

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,

or both. With some exceptions, the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA) prohibit activities with listed species unless Federal authorization is acquired that allows such activities.

DATES: We must receive comments or requests for documents on or before May 30, 2014. We must receive requests for marine mammal permit public hearings, in writing, at the address shown in the **ADDRESSES** section by May 30, 2014.

ADDRESSES: Brenda Tapia, Division of Management Authority, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 212, Arlington, VA 22203; fax (703) 358-2280; or email *DMAFR@fws.gov*.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358-2104 (telephone); (703) 358-2280 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I request copies of applications or comment on submitted applications?

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), along with Executive Order 13576, “Delivering an Efficient, Effective, and Accountable Government,” and the President’s Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and transparency in Government by disclosing information to the public, we invite public comment on these permit applications before final action is taken. Under the MMPA, you may request a hearing on any MMPA application received. If you request a hearing, give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Service Director.

III. Permit Applications

A. Endangered Species

Applicant: Dallas Zoo, Dallas, TX; PRT-32376B

The applicant requests a permit to import one male, captive-bred gorilla (*Gorilla gorilla*) from the Granby Zoo, Quebec, Canada, for the purpose of enhancement of the survival of the species through captive propagation.

Applicant: Woodland Park Zoological Society, Seattle, WA; PRT-23152B

The applicant requests a permit to export one male, captive-bred jaguar

(*Panthera onca*) to Canada for the purpose of enhancement of the survival of the species through captive propagation.

Applicant: San Antonio Zoological Society, San Antonio, Texas; PRT-22808B

The applicant requests a permit to export one male captive-born Tomistoma (*Tomistoma schlegelii*) to the Toronto Zoo, Ontario, Canada, for the purpose of enhancement of the survival of the species.

Applicant: IUCN Iguana Specialist Group, Chicago, IL, PRT-836457

The applicant requests renewal of their permit to import biological samples from the following species: Mayaguana iguana (*Cyclura carinata bartschi*), Turks and Caicos iguana (*Cyclura carinata carinata*), Jamaican iguana (*Cyclura collei*), rhinoceros iguana (*Cyclura cornuta*), Bahamas iguana (*Cyclura cychlura*), Cuban ground iguana (*Cyclura nubila*), Anegada ground iguana (*Cyclura pinguis*), Ricord’s ground iguana (*Cyclura ricordi*), San Salvador iguana (*Cyclura rileyi*), Grand Cayman blue iguana (*Cyclura lewisi*), and Mona ground iguana (*Cyclura stejnegeri*), for the purpose of scientific research. This notification covers activities to be conducted by the applicant of a 5-year period.

Applicant: Patricia Tucker, Feathering Crest Aviary, Sudbury, MA; PRT-31599B

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for golden parakeet (*Guarouba guarouba*) to enhance the species’ propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Connecticut Zoological Society, Bridgeport, CT; PRT-24407B

The applicant requests a permit to import one male and one female captive-bred Amur leopard (*Panthera pardus orientalis*) from the Copenhagen Zoological Garden, Denmark, for the purpose of enhancement of the survival of the species through captive propagation.

Applicant: Sedgwick County Zoological Society, Inc., Wichita, KS; PRT-28147B

The applicant requests a permit to import one female Sumatran orangutan (*Pongo abelii*) captive bred from Zoo Dortmund, Dortmund, Germany, for the purpose of enhancement of the survival of the species and zoological display.

Applicant: Roger Williams Park Zoo, Providence, RI; PRT-738517

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the families: Bovidae, Cebidae, Felidae (does not include jaguar, margay or ocelot), Hylobatidae, Lemuridae, Macropodidae, Mustelidae, and Rheidae, and the species: African wild dog (*Lycaon pictus*), Babirusa (*Babirousa babyrussa*), Mexican prairie dog (*Cynomys Mexicanus*), and Rothschild's starling (*Leucopsar rothschildi*), to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Jeffrey Kengor, Brunswick, MD; PRT-171815

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for radiated tortoise (*Astrochelys radiata*), to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Boulder Ridge Ranch LLC, Alto, MI; PRT-80856A

The applicant requests an amendment of his captive-bred wildlife registration under 50 CFR 17.21(g) to add the species listed below to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Species

Spotted pond turtle (*Geoclemys hamiltonii*)
Dwarf crocodile (*Osteolaemus tetraspis*)
Caiman (*Caiman yacare*)
Blyth's tragopan (*Tragopan blythii*)
Cabot's tragopan (*Tragopan caboti*)
Red-ruffed lemur (*Varecia rubra*)
South American tapir (*Tapirus terrestris*)
Przewalski's horse (*Equus przewalskii*)
Scimitar-horned oryx (*Oryx dammah*)
Bontebok (*Damaliscus pygargus pygargus*)
Anoa (*Bubalus depressicornis*)
Seladang (*Bos gaurus*)

Applicant: Melvin Bass, Kingwood, TX; PRT-28169B

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for Arabian oryx (*Oryx leucoryx*), addax (*Addax nasomaculatus*), and scimitar-horned oryx (*Oryx dammah*), dama gazelle (*Nanger dama*), red lechwe (*Kobus leche*), swamp barasingha (*Cervus duvaucelii*), and Eld's deer (*Rucervus eldii*), to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

eldii), to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: City of San Jose dba Happy Hollow Zoo, San Jose, CA; PRT-717994

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for family *Macropodidae* and cottontop tamarin (*Saguinus oedipus*), to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Tarzan Zerbini Circus, Webb City, Missouri; PRT-065146 and 065149

The applicant requests re-issuance of their permits to re-export and re-import two Asian elephants (*Elephas maximus*) born in the wild to worldwide locations for the purposes of enhancement of the species. The permit numbers and animals are 065146, Schell; and 065149, Marie. This notification covers activities to be conducted by the applicant over a 3-year period.

Applicant: Virginia Institute of Marine Science, Gloucester Point, VA; PRT-230437

The applicant requests the renewal of the permit to export/re-export and re-imports nonliving museum specimens of endangered and threatened species previously accessioned into the applicant's collection for scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: University of Hawaii at Manoa, Honolulu, HI; PRT-28506B

The applicant requests a permit to export/re-export and re-import nonliving museum specimens of endangered and threatened species previously accessioned into the applicant's collection for scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Multiple Applicants

The following applicants each request a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Zeev Nederman, San Antonio, TX; PRT-31433B

Applicant: Paul Jackson, Evergreen, CO; PRT-31023B

Applicant: James Kelly, Richmond, VA; PRT-33019B

Applicant: Dan Dinges, Houston, TX; PRT-33754B

B. Endangered Marine Mammals and Marine Mammals

Applicant: Steven Kazlowski, Kingston, WA; PRT-30427B

The applicant requests a permit to photograph polar bears in the wild on the north slope of Alaska from August to November from land-based vehicles and boats for commercial and educational purposes. This notification covers activities to be conducted by the applicant over a 5-year period.

Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of the above applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2014-09828 Filed 4-29-14; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCON00000 L10200000
DF0000.LXSS080C0000]

Notice of Public Meetings, Northwest Colorado Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Northwest Colorado Resource Advisory Council (RAC) will meet as indicated below.

DATES: The Northwest Colorado RAC scheduled meetings May 29, August 21 and December 4, 2014, from 8 a.m. to 3 p.m., with public comment periods regarding matters on the agenda at 10 a.m. and 2 p.m. A specific agenda for each meeting will be available prior to the meetings at www.blm.gov/co/st/en/BLM_Resources/racs/nwrac.html.