DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; American Health Information Community Electronic Health Record Workgroup Meeting

ACTION: Announcement of meeting.

SUMMARY: This notice announces the eighth 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: August 15, 2006 from 1 p.m. to 5 p.m.

ADDRESSES: Mary C. Switzer Building (330 C Street, SW., Washington, DC 20201), Conference Room 4090 (please bring photo ID for entry to a Federal building).

FOR FURTHER INFORMATION: *http://www.hhs.gov/healthit/ahic/bio_main.html.*

SUPPLEMENTARY INFORMATION: The meeting will be available via Web cast at *http://www.eventcenterlive.com/cfmx/ec/login/login1.cfm.?BID=67.*

Dated: July 25, 2006.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 06–6662 Filed 8–2–06; 8:45 am]

BILLING CODE 4150–24–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; American Health Information Community Chronic Care Workgroup Meeting

ACTION: Announcement of meeting.

SUMMARY: This notice announces the eighth meeting of the American Health Information Community Chronic Care Workgroup in accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S., App.).

DATES: August 16, 2006 from 1 p.m. to 5 p.m.

ADDRESSES: Mary C. Switzer Building (330 C Street, SW., Washington, DC 20201), Conference Room 4090 (please bring photo ID for entry to a Federal building).

FOR FURTHER INFORMATION CONTACT: *http://www.hhs.gov/healthit/ahic/bio_main.html.*

SUPPLEMENTARY INFORMATION: The meeting will be available via Web cast at *http://www.eventcenterlive.com/cfmx/ec/login/login1.cfm?BID=67.*

Dated: July 25, 2006.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 06–6661 Filed 8–2–06; 8:45am]

BILLING CODE 4150–24–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Non-Pharmaceutical Interventions for Pandemic Influenza, Request for Applications (RFA) CI06–010

Correction: This notice was published in the **Federal Register** on July 13, 2006, Volume 71, Number 134, page 39683. The date has been changed due to reviewer's conflict with the original date. The meeting will be held on August 28, 2006.

Title: Non-Pharmaceutical Interventions for Pandemic Influenza, RFA CI06–010.

Contact Person for more Information: Felix Rogers, Ph.D., Scientific Review Administrator, National Immunization Program, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS E–05, Atlanta, GA 30333, Telephone 404.639.6101.

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: July 27, 2006.

Alvin Hall,

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

[FR Doc. E6–12542 Filed 8–2–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0189]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for IPLEX 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: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 human drug 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 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 IPLEX (mecasermin rinfabate [rDNA origin]). IPLEX is indicated for treatment of growth failure in children with severe primary IGF-1 deficiency or with growth hormone (GH) gene depletion who have developed neutralizing antibodies to GH. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for IPLEX (U.S. Patent No. 5,681,818) from Insmed Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 19, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of IPLEX 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 IPLEX is 3,527 days. Of this time, 3,183 days occurred during the testing phase of the regulatory review period, while 344 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 (the act) (21 U.S.C. 355(i)) became effective*: April 18, 1996. The applicant claims April 24, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 18, 1996, 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(b) of the act*: January 3, 2005. FDA has verified the applicant's claim that the new drug application (NDA) for IPLEX (NDA 21–884) was initially submitted on January 3, 2005.

3. *The date the application was approved*: December 12, 2005. FDA has verified the applicant's claim that NDA 21–884 was approved on December 12, 2005.

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 1,657 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 October 2, 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 January 30, 2007. 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: July 21, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–12571 Filed 8–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999E–5113]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CLINACOX 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 animal 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: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal 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 an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA approved for marketing the animal drug product CLINACOX (diclazuril). CLINACOX is indicated for use in broiler chickens, for the prevention of coccidicosis caused by