

**ADDRESSES:** Hubert H. Humphrey building (200 Independence Ave., SW., Washington, DC 20201), Conference Room 800.

**FOR FURTHER INFORMATION CONTACT:** <http://www.hhs.gov/healthit>.

**SUPPLEMENTARY INFORMATION:** A webcast of the third Community meeting will be available on the NIH Web site at: <http://www.videocast.nih.gov/>. If you have special needs for the meeting please contact Amanda Smith at [Amanda.Smith@hhs.gov](mailto:Amanda.Smith@hhs.gov) or (202) 690-7385.

Dated: January 23, 2006.

**Dana Haza,**

*Office of Programs and Coordination, Office of the National Coordinator.*

[FR Doc. 06-832 Filed 1-27-06; 8:45 am]

**BILLING CODE 4150-24-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### American Health Information Community Consumer Empowerment Workgroup Meeting

**ACTION:** Announcement of meeting.

**SUMMARY:** This notice announces the first meeting of the American Health Information Community Consumer Empowerment Workgroup in accordance with the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C., App.).

**DATES:** January 30, 2006 from 1 p.m. to 5 p.m.

**ADDRESSES:** Hubert H. Humphrey Building (200 Independence Ave., SW., Washington, DC 20201), conference room 705A.

**FOR FURTHER INFORMATION CONTACT:** <http://www.hhs.gov/healthit>.

**SUPPLEMENTARY INFORMATION:** For information on how to access this workgroup meeting via the Web, including ensuring your PC's compatibility, go to: <http://www.hsrnet.net/onc/workgroups/>.

This notice is published less than 15 days in advance of the meeting due to logistical difficulties.

Dated: January 23, 2006.

**Dana Haza,**

*Office of Programs and Coordination, Office of the National Coordinator.*

[FR Doc. 06-833 Filed 1-27-06; 8:45 am]

**BILLING CODE 4150-24-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### American Health Information Community Electronic Health Record Workgroup Meeting

**ACTION:** Announcement of meeting.

**SUMMARY:** This notice announces the first meeting of the American Health Information Community Electronic Health Record Workgroup in accordance with the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C., App.).

**DATES:** January 31, 2006 from 1 p.m. to 5 p.m.

**ADDRESSES:** Hubert H. Humphrey Building (200 Independence Ave., SW., Washington, DC 20201), conference room 800.

**FOR FURTHER INFORMATION CONTACT:** <http://www.hhs.gov/healthit>.

**SUPPLEMENTARY INFORMATION:** For information on how to access this workgroup meeting via the Web, including ensuring your PC's compatibility, go to: <http://www.hsrnet.net/onc/workgroups/>.

This notice is published less than 15 days in advance of the meeting due to logistical difficulties.

Dated: January 23, 2006.

**Dana Haza,**

*Office of Programs and Coordination, Office of the National Coordinator.*

[FR Doc. 06-834 Filed 1-27-06; 8:45 am]

**BILLING CODE 4150-24-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Amendment To Extend the January 24, 2003, Declaration Regarding Administration of Smallpox Countermeasures, as Amended on January 24, 2004 and January 24, 2005

**AGENCY:** Office of the Secretary (OS), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** Concern that terrorists may have access to the smallpox virus and attempt to use it against the American public and United States Government facilities abroad continues to exist. The January 24, 2003, declaration regarding administration of smallpox countermeasures is revised to incorporate statutory definitions from the Smallpox Emergency Personnel Protection Act of 2003 and extended for one year until and including January 23, 2007.

**DATES:** This notice and the attached amendment are effective as of January 24, 2006.

**FOR FURTHER INFORMATION CONTACT:** Stewart Simonson, Assistant Secretary for the Office of Public Health Emergency Preparedness, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201, Telephone (202) 205-2882 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:** Section 224(p) of the Public Health Service Act, which was established by section 304 of the Homeland Security Act of 2002 and amended by section 3 of the Smallpox Emergency Personnel Protection Act of 2003 ("SEPPA"), is intended to alleviate certain liability concerns associated with administration of smallpox countermeasures and, therefore, ensure that the countermeasures are available and can be administered in the event of a smallpox-related actual or potential public health emergency such as a bioterrorist incident.

On January 24, 2003, due to concerns that terrorists may have access to the smallpox virus and attempt to use it against the American public and U.S. Government facilities abroad, the Secretary issued a declaration making section 224's legal protections available. The declaration was effective until and including January 23, 2004; it included in section VI a number of definitions, which are no longer appropriate because of the statutory amendments in section 3 of SEPPA.

