

health care efficiency; and an overview of the National Healthcare Quality and Disparities Reports. The final agenda will be available on AHRQ's Web site at <http://www.ahrq.gov> no later than July 14, 2006.

The meeting will adjourn at 4 p.m.

Dated: July 5, 2006.

Carolyn M. Clancy,
Director.

[FR Doc. 06-6164 Filed 7-7-06; 2:05 pm]

BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Targeted Evaluation of the President's Emergency Plan for AIDS Relief (PEPFAR) Funded Prevention of Mother-to-Child HIV Transmission (PMTCT), and Adherence to Antiretroviral Therapy (ART) Programs, Contract Solicitation Numbers (CSN) 2006-N-08428, 2006-N-08429, and 2006-N-08430

Correction: This notice was published in the **Federal Register** on June 9, 2006, Volume 71, Number 111, page 33456. The location of the meeting was changed due to insufficient meeting space at the Renaissance Concourse Hotel—Marriott, One Hartsfield Center Parkway, Atlanta, GA 30354. The meeting was held at the Hilton Atlanta Airport, 1031 Virginia Avenue, Atlanta, Georgia 30354.

Titles: Targeted Evaluation of the President's Emergency Plan for AIDS Relief (PEPFAR) Funded Prevention of Mother-to-Child HIV Transmission (PMTCT), and Adherence to Antiretroviral Therapy (ART) Programs, Contract Solicitation Numbers (CSN) 2006-N-08428, 2006-N-08429, and 2006-N-08430.

For Further Information Contact: Amy L. Sandul, Health Scientist, National Center for HIV, STD, and Tuberculosis Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS E-41, Atlanta, GA 30333, Telephone 404-639-6485.

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 3, 2006.

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

[FR Doc. E6-10774 Filed 7-10-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005E-0236]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MULTIHANCE 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 that 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 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 MULTIHANCE (gadobenate dimeglumine). MULTIHANCE is indicated for intravenous use in magnetic resonance imaging (MRI) of the central nervous system in adults to visualize lesions with abnormal blood brain barrier or abnormal vascularity of the brain, spine, and associated tissues. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for MULTIHANCE (U.S. Patent No. 4,916,246) from Bracco International B.V., 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 MULTIHANCE 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 MULTIHANCE is 3,789 days. Of this time, 2,482 days occurred during the testing phase of the regulatory review period, while 1,307 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) became effective:* July 12, 1994. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 12, 1994.

2. *The date the application was initially submitted with respect to the human drug product under section*