

documents in the docket at <http://www.regulations.gov>.

References

The following references are on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857, under Docket No. FDA-2010-P-0176 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter from Christy Foreman, FDA, CDRH, to Ken Charak, Ethicon Endo-Surgery, Inc., containing the order denying approval of the PMA for the SEDASYS system, October 26, 2010.

2. Charter Medical Devices Advisory Committee; Charter Amendment, Medical Devices Advisory Committee; FDA; July 15, 2008, <http://www.fda.gov/AdvisoryCommittees/Committees/MeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ucm124098.htm>.

3. "Resolving Scientific Disputes Concerning the Regulation of Medical Devices, A Guide To Use of the Medical Devices Dispute Resolution Panel; Final Guidance for Industry and FDA" FDA, CDRH; July 2, 2001, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>.

Dated: March 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-6520 Filed 3-18-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-E-0400]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VPRIV 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>.

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 VPRIV (velaglucerase alfa). VPRIV is indicated for long-term enzyme replacement therapy for pediatric and adult patients with type 1 Gaucher Disease. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for VPRIV (U.S. Patent No. 7,138,262) from Shire Human Genetic Therapies, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September

30, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VPRIV 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 VPRIV is 2,221 days. Of this time, 2,041 days occurred during the testing phase of the regulatory review period, while 180 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:* January 30, 2004. The applicant claims May 20, 2004, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 30, 2004, 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:* August 31, 2009. FDA has verified the applicant's claim that the new drug application (NDA) for VPRIV (NDA 22-575) was initially submitted on August 31, 2009.

3. *The date the application was approved:* February 26, 2010. FDA has verified the applicant's claim that NDA 22-575 was approved on February 26, 2010.

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 687 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 May 20, 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 September 19, 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: February 14, 2011.

Jane A. Axelrad,

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

[FR Doc. 2011-6514 Filed 3-18-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-E-0241]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ATRYN 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 biological 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product ATRYN (antithrombin (recombinant)). ATRYN is indicated for the prevention of peri-operative and peri-partum thromboembolic events in hereditary antithrombin deficient patients. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ATRYN (U.S. Patent No. 6,441,145) from GTC Biotherapeutics, Inc., 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 17, 2010, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of ATRYN represented the first permitted commercial marketing or use of the recombinant product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA determined that the applicable regulatory review period for ATRYN is 4,468 days. Of this time, 4,285 days occurred during the testing

phase of the regulatory review period, while 183 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:* November 15, 1996. The applicant claims November 14, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 15, 1996, which was 30 days after FDA receipt of the IND.

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):* August 8, 2008. The applicant claims January 31, 2008, as the date the biologics license application (BLA) for ATRYN (BLA 125284) was initially submitted. However, FDA records indicate that BLA 125284 was submitted on August 8, 2008.

3. *The date the application was approved:* February 6, 2009. FDA has verified the applicant's claim that BLA 125284 was approved on February 6, 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 application for patent extension, this applicant seeks 1,243 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 May 20, 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 September 19, 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