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.*

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