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 ControlSpecial 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]

BILLING CODE 4163–18–P

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*

505(b) of the act: April 27, 2001. FDA has verified the applicant's claim that the new drug applications (NDA) for Multihance (NDA 21–357 and NDA 21–358) were initially submitted on April 27, 2001.

3. *The date the applications were approved*: November 23, 2004. FDA has verified the applicant's claims that NDA 21–357 and NDA 21–358 were approved on November 23, 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 5 years 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 September 11, 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 8, 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: June 13, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–10796 Filed 7–10–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP), Liaison and Scientific Review Office; Meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM)

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), HHS.

ACTION: Meeting announcement and request for comment.

SUMMARY: Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a teleconference meeting of the SACATM on August 3, 2006. The teleconference is scheduled from 1 p.m. to 4 p.m. and is open to the public. At the teleconference, SACATM will discuss the conclusions of a peer review panel that met on May 23, 2006 to evaluate the validation status of the *in vitro* 3T3 and normal human keratinocyte (NHK) neutral red uptake (NRU) basal cytotoxicity test methods (see ''Background'' for more detail). The public is invited to participate in the teleconference and will be provided with an opportunity to make oral comments during the public comment period. Participation is limited only by the number of phone lines available.

DATES: In order to facilitate planning for this meeting, persons wishing to make an oral presentation are asked to notify Dr. Kristina Thayer via phone or e-mail by July 25, 2006, (see **ADDRESSES** below). Please note that a request for written comments on the peer review report is being announced in a separate **Federal Register** notice (available at *http://ntp.niehs.nih.gov/go/frn*).

ADDRESSES: Correspondence should be directed to Dr. Kristina Thayer, Executive Secretary for SACATM (NTP Liaison and Scientific Review Office, NIEHS, P.O. Box 12233, MD A3–01, Research Triangle Park, NC 27709; telephone: 919–541–5021, fax: 919–541–0295; or e-mail: *thayer@niehs.nih.gov*). Persons needing special assistance to participate should contact 919–541–2475 voice, 919–541–4644 TTY (text telephone), through the Federal TTY Relay System at 800–877–8339, or by e-mail to *niehsoeeo@niehs.nih.gov*. Requests should be made at least 7 days in advance of the event.

SUPPLEMENTARY INFORMATION:

Background

The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), organized an independent, scientific peer review meeting on May 23, 2006, to evaluate the validation status of the *in vitro* 3T3 and normal human keratinocyte (NHK) neutral red uptake (NRU) basal cytotoxicity test methods. These two *in vitro* cytotoxicity test methods are proposed as adjuncts (for the purpose of determining the starting dose) to *in vivo* acute oral toxicity tests. The peer review panel prepared a report that contains (1) a summary of the peer review evaluation and (2) the peer review panel's conclusions on the draft ICCVAM test method recommendations regarding the proposed usefulness, limitations, and validation status of the 3T3 and NHK cytotoxicity test methods. The availability of the report, entitled *Peer Review Panel Evaluation of the Use of In Vitro Basal Cytotoxicity Test Methods for Estimating Starting Doses for Acute Oral Systemic Toxicity Testing*, and a request for written public comments on the peer review panel's conclusions regarding the draft ICCVAM test method recommendations are announced in a separate **Federal Register** notice (available at *http://ntp.niehs.nih.gov/go/frn).* Copies of the report may be obtained on the ICCVAM/NICEATM Web site at *http://iccvam.niehs.nih.gov* or by contacting the Dr. Kristina Thayer (see **ADDRESSES** above).

At the teleconference, SACATM will discuss peer review panel's report, focusing on the panel's conclusions regarding the draft ICCVAM recommendations for the proposed use of these test methods, draft test method protocols, draft performance standards, and draft recommended future studies. ICCVAM will consider the peer review report, SACATM comments, and any written public comments received on that report as it prepares final ICCVAM recommendations for the two *in vitro* basal cytotoxicity test methods. An ICCVAM test method evaluation report, which will include the final ICCVAM recommendations, will be forwarded to the appropriate federal agencies for their consideration and made available to the public.

Request for Comments

Public input at the SACATM teleconference is invited and time is set aside for the presentation of public