status:

Subcommittee Meeting Time and Date: Open 8:30 a.m.–9:30 a.m., December 13, 2004.

Committee Meeting Times and Dates: Open 9:45 a.m.–1 p.m., December 13, 2004; Closed 1 p.m.–4:30 p.m., December 13, 2004; Open 8 a.m.–4:30 p.m., December 14, 2004; Open 7 p.m.–8:30 p.m., December 14, 2004; Open 8:30 a.m.–4:30 p.m., December 15, 2004; The open portions of the meeting are limited only by the space available. The meeting room accommodates approximately 65 people.

Background

The ABRWH was established under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) of 2000 to advise the President, on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Board include providing advice on the development of probability of causation guidelines which have been promulgated by HHS as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000 the President delegated responsibility for funding, staffing, and operating the Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, and renewed on August 3, 2003.

Purpose

This board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this Program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters to Be Discussed

The agenda for this meeting will focus on Program Status Reports from NIOSH

and the Department of Labor, Contract Process and Requirements, Board Discussion of Case Reviews, Subcommittee Report and Recommendations, Site Profile Review, NIOSH's Response to Site Profile Review, SEC Petition Process Procedures, SEC Petition Evaluation Review Plan Workgroup Report, Scientific Research Issues Update, and a Board working session. There will be an evening public comment period scheduled for December 14, 2004, and a public comment period on December 15, 2004.

The Subcommittee will convene on December 13, 2004, from 8:30 a.m.–9:30 a.m. and will focus on review of draft minutes and selection of Individual Dose Reconstruction Cases for Board Review.

The closed portion of the meeting on December 13th will involve discussion of individual dose reconstruction case reviews, and is required to avoid the public disclosure of confidential information and claimant's privacy.

The agenda is subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT:

Larry Elliott, Executive Secretary, ABRWH, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/533-6825, fax 513/533-6826.

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 the Agency for Toxic Substances and Disease Registry.

Dated: November 24, 2004.

B. Kathy Skipper,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04-26490 Filed 11-30-04; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0062]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Color Additive Certification Requests and Recordkeeping

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Color Additive Certification Requests and Recordkeeping" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 19, 2004 (69 FR 42998), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0216. The approval expires on November 30, 2007. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: November 19, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-26441 Filed 11-30-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program: Inclusion of Hepatitis A Vaccines in the Vaccine in the Injury Table

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice.

SUMMARY: Through this notice, the Secretary of Health and Human Services announces that Hepatitis A 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 Hepatitis A 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 Hepatitis A

vaccines with the VICP even before such vaccines are added as a separate and distinct category to the Table through rulemaking.

DATES: This Notice is effective on December 1, 2004. As described below, Hepatitis A vaccines will be covered under the VICP on December 1, 2004.

FOR FURTHER INFORMATION CONTACT: Geoffrey Evans, M.D., Medical 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) 443-4198.

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) to the Secretary 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 Public Law 103-66, the regulations governing the VICP provide that such vaccines will be included in the Table as covered vaccines 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 Hepatitis A vaccines to the VICP as covered vaccines as well as to the Table have been satisfied. First, the CDC published its recommendation that Hepatitis A vaccines be routinely administered to certain children in the October 1, 1999, issue of the Morbidity and Mortality Weekly Report (MMWR). Specifically, the CDC recommended that all children in States, counties, and communities with rates of Hepatitis A that are twice the 1987-1997 national average or greater (i.e., greater than or equal to 20 cases per 100,000 population) receive the Hepatitis A vaccine.

Second, on October 22, 2004, the excise tax for Hepatitis A vaccines was enacted by Public Law 108-357, the "American Jobs Creation Act of 2004." Section 889 of this Act adds all vaccines against Hepatitis A to section 4132(a)(1) of the Internal Revenue Code of 1986, which defines all taxable vaccines. Unlike the CDC's recommendation, the American Jobs Creation Act of 2004 does not distinguish between Hepatitis A vaccines administered in areas in which rates of Hepatitis A are at least twice the national average and Hepatitis A vaccines administered in other areas of the country. For this reason, all

Hepatitis A vaccines manufactured or produced in the United States, or entered into the United States for consumption, use, or warehousing, will be subject to this excise tax (26 U.S.C. 4132(a)(1)).

Under the regulations governing the VICP, Item XIV of the Table specifies that "[a]ny new vaccine recommended by the Centers for Disease Control and Prevention 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's recommendation was accepted. This notice serves to satisfy the regulation's publication requirement. Through this notice, Hepatitis A vaccines are included as covered vaccines under Category XIV of the Table. As explained above, because the American Jobs Creation Act of 2004 enacted an excise tax for Hepatitis A vaccines administered throughout the United States, all Hepatitis A vaccines will be covered under the VICP and under 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. The American Jobs Creation Act of 2004 provides that the addition of Hepatitis A vaccines to the list of taxable vaccines applies to sales 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 the Act. It further provides that if the vaccines were sold before or on the effective date of the excise tax, but delivered after this date, the delivery date of such vaccines shall be considered the sale date. Because the American Jobs Creation Act of 2004 was enacted on October 22, 2004, the effective date of the excise tax adding Hepatitis A vaccines as taxable vaccines is December 1, 2004. Thus, Hepatitis A vaccines are included as covered vaccines under Category XIV of the Table as of December 1, 2004. Petitioners may file petitions related to Hepatitis A vaccines as of December 1, 2004.

Petitions filed concerning vaccine-related injuries or deaths associated with Hepatitis A vaccines must, of course, be filed within the applicable statute of limitations. The statutes of 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)). 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, a person who may be eligible to file a petition 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 satisfy the limitations periods described in section 2116(a) of the PHS Act may still file petitions concerning vaccine-related injuries or deaths associated with Hepatitis A vaccines until December 1, 2006, as long as the vaccine-related injury or death occurred on or after December 1, 1996 (8 years prior to the effective date of the addition that included Hepatitis A as a covered vaccine).

The Secretary plans to amend the Table through the rulemaking process by including Hepatitis A vaccines as a separate category of vaccines in the Table. December 1, 2004, will remain the applicable effective date when the Secretary makes a corresponding amendment to add Hepatitis A vaccines as a separate category on the Table through rulemaking.

Dated: November 22, 2004.

Elizabeth M. Duke,
Administrator, HRSA.

[FR Doc. 04-26273 Filed 11-30-04; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of subpart C of the Mandatory Guidelines