claim that the date the investigational new drug application became effective was on January 19, 1997.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: September 29, 2004. FDA has verified the applicant's claim that the new drug application (NDA) for BARACLUDE (NDA 21–797) was initially submitted on September 29, 2004.

3. *The date the application was approved*: March 29, 2005. FDA has verified the applicant's claim that NDA 21–797 was approved on March 29, 2005.

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 1,587 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**) written or electronic comments and ask for a redetermination by April 24, 2007. 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 August 22, 2007. 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.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 25, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–3042 Filed 2–22–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2004E–0300, 2004E–0301, 2004E–0302, 2004E–0303, 2004E–0304, 2004E–0306, 2004E–0426, and 2006E–0206]

Determination of Regulatory Review Period for Purposes of Patent Extension; S8 OVER–THE–WIRE SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for S8 OVER–THE–WIRE SYSTEM 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 medical device.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA approved for marketing the medical device, S8 OVER–THE–WIRE SYSTEM. S8 OVER–THE–WIRE SYSTEM is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de novo or restenotic lesions with reference vessel diameters of 3.0—4.0 mm and = 30 mm in length using direct stenting or predilatation. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for S8 OVER–THE–WIRE SYSTEM (U.S. Patent Nos. 5,292,331; 5,800,509; 5,836,965; 5,879,382; 5,891,190; 6,159,229; 6,309,402; and 6,344,053) from Medtronic Vascular, and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibilities for patent term restoration. In letters dated February 24, 2006, and June 14, 2006, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of S8 OVER–THE–WIRE SYSTEM 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 S8 OVER–THE–WIRE SYSTEM is 652 days. Of this time, 477 days occurred during the testing phase of the regulatory review period, while 175 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) involving this device became effective*: December 20, 2001. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the act for human tests to begin became effective December 20, 2001.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: April 10, 2003. The

applicant claims April 9, 2003, as the date the premarket approval application (PMA) for S8 OVER–THE–WIRE SYSTEM (PMA P030009) was initially submitted. However, FDA records indicate that PMA P030009 was submitted on April 10, 2003.

3. *The date the application was approved*: October 1, 2003. FDA has verified the applicant's claim that PMA P030009 was approved on October 1, 2003.

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 413 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 24, 2007. 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 August 22, 2007. 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.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 25, 2007.

Jane A. Axelrad,

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

[FR Doc. E7–3127 Filed 2–22–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006E–0355]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for AMITIZA 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 written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 human drug products, the testing phase begins when the exemption to permit the clinical investigations of the human drug product 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 AMITIZA (lubiprostone). AMITIZA is indicated for the treatment of chronic idiopathic constipation in the adult population. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for AMITIZA (U.S. Patent No. 5,284,858) from Sucampo AG, 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 5, 2006, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of AMITIZA represented the first permitted commercial marketing or use of the product. Shortly 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 AMITIZA is 2,197 days. Of this time, 1,890 days occurred during the testing phase of the regulatory review period, while 307 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 act) (21 U.S.C. 355(i)) became effective*: January 28, 2000. The applicant claims January 29, 2000, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 28, 2000, 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 act*: March 31, 2005. FDA has verified the applicant's claim that the new drug application (NDA) for AMITIZA (NDA 21–908) was initially submitted on March 31, 2005.

3. *The date the application was approved*: January 31, 2006. FDA has verified the applicant's claim that NDA 21–908 was approved on January 31, 2006.

This determination of the regulatory review period establishes the maximum