

electronic comments. Attachments should be in Microsoft Word, WordPerfect, or Excel; however, Microsoft Word is preferred.

• *Regular, Express, or Overnight Mail:*

Written nominations may be submitted (one original and two copies) to the following address only: NIOSH Docket 229 or Zaida Burgos, Committee Management Specialist, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., M/ S E-20, Atlanta, Georgia 30333. Telephone and facsimile submissions cannot be accepted.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 16, 2011.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2011-15684 Filed 6-22-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-E-0315]

Determination of Regulatory Review Period for Purposes of Patent Extension; Fusilev, Levoleucovorin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Fusilev (Levoleucovorin) 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 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 Fusilev (levoleucovorin calcium), a folate analog. Levoleucovorin rescue is indicated after high-dose methotrexate therapy in osteosarcoma and is also indicated to diminish the toxicity and counteract the effects of impaired methotrexate elimination and/or inadvertent overdosage of folic acid antagonists. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Fusilev (U.S. Patent No. 6,500,829) from the University of Strathclyde, and the Patent and Trademark Office requested FDA's assistance in determining this patent's 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 Fusilev represented the first permitted commercial marketing or use of the product.

FDA has determined that the applicable regulatory review period for Fusilev is 6,993 days. Of this time, 703 days occurred during the testing phase of the regulatory review period, while 6,290 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 15, 1989. The applicant claims December 15, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 15, 1989, 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:* December 18, 1990. The applicant claims December 14, 1990, as the date the new drug application (NDA) for FUSILEV (NDA 20-140) was initially submitted. However, FDA records indicate that NDA 20-140 was submitted on December 18, 1990.

3. *The date the application was approved:* March 7, 2008. FDA has verified the applicant's claim that NDA 20-140 was approved on March 7, 2008.

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 797 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.

Jane A. Axelrad,

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

[FR Doc. 2011-15689 Filed 6-22-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-E-0226]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for BROVANA 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 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 BROVANA (arformoterol tartrate). BROVANA is indicated for the long term, twice daily (morning and evening) maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for BROVANA (U.S. Patent No. 6,589,508) from Sepracor Inc. (now Sunovion Pharmaceuticals, Inc.), and the Patent and Trademark Office requested FDA's assistance in determining this patent's 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 BROVANA represented the first permitted commercial marketing or use of the product.

FDA has determined that the applicable regulatory review period for BROVANA is 3,118 days. Of this time, 2,819 days occurred during the testing phase of the regulatory review period, while 299 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:* March 26, 1998. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on March 26, 1998.

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 12, 2005. The applicant claims December 8, 2005, as the date the new drug application (NDA) for Brovana (NDA 21-912) was initially submitted. However, FDA records indicate that NDA 21-912 was submitted on December 12, 2005.

3. *The date the application was approved:* October 6, 2006. FDA has verified the applicant's claim that NDA 21-912 was approved on October 6, 2006.

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 745 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.

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