

and cost-effectiveness analysis, information systems, primary care, and management and policy.

#### Solicitation of Topic Nominations

The purpose of this solicitation for new topics by CDC and the Task Force is to create a balanced portfolio of relevant topics for the current Task Force library. The current library is based on reviews and recommendations across a broad range of high burden, high interest topic areas: Changing health risk behaviors (adolescent health, physical activity, tobacco product use, nutrition, sexual behavior, alcohol abuse and misuse, substance abuse); addressing specific health conditions (cancer, diabetes, mental health, motor vehicle occupant injury, obesity, oral health, vaccine-preventable diseases, and violence prevention); and addressing the environment (improving health through changing the social environment, worksite health promotion). Selection of suggested topics will be made on the basis of qualifications of nominations as outlined above (see basic topic nomination requirements) and the current expertise of the Task Force.

#### *Topics That Have Been Reviewed:*

Diabetes, Informed Decision Making for Cancer Screening, Motor Vehicle Occupant Injury, Oral Health, Physical Activity, Skin Cancer Prevention, Social Environment, Tobacco, Vaccine Coverage, Vaccine Coverage in Adults at High Risk.

#### *Topics Currently Under Review:*

Adolescent Health, Alcohol, Cancer Screening (Breast, Cervical, and Colorectal), Improving Pregnancy Outcomes, Mental Health, Nutrition, Obesity, Sexual Behavior, Violence Prevention, Worksite Health Promotion.

Dated: May 23, 2006.

**James D. Seligman,**

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

[FR Doc. E6-8351 Filed 5-30-06; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### **Disease, Disability, and Injury Prevention and Control Special Emphasis Panels (SEP): HIV IV—Rapid Test Algorithms for Diagnosis of HIV Infection and Improved Linkage to Care, Program Announcement Number (PA) PS06-002.**

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 meeting:

*Name:* Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): HIV IV—Rapid Test Algorithms for Diagnosis of HIV Infection and Improved Linkage to Care, PA PS06-002.

*Time and Date:* 12 p.m.–5 p.m., June 23, 2006 (Closed).

*Place:* Teleconference.

*Status:* The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

*Matters to be Discussed:* The meeting will include the review, discussion, and evaluation of applications received in response to “HIV IV—Rapid Test Algorithms for Diagnosis of HIV Infection and Improved Linkage to Care, PA PS06-002.”

*For Further Information Contact:* Jim Newhall, PhD, Scientific Review Administrator, Office of Public Health Research, CDC, 1600 Clifton Road NE, Mailstop D72, Atlanta, GA 30333, Telephone 404-639-4641.

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: May 24, 2006.

**Alvin Hall,**

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

[FR Doc. E6-8346 Filed 5-30-06; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### **Vaccine Information Statement for Hepatitis A Vaccine; Revised Instructions for Use of Vaccine Information Statements**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** Under the National Childhood Vaccine Injury Act (NCVIA) (42 U.S.C. § 300aa-26), the CDC must develop vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. On July 28, 2005, CDC published a notice in the **Federal Register** (70 FR 43694) seeking public comments on proposed new vaccine information materials for hepatitis A vaccine. Following review of the comments submitted and consultation as required under the law, CDC has finalized the hepatitis A vaccine information materials. The final hepatitis A materials are contained in this notice. Also noted are edits to the instructions for use of vaccine information materials.

**DATES:** Beginning no later than July 1, 2006, each health care provider who administers any hepatitis A vaccine to any child or adult in the United States shall provide copies of the relevant vaccine information materials contained in this notice, dated March 21, 2006, in conformance with the April 7, 2006 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 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). Section 2126 requires that the materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) A concise description of the benefits of the vaccine,
- (2) A concise description of the risks associated with the vaccine,
- (3) A statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) Such other relevant information as may be determined by the Secretary.

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 and materials for trivalent influenza vaccines since January 1, 2006.

Instructions for use of the vaccine information materials and copies of the materials can be downloaded in PDF format from the CDC Web site at: <http://www.cdc.gov/nip/publications/VIS>. In addition, 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).

## New Vaccine Information Materials

### *Hepatitis A Vaccine Information Statement*

Following the addition of hepatitis A vaccine to the National Vaccine Injury Compensation Program, CDC, as required under 42 U.S.C. 300aa–26, proposed vaccine information materials covering hepatitis A vaccine in a **Federal Register** notice published on July 28, 2005 (70 FR 43694).

The hepatitis A vaccine information materials referenced in this notice were developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, the American Academy of Family Physicians, American Academy of Pediatrics, American Medical Association, Emory Vaccine Research Center, Every Child By Two, Immunization Action Coalition and the National PTA. Also, CDC sought consultation with other organizations; however, those organizations did not provide comments.

Following consultation and review of comments submitted, the vaccine information materials covering hepatitis A vaccine have been finalized and are contained in this notice. The Vaccine Information Statement (VIS), dated March 21, 2006, is entitled: “Hepatitis A Vaccine: What You Need to Know.” CDC has also revised the “Instructions for the Use of Vaccine Information Statements,” which are dated April 7, 2006, to add the VIS for hepatitis A and to note the effective date for its mandatory use.

