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

comments. Each organization is allowed one time slot per public comment period. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes. Persons registering to make oral comments are asked, if possible, to send a copy of their statement to Dr. Kristina Thayer by July 25, 2006, to enable review by SACATM and NTP staff prior to the meeting. Please not that this teleconference provides an additional opportunity for the public to provide comment on the peer review panel's conclusions regarding the draft ICCVAM test method recommendations. Written comments submitted to NICEATM in response to a NICEATM notice published in this issue of the **Federal Register** do not need to be resubmitted. Any written comments on the peer review report received prior to July 25, 2006, will be distributed to SACATM.

Background Information on ICCVAM, NICEATM, and SACATM

The SACATM was established January 9, 2002, to fulfill section 3(d) of the ICCVAM Authorization Act of 2000 [42 U.S.C. 285*l*–3(d)] and is composed of scientists from the public and private sectors (**Federal Register**: March 13, 2002: Vol. 67, No. 49, page 11358). The SACATM provides advice to the Director of the NIEHS, ICCVAM, and NICEATM regarding statutorily mandated duties of ICCVAM and activities of NICEATM. Additional information about SACATM, including the charter, roster, and records of past meetings can be found at *http://ntp.niehs.nih.gov/go/167*. Information about NICEATM and ICCVAM activities can be found at the NICEATM/ICCVAM Web site (*http://iccvam.niehs.nih.gov*) or by contacting the Director of NICEATM, Dr. William Stokes (telephone: 919–541–2384, or e-mail: *niceatm@niehs.nih.gov*).

Dated: June 30, 2006.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences and National Toxicology Program.

[FR Doc. E6–10790 Filed 7–10–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP), NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Availability of Peer Review Panel Report on the Use of *In Vitro* Basal Cytotoxicity Test Methods for Estimating Starting Doses for Acute Oral Systemic Toxicity Testing and Request for Comments

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

ACTION: Request for comments.

SUMMARY: 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 report from this meeting, 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*, is now available. The report contains (1) a summary of the peer review evaluation and (2) the peer review panel's (Panel) 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 NICEATM invites public comment on the Panel's conclusions on the draft ICCVAM test method recommendations. Copies of the Panel report may be obtained on the ICCVAM/NICEATM Web site at *http://iccvam.niehs.nih.gov*, or by contacting NICEATM at the address given below.

DATES: Written comments should be received at NICEATM by August 25, 2006.

ADDRESSES: Public comments and any other correspondence should be sent by mail, fax, or e-mail to Dr. William S. Stokes, NICEATM, NIEHS, P. O. Box 12233, MD EC–17, Research Triangle Park, NC, 27709, (phone) 919–541–2384, (fax) 919–541–0947, (e-mail) niceatm@niehs.nih.gov.

SUPPLEMENTARY INFORMATION:

Background

The 3T3 and NHK cytotoxicity test methods are proposed as adjuncts (for the purpose of determining the starting dose) to *in vivo* acute oral toxicity test methods (*i.e.*, the Up-and-Down Procedure [EPA 2002a; OECD 2001a], the Acute Toxic Class method [OECD 2001b]) to refine (*i.e.*, to lessen or avoid pain and distress) and/or reduce animal use. Both *in vitro* cytotoxicity test methods have been assessed in a NICEATM and European Centre on the Validation of Alternative Methods (ECVAM) collaborative independent validation study. At this peer review meeting, the Panel reviewed the background review document (BRD) on the 3T3 and NHK cytotoxicity test methods and evaluated the extent that established validation and acceptance criteria had been adequately addressed for the intended purpose of the test methods. The Panel also provided comments on draft ICCVAM recommendations regarding the proposed use of these test methods, draft test method protocols, draft performance standards, and draft recommended future studies. The Panel's conclusions and recommendations on the two *in vitro* cytotoxicity test methods are described in the *Peer Review Panel Evaluation of the Use of In Vitro Basal Cytotoxicity Test Methods for Estimating Starting Doses for Acute Oral Systemic Toxicity Testing* (available at *http://iccvam.niehs.nih.gov/*).

Prior to the Panel meeting, NICEATM issued **Federal Register** notices to (1) recommend that in vitro basal cytotoxicity test methods be considered as tools for estimating starting doses for in vivo acute systemic toxicity tests (66FR49686), (2) announce a request for nominations for Panel members and submission of existing in vivo and in vitro data (70FR14473), (3) announce the independent peer review meeting on the use of the 3T3 and NHK cytotoxicity test methods for estimating starting doses for acute oral systemic toxicity tests, and (4) request comments on the draft BRD and draft ICCVAM recommendations (71FR14229). All **Federal Register** notices, the draft BRD, and the draft ICCVAM recommendations are available at *http://iccvam.niehs.nih.gov/*.

Request for Comments

NICEATM invites the submission of written comments on the Panel's