HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PERJETA (U.S. Patent Nos. 6,949,245; 7,560,111; 7,862,817) from Genentech, Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated February 4, 2013, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of PERJETA 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 PERJETA is 3,925 days. Of this time, 3,741 days occurred during the testing phase of the regulatory review period, while 184 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 (21 U.S.C. 355(i)) became effective:* September 11, 2001. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on September 11, 2001.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262*): December 8, 2011. The applicant claims December 6, 2011, as the date the biologics license application (BLA) for PERJETA (BLA 125409) was initially submitted. However, FDA records indicate that BLA 125409 was submitted on December 8, 2011.

3. *The date the application was approved:* June 8, 2012. FDA has verified the applicant's claim that BLA 125409 was approved on June 8, 2012.

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 1,317 or 624 or 354 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 18, 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 November 17, 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. 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: May 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11515 Filed 5–16–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–E–0056]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ZIOPTAN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application 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 ZIOPTAN (tafluprost). ZIOPTAN is indicated for reducing elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Subsequent to this

approval, the Patent and Trademark Office received a patent term restoration application for ZIOPTAN (U.S. Patent No. 5,886,035) from Asahi Glass Company Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 19, 2013, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ZIOPTAN 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 ZIOPTAN is 3,881 days. Of this time, 3,481 days occurred during the testing phase of the regulatory review period, while 400 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:* June 28, 2001. The applicant claims June 24, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 28, 2001, 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:* January 7, 2011. FDA has verified the applicant's claim that the new drug application (NDA) for ZIOPTAN (NDA 202514) was submitted on January 7, 2011.

3. *The date the application was approved:* February 10, 2012. FDA has verified the applicant's claim that NDA 202514 was approved on February 10, 2012.

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 5 years 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 18, 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 November 17, 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: May 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11517 Filed 5–16–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0176 (Formerly Docket No. 2008N–0011)]

Defining Small Numbers of Animals for Minor Use Designation; Periodic Reassessment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its periodic reassessment for defining the small numbers of animals for minor use in major species.

DATES: Submit either electronic or written comments at any time.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov/.* Submit 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: Margaret Oeller, Center for Veterinary Medicine (HVF–50), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0566, email: *margaret.oeller@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Minor Use and Minor Species Animal Health Act of 2004 (Pub. L. 108–282) (the MUMS Act), defines the term *minor use* to mean the intended use of a new animal drug in a major species for an indication that occurs infrequently and in only a small number of animals annually, or in limited geographical areas and in only a small number of animals annually (21 U.S.C. 321(pp)). As provided by the MUMS Act, major species of animals are dogs, cats, horses, cattle, pigs, turkeys, and chickens (21 U.S.C. 321(nn). This statutory definition of minor use creates the need for FDA to establish a small number of animals for each of the major species of animals (*small number*). In accordance with the provisions of the MUMS Act, the small number is used to determine whether an intended use of a new animal drug in a major species of animal qualifies as a minor use.

FDA established the small numbers by a final rule published in the **Federal Register** on August 26, 2009 (74 FR 43043). In the preamble for the final rule FDA responded to comments with the following:

''FDA agrees that there is a need to periodically reevaluate the definition of ''small number of animals.'' Because Congress did not establish by statute what a ''small number'' is, it affords FDA the opportunity to periodically reevaluate and update the definition of ''small number'' as necessary. We further agree that such a reevaluation should take into account the potential for increases in the development cost of new animal drugs, but note that it also should take into account potential increases in the cost that animal owners are willing to pay to treat affected animals as well as other factors involved in establishing ''small numbers,'' such as changes in the total population of major animal species.''

This is the first time FDA is reassessing the small numbers.

II. Processes Used to Determine Small Numbers of Animals for Minor Use in Major Species

The process used to establish small numbers of animals in major species of food-producing animals is different from the process used to establish small numbers of companion animals (non-food-producing). The processes FDA uses to establish the small numbers were published in the preamble to the proposed rule (73 FR 14411).