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,