patent's eligibility for patent term restoration. In a letter dated May 2, 2014, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of KAZANO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for KAZANO is 1,365 days. Of this time, 934 days occurred during the testing phase of the regulatory review period, while 431 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 FD&C Act) (21 U.S.C. 355(i)) became effective:* May 3, 2009. The applicant claims May 4, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 3, 2009, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* November 22, 2011. FDA has verified the applicant's claim that the new drug application (NDA) for KAZANO (NDA 203–414) was submitted on November 22, 2011.

3. *The date the application was approved:* January 25, 2013. FDA has verified the applicant's claim that NDA 203–414 was approved on January 25, 2013.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 102 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 July 6, 2015. 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 November 2, 2015. 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 or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–10335 Filed 5–1–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–E–0476 and FDA–2013–E–0654]

Determination of Regulatory Review Period for Purposes of Patent Extension; TUDORZA PRESSAIR

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for TUDORZA PRESSAIR 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 the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Campus, Rm. 3180, Silver Spring, MD 20993, 301–796–7900.

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 USPTO 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 has approved for marketing the human drug product TUDORZA PRESSAIR (aclidinium bromide). TUDORZA PRESSAIR is indicated for the long-term maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema. Subsequent to this approval, the USPTO received patent term restoration applications for TUDORZA PRESSAIR (U.S. Patent Nos. 6,750,226 and 7,078,412) from Almiral, S.A., and the USPTO requested FDA's assistance in determining the patents eligibilities for patent term restoration. In a letter dated July 16, 2013, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of TUDORZA PRESSAIR represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO

requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for TUDORZA PRESSAIR is 3,136 days. Of this time, 2,739 days occurred during the testing phase of the regulatory review period, while 397 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 FD&C Act) (21 U.S.C. 355(i)) became effective:* December 24, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 24, 2003.

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 23, 2011. FDA has verified the applicant's claim that the new drug application (NDA) for TUDORZA PRESSAIR (NDA 202–450) was submitted on June 23, 2011.

3. *The date the application was approved:* July 23, 2012. FDA has verified the applicant's claim that NDA 202–450 was approved on July 23, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,679 or 1,298 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 July 6, 2015. 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 November 2, 2015. 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 or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610.

Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–10336 Filed 5–1–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Council on Graduate Medical Education (COGME).

Dates and Times: May 21, 2015 (10:00 a.m.–4:00 p.m. EST).

Place: Webinar, and Conference Call Format.

Status: The meeting will be open to the public.

Purpose: The COGME provides advice and recommendations to the Secretary of the Department of Health and Human Services and to Congress on a range of issues including the supply and distribution of physicians in the United States, current and future physician shortages or excesses, issues relating to foreign medical school graduates, the nature and financing of medical education training, and the development of performance measures and longitudinal evaluation of medical education programs. The COGME members will continue their discussion on Graduate Medical Education (GME) innovations.

Agenda: The COGME agenda includes an opportunity for members to continue their discussion on Graduate Medical Education (GME) innovations including GME architecture, reform, and financing.

The official agenda will be available 2 days prior to the meeting on the HRSA Web site at *http://www.hrsa.gov/advisorycommittees/bhpradvisory/cogme/index.html*

SUPPLEMENTARY INFORMATION: Members of the public will have the opportunity to provide comments. Requests to make oral comments or provide written comments to the COGME should be sent to Dr. Joan Weiss, Designated Federal Official, using the address and phone number below. Individuals who plan to participate on the conference call or webinar should notify Dr. Weiss at least 3 days prior to the meeting, using the address and phone number below. Interested parties should refer to the meeting subject as the HRSA Council on Graduate Medical Education.

The conference call-in number is: 888–566–5974. The passcode is: 4439136.

The webinar link is *https://hrsa.connectsolutions.com/bhw_cogmemay2015/*.

Contact: Anyone requesting information regarding the COGME should contact Dr. Joan Weiss, Designated Federal Official within the Bureau of Health Workforce, Health Resources and Services Administration, in one of three ways: (1) Send a request to the following address: Dr. Joan Weiss, Designated Federal Official, Bureau of Health Workforce, Health Resources and Services Administration, Parklawn Building, Room 12C–05, 5600 Fishers Lane, Rockville, Maryland 20857; (2) call (301) 443–0430; or (3) send an email to *jweiss@hrsa.gov.*

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–10354 Filed 5–1–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than June 3, 2015.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests