applicant's claim that there was no investigational new drug application for COARTEM.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C act:* June 27, 2008. FDA has verified the applicant's claim that the new drug application (NDA) 22–268 was submitted on June 27, 2008.

3. *The date the application was approved:* April 7, 2009. FDA has verified the applicant's claim that NDA 22–268 was approved on April 7, 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 application for patent extension, this applicant seeks 284 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**) 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. 2010–31074 Filed 12–9–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2010–E–0039 and FDA–2010–E–0040]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MULTAQ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 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 drug 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 MULTAQ (dronedarone hydrochloride). MULTAQ is indicated to reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL), with a recent episode of AF/AFL and associated cardiovascular risk factors who are in sinus rhythm or who will be cardioverted. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for MULTAQ (U.S. Patent Nos. 5,223,510 and 7,323,493) from Sanofi-Aventis, and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated March 3, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of MULTAQ 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 MULTAQ is 5,076 days. Of this time, 3,593 days occurred during the testing phase of the regulatory review period, while 1,483 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 FFD&C act) (21 U.S.C. 355(i)) became effective:* August 10, 1995. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 10, 1995.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FFD&C act:* June 10, 2005. FDA has verified the applicant's claim that the first new drug application (NDA) for MULTAQ (NDA 21–913) was submitted on June 10, 2005.

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