respond to FDA's letter within the specified response period.

In accordance with §§ 601.5(b) and 12.21(b), FDA is issuing a notice of opportunity for a hearing on a proposal to revoke the U.S. License No. 103, of Allergy Laboratories, Inc. with regard to nonstandardized allergenic extract Dust, House Mixture.

FDA has placed copies of letters between FDA and Allergy Laboratories, Inc. relevant to the proposed revocation on file, with the Division of Dockets Management (see **ADDRESSES**) under the docket number found in brackets in the heading of this notice. These documents include the following: (1) March 15, 2013, letter from FDA to Allergy Laboratories, Inc. providing notice of the intent to institute proceedings to revoke its biologics license with regard to six specific nonstandardized allergenic extracts that raised specific safety concerns; (2) April 12, 2013, response letter from Allergy Laboratories, Inc. to FDA; and (3) June 12, 2013, letter from FDA to Allergy Laboratories, Inc. These documents are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Allergy Laboratories, Inc. may submit an electronic or written request for a hearing to the Division of Dockets Management May 30, 2014, and any data and information justifying a hearing must be submitted by June 30, 2014 . Other interested persons may submit comments on the proposed license revocation to the Division of Dockets Management byJune 30, 2014. The failure of the licensee to file a timely written request for a hearing constitutes an election by the licensee not to avail itself of the opportunity for a hearing concerning the proposed license revocation (§ 12.22(b)).

FDA's procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for a hearing, grant or denial of a hearing, and submission of data and information to justify a hearing on proposed revocation of a license are contained in 21 CFR parts 12 and 601. A request for a hearing may not rest on mere allegations or denials, but must set forth a genuine and substantial issue of fact that requires a hearing (§ 12.24(b)). If it conclusively appears from the face of the data, information, and factual analyses submitted in support of the request for a hearing that there is no genuine and substantial issue of fact for resolution at a hearing, the Commissioner of Food and Drugs will deny the hearing request, making findings and conclusions that justify the denial.

Only one copy of any submission need be provided to FDA. Submissions are to be identified with the docket number found in brackets in the heading of this document. Submissions, except for data and information prohibited from public disclosure under 21 CFR 10.20(j)(2)(i), 21 U.S.C. 331(j), or 18 U.S.C. 1905, may be examined in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 351 of the Public Health Service Act (42 U.S.C. 262) and sections 201, 501, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, and 371), and under the authority delegated to Commissioner of Food and Drugs and redelegated to the Director and Deputy Director of the Center for Biologics Evaluation and Research (FDA Staff Manual Guide 1410.203).

Dated: April 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09771 Filed 4–29–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2012–E–0036; FDA–2012–E–0149; FDA–2012–E–0150; and FDA–2012–E–0151]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for BRILINTA 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 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, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 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 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 has approved for marketing the human drug product BRILINTA (ticagrelor). BRILINTA is indicated to reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for BRILINTA (U.S. Patent Nos. 6,525,060; 6,251,910; 7,250,419; and 7,265,124) from AstraZeneca UK Limited, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated

August 7, 2012, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of BRILINTA 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 BRILINTA is 2,976 days. Of this time, 2,364 days occurred during the testing phase of the regulatory review period, while 612 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 29, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 29, 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:* November 16, 2009. FDA has verified the applicant's claim that the new drug application (NDA) for BRILINTA (NDA 22–433) was submitted on November 16, 2009.

3. *The date the application was approved:* July 20, 2011. FDA has verified the applicant's claim that NDA 22–433 was approved on July 20, 2011.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the 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 1,014 days, 1,032 days, or 1,794 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 June 30, 2014. 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 October 27, 2014. 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 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–09772 Filed 4–29–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[DS10100000/33D5670LC/DLCAP0000.000000/DX.10120]

Land Buy-Back Program for Tribal Nations Under Cobell Settlement

AGENCY: Office of the Deputy Secretary, Interior.

ACTION: Notice of tribal listening session.

SUMMARY: The Office of the Secretary will conduct a listening session on the status of implementation of the Land Buy-Back Program for Tribal Nations. The purpose of the session is to meet with Indian tribes to discuss progress to date and receive feedback. Indian landowners may also attend to provide input.

DATES: The listening session will take place on May 29, 2014, from 1 p.m. to 4 p.m. Pacific Time.

ADDRESSES: Federal Building, Auditorium, 911 NE 11th Avenue, Portland, OR 97232–4128.

FOR FURTHER INFORMATION CONTACT: Genevieve Giaccardo, Senior Advisor on Tribal Relations, (202) 208–1541.

SUPPLEMENTARY INFORMATION:

I. Background

The *Cobell* Settlement was approved with finality on November 24, 2012, following the exhaustion of appeals through the U.S. Supreme Court. Within a month following final approval, the Department of the Interior established the Land Buy-Back Program for Tribal Nations (Buy-Back Program) and published an Initial Implementation Plan. The Department engaged in government-to-government consultation on this plan and released an Updated Implementation Plan in November 2013.

The Department is currently implementing the Buy-Back Program at multiple locations across Indian Country. Since November 24, 2012, the Department has sent offers to nearly 19,000 landowners. Thus far, Interior has paid over $40 million to Indian landowners across the United States for voluntarily restoring the equivalent of more than 122,000 acres of land to tribal governments. Tribal governments are helping plan for and implement the Buy-Back Program at specific locations through cooperative agreements or other arrangements.

The purpose of this session is to gather input from tribes in order for the Department to continue to refine its land consolidation processes. Landowners may also attend the session to provide input.

II. Additional Resources

The Updated Implementation Plan and additional information about the Buy-Back Program is available at: *http://www.doi.gov/buybackprogram.* In addition, landowners can contact their local Fiduciary Trust Officer or call Interior's Trust Beneficiary Call Center at (888) 678–6836.

III. Listening Session Details

Time and Date: May 29, 2014, 1 p.m.–4 p.m. PT.

Place: Federal Building, Auditorium, 911 NE 11th Avenue, Portland, OR 97232–4128.

Dated: April 24, 2014.

Michael L. Connor,

Deputy Secretary.

[FR Doc. 2014–09817 Filed 4–29–14; 8:45 am]

BILLING CODE 4310–10–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–IA–2014–N080; FXIA16710900000–145–FF09A30000]

Endangered Species; Marine Mammals; Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species, marine mammals,