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

actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ENABLEX (darifenacin hydrobromide). ENABLEX is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ENABLEX (U.S. Patent No. 5,096,890) from Novartis International Phamaceutical Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 8, 2005, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ENABLEX represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ENABLEX is 3,824 days. Of this time, 3,073 days occurred during the testing phase of the regulatory review period, while 751 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: July 6, 1994. The applicant claims June 13, 1994, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 6, 1994, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: December 3, 2002. The applicant claims December 30, 2002, as the date the new drug application (NDA) for ENABLEX (NDA 21–513) was initially submitted. However, FDA records indicate that NDA 21–513 was submitted on December 3, 2002.

3. *The date the application was approved*: December 22, 2004. FDA has verified the applicant's claim that NDA 21–513 was approved on December 22, 2004.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 2,298 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see *ADDRESSES*) written or electronic comments and ask for a redetermination by March 31, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 31, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 5, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–1072 Filed 1–27–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E–0021]

Determination of Regulatory Review Period for Purposes of Patent Extension; XOLAIR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for XOLAIR 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 biological 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biological product XOLAIR (omalizumab). XOLAIR is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have a positive