With publication of this notice, as of July 1, 2006, all health care providers will be required to provide copies of hepatitis A vaccine information materials prior to immunization in conformance with CDC’s April 7, 2006 “Instructions for the Use of Vaccine Information Statements.”

### Hepatitis A Vaccine Information Statement

Hepatitis A Vaccine: What You Need to Know.

#### 1. What is hepatitis A?

Hepatitis A is a serious liver disease caused by the hepatitis A virus (HAV). HAV is found in the stool of persons with hepatitis A. It is usually spread by close personal contact and sometimes by eating food or drinking water containing HAV.

Hepatitis A can cause:

- Mild “flu-like” illness.
- Jaundice (yellow skin or eyes).
- Severe stomach pains and diarrhea.

People with hepatitis A often have to be hospitalized (up to about 1 person in 5).

Sometimes, people die as a result of hepatitis A (about 3–5 deaths per 1,000 cases). A person who has hepatitis A can easily pass the disease to others within the same household. Hepatitis A vaccine can prevent hepatitis A.

#### 2. Who should get hepatitis A vaccine and when?

##### WHO?

Some people should be routinely vaccinated with hepatitis A vaccine:

- All children 1 year (12 through 23 months) of age.
- Persons 1 year of age and older traveling to or working in countries with high or intermediate prevalence of hepatitis A, such as those located in Central or South America, Mexico, Asia (except Japan), Africa, and eastern Europe. For more information see [www.cdc.gov/travel](http://www.cdc.gov/travel)
- Children and adolescents through 18 years of age who live in states or communities where routine vaccination has been implemented because of high disease incidence.

- Men who have sex with men.
- Persons who use street drugs.
- Persons with chronic liver disease.
- Persons who are treated with clotting factor concentrates.
- Persons who work with HAV-infected primates or who work with HAV in research laboratories.

Other people might get hepatitis A vaccine in special situations:

- Hepatitis A vaccine might be recommended for children or adolescents in communities where outbreaks of hepatitis A are occurring.

Hepatitis A vaccine is not licensed for children younger than 1 year of age.

##### WHEN?

For children, the first dose should be given at 12–23 months of age. Children who are not vaccinated by 2 years of age can be vaccinated at later visits.

For travelers, the vaccine series should be started at least one month before traveling to provide the best protection.

Persons who get the vaccine less than one month before traveling can also get a shot called immune globulin (IG). IG gives immediate, temporary protection.

For others, the hepatitis A vaccine series may be started whenever a person is at risk of infection.

Two doses of the vaccine are needed for lasting protection. These doses should be given at least 6 months apart.

Hepatitis A vaccine may be given at the same time as other vaccines.

#### 3. Some people should not get hepatitis A vaccine or should wait.

- Anyone who has ever had a severe (life-threatening) allergic reaction to a

previous dose of hepatitis A vaccine should not get another dose.

- Anyone who has a severe (life threatening) allergy to any vaccine component should not get the vaccine. Tell your doctor if you have any severe allergies. All hepatitis A vaccines contain alum and some hepatitis A vaccines contain 2-phenoxyethanol.

- Anyone who is moderately or severely ill at the time the shot is scheduled should probably wait until they recover. Ask your doctor or nurse. People with a mild illness can usually get the vaccine.

- Tell your doctor if you are pregnant. The safety of hepatitis A vaccine for pregnant women has not been determined. But there is no evidence that it is harmful to either pregnant women or their unborn babies. The risk, if any, is thought to be very low.

#### 4. What are the risks from hepatitis A vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of hepatitis A vaccine causing serious harm, or death, is extremely small.

Getting hepatitis A vaccine is much safer than getting the disease.

Mild problems.

- Soreness where the shot was given (about 1 out of 2 adults, and up to 1 out of 6 children).

- Headache (about 1 out of 6 adults and 1 out of 25 children).

- Loss of appetite (about 1 out of 12 children).

- Tiredness (about 1 out of 14 adults). If these problems occur, they usually last 1 or 2 days.

Severe problems.

- Serious allergic reaction, within a few minutes to a few hours of the shot (very rare).

#### 5. What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- Call a doctor, or get the person to a doctor right away.

- Tell your doctor what happened, the date and time it happened, and when the vaccination was given.

- Ask your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS Web site at <http://www.vaers.hhs.gov>, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

#### 6. The National Vaccine Injury Compensation Program

In the event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their Web site at <http://www.hrsa.gov/vaccinecompensation>.

#### 7. How can I learn more?

- Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.

- Call your local or state health department.

- Contact the Centers for Disease Control and Prevention (CDC):

—Call 1-800-232-4636 (1-800-CDC-INFO)

—Visit CDC Web sites at: <http://www.cdc.gov/hepatitis> or <http://www.cdc.gov/nip>

Department of Health and Human Services, Centers for Disease Control and Prevention, National Immunization Program.

Vaccine Information Statement, Hepatitis A (3/21/06), 42 U.S.C. 300aa-26.

Dated: May 20, 2006.

**James D. Seligman,**

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E6-8350 Filed 5-30-06; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0202]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response 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 information collection provisions of FDA's regulations requiring that the agency receive prior notice before food is imported or offered for import into the United States.

**DATES:** Submit written or electronic comments on the collection of information by July 31, 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:

Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**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