## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–2010–E–0328, FDA–2010–E–0324, and FDA–2010–E–0325]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; ACTEMRA

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for ACTEMRA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that human biological product.

**ADDRESSES:** Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 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 approved for marketing the human biologic product ACTEMRA (tocilizumab). ACTEMRA is indicated for treatment of rheumatoid arthritis. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for ACTEMRA (U.S. Patent Nos. 5,670,373 and 5,795,965), filed by Chugai Seiyaku Kabushiki Kaisha, and for U.S. Patent No. 5,888,510, filed by Chugai Seiyaku Kabushiki Kaisha and Tadamitsu Kishimoto for ACTEMRA. The Patent and Trademark Office requested FDA's assistance in determining these patents' eligibilities for patent term restoration. In a letter dated September 30, 2010, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of ACTEMRA represented the first permitted commercial marketing or use of the product. 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 ACTEMRA is 1,893 days. Of this time, 1,111 days occurred during the testing phase of the regulatory review period, while 782 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* November 4, 2004. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 4, 2004.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262*): November 19, 2007. FDA has verified the applicant's claim that the biologics license application (BLA) for ACTEMRA (BLA 125276/0) was initially submitted on November 19, 2007.

3. *The date the application was approved:* January 8, 2010. FDA has verified the applicant's claim that BLA 125276/0 was approved on January 8, 2010.

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 1,338 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**) either electronic or written comments and ask for a redetermination by August 1, 2011. 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 November 28, 2011. 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.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 15, 2011.

**Jane A. Axelrad,**

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

[FR Doc. 2011–13388 Filed 5–27–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Office of the Director Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Advisory Committee to the Director, National Institutes of

Health (NIH), June 9, 2011, 9:30 a.m. to June 10, 2011, 12 p.m., 31 Center Drive, Building 31, C–Wing, Conference Room 6, Bethesda, MD, 20892 which was published in the **Federal Register** on May 13, 2011, 76 FR 28055.

The open sessions of the Advisory Committee to the Director, NIH, will be held on June 9, 2011, 9:30 a.m. to 3:45 p.m. and June 10, 2011, 8:30 a.m. to 12 p.m. The closed session of the Advisory Committee to the Director, NIH, will be held on June 9, 2011, 4 p.m. to 5 p.m.. The meeting location remains the same.

Dated: May 24, 2011.

**Anna P. Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011–13353 Filed 5–27–11; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Office of the Secretary

### Public Workshop; Privacy Compliance Basics and 2011 Developments

**AGENCY:** Privacy Office, DHS.

**ACTION:** Notice announcing public workshop.

**SUMMARY:** The Department of Homeland Security Privacy Office will host a public workshop, "Privacy Compliance Basics and 2011 Developments."

**DATES:** The workshop will be held on June 24 and 27, 2011, from 8:30 a.m. to 4:30 p.m.

**ADDRESSES:** The workshop will be held in the auditorium at the DHS Offices at the GSA Regional Headquarters Building located at 7th and D Streets, SW., Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:** Shannon Kelso, Privacy Office, Department of Homeland Security, Washington, DC 20528; by telephone 703–235–0780; by facsimile 703–235–0442; or by e-mail at *PIA@dhs.gov.*

**SUPPLEMENTARY INFORMATION:** The Department of Homeland Security (DHS) Privacy Office is holding a public workshop that will provide in-depth training on the privacy compliance process at DHS. June 24 is a primer for the new and developing privacy professional, presenting baseline Federal privacy compliance requirements including the Privacy Act of 1974, as amended, the E-Government Act of 2002, Office of Management and Budget memoranda, and other policy. June 27 consists of advanced presentations for the experienced privacy professional, including review of recent Privacy Act rulings, program case studies, mapping to IT security requirements, and developments in privacy compliance at the Department.

Individuals are invited to attend just one or both days. The workshop is open to the public and there is no fee for attendance.

*Registration and Security:* In order to facilitate security requirements of the GSA facility, attendees must register in advance for this workshop. Registration closes at 9 a.m., Wednesday, June 22, 2011. To register, please send an e-mail to *PIA@dhs.gov,* with "PRIVComplianceWorkshop" in the subject line, and your full name and organizational affiliation in the body of the e-mail. Alternatively, you may call 703–235–0780 to register by providing the Privacy Office with your full name and organizational affiliation.

All attendees who are employed by a federal agency will be required to show their federal agency employee photo identification badge to enter the building. Attendees who do not possess a federal agency employee photo identification badge will need to show a form of government-issued photo identification, such as a driver's license, in order to verify their previously-provided registration information. This is a security requirement of the facility.

The Privacy Office will only use your name for the security purposes of this specific workshop and to contact you in the event of a change to the workshop.

*Special Assistance:* Persons with disabilities who require special assistance should indicate this in their admittance request and are encouraged to identify anticipated special needs as early as possible.

**Mary Ellen Callahan,**

*Chief Privacy Officer, Department of Homeland Security.*

[FR Doc. 2011–13415 Filed 5–27–11; 8:45 am]

**BILLING CODE 9110–9L–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

**[Docket No. USCG–2011–0357]**

### Cruise Vessel Safety and Security Act of 2010, Available Technology

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of request for comments; correction.

**SUMMARY:** In the **Federal Register** published on May 25, 2011, the United States Coast Guard solicited public comment on the availability of technology to meet certain provisions of the Cruise Vessel Security and Safety Act of 2010(CVSSA), specifically related to video recording and overboard detection technologies. The Notice of request for comments published with errors in the preamble, specifically, the addresses for submitting comments was incorrect and should have directed commenters to *http://www.regulations.gov* for online comment submissions, and to the "Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001" for mailing comments.

**DATES:** This correction is effective May 31, 2011.

**FOR FURTHER INFORMATION CONTACT:** For information about this correction, contact Jennifer Mehaffey, Office of Regulations and Administrative Law, (202) 372–3859, or by email at *jennifer.a.mehaffey@uscg.mil.* For information about the original regulation, call or e-mail Lieutenant Commander Latasha Pennant, Office of Design and Engineering Standards (CG–5211), U.S. Coast Guard Headquarters, by telephone at 202–372–1358, or by e-mail at *Latasha.E.Pennant@uscg.mil.*

**SUPPLEMENTARY INFORMATION:** In FR doc 2011–12988 appearing on page 30374 in the issue of Wednesday, May 25, 2011, the following corrections are made:

1. On page 30374, in the second column, revise the **ADDRESSES** section, to read as follows:

"**ADDRESSES**: You may submit comments identified by docket number USCG–2011–0357 using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–372–1925.

(3) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments."

2. On page 30374, in the third column, revise the **SUPPLEMENTARY INFORMATION** section, to read as follows: