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: June 2, 2011.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2009–E–0237; FDA–2009–E–0238; FDA–2009–E–0239]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for DEXILANT (previously KAPIDEX) 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 along with three copies and 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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

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 recently approved for marketing the human drug product DEXILANT (dexlansoprazole). DEXILANT is indicated for healing of all grades of erosive esophagitis (EE); maintaining healing of EE; and treating heartburn associated with symptomatic nonerosive gastroesophageal reflux disease. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for DEXILANT (U.S. Patent Nos. 6,462,058; 6,664,276, and 6,939,971) from Takeda Pharmaceutical Co., Ltd., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration and that FDA determine the product's regulatory review period. In a letter dated June 1, 2011, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of DEXILANT represented the first permitted commercial marketing or use of the product.

FDA has determined that the applicable regulatory review period for DEXILANT is 1,675 days. Of this time, 1,278 days occurred during the testing phase of the regulatory review period, while 397 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:* July 2, 2004. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 2, 2004.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 31, 2007. The applicant claims December 28, 2007, as the date the new drug application (NDA) for DEXILANT (NDA 22–287) was initially submitted. However, FDA records indicate that NDA 22–287 was submitted on December 31, 2007.

3. *The date the application was approved:* January 30, 2009. FDA has verified the applicant's claim that NDA 22–287 was approved on January 30, 2009.

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 822 or 959 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 August 22, 2011. 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 December 20, 2011. 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 petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

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: June 2, 2011.

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Associate Director for Policy, Center for Drug Evaluation and Research.

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