3. *The date the application was approved:* July 1, 2009. FDA has verified the applicant's claim that NDA 21–425 for MULTAQ was approved on July 1, 2009.

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 applications for patent extension, this applicant seeks 519 days and 5 years, respectively, 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 February 8, 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 June 8, 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 regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 22, 2010.

Jane A. Axelrad,

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

[FR Doc. 2010–31064 Filed 12–9–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–D–0072] (formerly Docket No. 2005D–0042)

Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: The Open Public Hearing at FDA Advisory Committee Meetings; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: The Open Public Hearing at FDA Advisory Committee Meetings." We are issuing the guidance to provide information on how the public may participate at the open public hearing (OPH) portion of FDA advisory committee meetings. The guidance also provides recommendations regarding financial disclosure by persons participating in the OPH portion of advisory committee meetings.

DATES: Submit electronic or written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Special Medical Programs, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance. Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michael Ortwerth, Office of Special Medical Programs, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993, *e-mail: Michael.Ortwerth@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the February 15, 2005, issue of the **Federal Register** (70 FR 7747), FDA issued a notice announcing the availability of a draft guidance entitled "The Open Public Hearing; FDA Advisory Committee Meetings." The guidance is intended for members of the public who choose to participate in the OPH portion of an FDA advisory committee meeting.

FDA issues guidance documents for FDA staff, applicants and sponsors of regulated products, and the public that describe the agency's current thinking on a regulatory matter, including its interpretation of, and policies regarding, statutes and regulations. FDA's advisory committees provide independent expert advice and recommendations to the agency on scientific, technical, and policy matters related to FDA-regulated products. Although advisory committees provide recommendations to FDA, FDA makes the final decisions on any matters considered by an advisory committee (21 CFR 14.5). Under 21 CFR 14.25(a), every meeting of an FDA advisory committee includes an OPH session during which interested persons may present relevant information or views orally or in writing. The hearing session is conducted in accordance with the procedures set forth in 21 CFR 14.29.

FDA encourages participation from all public stakeholders in our decisionmaking processes. We issued the draft guidance to answer questions about how the public may participate at an OPH session. Participants may include, but are not limited to, general members of the public, individuals or spokespersons from the regulated industry, consumer advocacy groups, and professional organizations, societies, and associations. The guidance provides information on such matters as how to submit a request to speak at an OPH session, logistical procedures, and disclosure of financial relationships relevant to the meeting topic.

We received two comments on the draft guidance. In response to the comments and at our own initiative, we have revised the guidance in several respects, including with regard to how the OPH session is conducted and instructions regarding financial disclosure.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's thinking on participation in the OPH portion of FDA advisory committee meetings. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the

requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/oc/advisory/default.htm.*

Dated: December 6, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–31022 Filed 12–9–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Tobacco Products Scientific Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Tobacco Products Scientific Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 10 and 11, 2011 from 8 a.m. until 5 p.m.

Location: FDA White Oak Conference Center, Bldg. 31, rm. 1503, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm*; under the heading "Resources for You," click on "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings." Please note that visitors to the White Oak Campus must have a valid driver's license or other picture ID, and must enter through Building 1.

Contact Person: Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373 (choose Option 4), e-mail: *TPSAC@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732110002. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On January 10 and 11, 2011, the Committee will continue to (1) receive updates from the Menthol Report Subcommittee and (2) receive and discuss presentations regarding the data requested by the Committee at the March 30 and 31, 2010, meeting of the Tobacco Products Scientific Advisory Committee.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before December 30, 2010. Oral presentations from the public will be scheduled between approximately 3 p.m. and 4 p.m. on January 10, 2011. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 21, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 22, 2010.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Caryn Cohen at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 3, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–31066 Filed 12–9–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Generic Clearance for Surveys of Customers and Partners of the Office of Extramural Research of the National Institutes of Health

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of Extramural Research (OER), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 13, 2010 (Volume 75, Number 176, page 55585) and allowed 60 days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Generic Clearance for Surveys of Customers and Partners of the Office of Extramural Research of the National Institutes of Health. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* OER develops, coordinates the implementation of, and evaluates NIH-wide policies and procedures for the award of extramural funds . To move forward with our initiatives to ensure success in accomplishing the NIH mission, input from partners and customers is