4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2011-E-0677 and FDA-2011-E-0678]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ONSIOR 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 animal 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, 301-796-3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 animal 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 animal drug product and continues until FDA grants permission to market the animal 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 an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA has approved for marketing the animal drug product ONSIOR (robenacoxib). ONSIOR is indicated for control of postoperative pain associated with orthopedic surgery, ovariohysterectomy and castration in cats $\geq$ 5.5 pounds and > 6 months of age; for up to a maximum of 3 days. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for ONSIOR (U.S. Patent Nos. 6,291,523 and 7,115,662) from Novartis Animal Health US, Inc., and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated July 9, 2012, FDA advised the Patent and Trademark Office that this animal drug product had

undergone a regulatory review period and that the approval of ONSIOR 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 ONSIOR is 1,704 days. Of this time, 1,650 days occurred during the testing phase of the regulatory review period, while 54 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(j)) became effective: July 10, 2006. The applicant claims March 2, 2004, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the INAD effective date was July 10, 2006, which was the received date of the first submission that includes a study with substantial data (submission of a major health test) or the first submission containing a Notice of Claimed Investigational Exemption.

2. The date the application was initially submitted with respect to the animal drug product under section 512 of the FD&C Act: January 14, 2011. The applicant claims January 13, 2011, as the date the new animal drug application (NADA) for ONSIOR (NADA 141-320) was initially submitted. However, FDA records indicate that NADA 141-320 was submitted on January 14, 2011.

3. The date the application was approved: March 8, 2011. FDA has verified the applicant's claim that NADA 141-320 was approved on March 8, 2011.

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 applications for patent extension, this applicant seeks 1,308 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 2, 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 September 29, 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 numbers 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: March 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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