On January 24, 2004, the Secretary amended the definitions contained in the January 24, 2003 declaration in light of the statutory amendments in section 3 of SEPPA because such definitions were no longer appropriate, and extended the declaration for one year until January 23, 2005. On January 24, 2005, the Secretary extended the declaration for another year through January 23, 2006. Pursuant to section 224(p)(2)(A), the Secretary issues the amendment below to extend for one year, up to and including January 23, 2007, the January 24, 2003 declaration, as amended.

#### Amendment To Extend January 24, 2003 Declaration Regarding Administration of Smallpox Countermeasures

*I. Policy Determination:* The underlying policy determinations of the January 24, 2003 declaration continue to exist, including the heightened concern that terrorists may have access to the smallpox virus and attempt to use it

against the American public and U.S. Government facilities abroad.

II. *Amendment of Declaration:* I, Michael O. Leavitt, Secretary of the Department of Health and Human Services, have concluded, in accordance with the authority vested in me under section 224(p)(2)(A) of the Public Health Service Act, that a potential bioterrorist incident makes it advisable to extend the January 24, 2003 declaration regarding administration of smallpox countermeasures until and including January 23, 2007. The January 24, 2003, declaration as hereby amended may be further amended as circumstances require.

III. *Effective Dates:* This extension is effective January 24, 2006 until and including January 23, 2007. The effective period may be extended or shortened by subsequent amendment to the January 24, 2003, declaration as hereby amended.

Dated: January 24, 2006.

**Michael O. Leavitt,**  
Secretary.

**Amendment To Extend January 24, 2003 Declaration Regarding Administration of Smallpox Countermeasures as Amended on January 24, 2004 and January 24, 2005**

I. *Policy Determination:* The underlying policy determinations of the January 24, 2003 declaration continue to exist, including the heightened concern that terrorists may have access to the smallpox virus and attempt to use it against the American public and U.S. Government facilities abroad.

II. *Amendment of Declaration:* I, Michael O. Leavitt, Secretary of the Department of Health and Human Services, have concluded, in accordance with the authority vested in me under section 224(p)(2)(A) of the Public Health Service Act, that a potential bioterrorist incident makes it advisable to extend the January 24, 2003 declaration regarding administration of smallpox countermeasures until and including January 23, 2007. The January 24, 2003, declaration as hereby amended may be further amended as circumstances require.

III. *Effective Dates:* This extension is effective January 24, 2006 until and including January 23, 2007. The effective period may be extended or shortened by subsequent amendment to the January 24, 2003, declaration as hereby amended.

Dated: January 24, 2006.

**Michael O. Leavitt,**  
Secretary.

[FR Doc. 06-820 Filed 1-24-06; 4:50 pm]

**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Advisory Committee on Immunization Practices: Meeting**

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) announce the following Federal Committee meeting.

*Correction:* This notice was published in the **Federal Register** on January 19, 2006, volume 71, number 12, page 3096-3097. "Additional Information" has been added.

*Name:* Advisory Committee on Immunization Practices (ACIP).

*Times and Dates:* 8 a.m.-6:15 p.m., February 21, 2006. 8 a.m.-5 p.m., February 22, 2006.

*Place:* Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Building 19, Room 232, Atlanta, Georgia 30333.

*Additional Information:* In order to expedite the security clearance process at the CDC Clifton Road campus, all attendees at the ACIP meeting are now required to register on-line at <http://www.cdc.gov/nip/acip>, which can be found under the "Upcoming Meetings" tab. Please be sure to complete all of the required fields before submitting your registration.

All non-US citizens who have not pre-registered by January 25, 2006 will not be allowed access to the campus, and will not be allowed to register on site. All non-US citizens are required to complete the "Access Request Form" in addition to registering on line. This form can be obtained by contacting Demetria Gardner at (404) 639-8836 and should be e-mailed directly to her upon completion at [dgardner@cdc.gov](mailto:dgardner@cdc.gov).

*Contact Person for More Information:* Demetria Gardner, Epidemiology and Surveillance Division, National Immunization Program, CDC, 1600 Clifton Road, NE., (E-61), Atlanta, Georgia 30333, telephone 404/639-8836, fax 404/639-8616.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: January 24, 2006.

**Alvin Hall,**

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

[FR Doc. E6-1095 Filed 1-27-06; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005E-0249]

**Determination of Regulatory Review Period for Purposes of Patent Extension; ENABLEX**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for ENABLEX and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Claudia V. Grillo, Office of Regulatory Policy (HFD-013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-453-6681.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the