

Sponsors must provide specific data and information in a TEA to demonstrate that the condition has been marketed for a material time and to a material extent to become eligible for consideration in the OTC drug monograph system. When the condition is found eligible, FDA publishes a notice of eligibility and request for safety and effectiveness data for the proposed OTC use. The TEA that FDA reviewed (Ref. 1) and FDA's evaluation of the TEA (Ref. 2) have been placed on public display in the Division of Dockets Management (see **ADDRESSES**) under the docket number found in brackets in the heading of this document. Information deemed confidential under 18 U.S.C. 1905, 5 U.S.C. 552(b), or 21 U.S.C. 331(j) was deleted from the TEA before it was placed on public display.

II. Request for Data and Information

FDA determined that the information submitted in this TEA satisfies the criteria of § 330.14. FDA will evaluate sodium picosulfate, up to 10 mg, as a laxative single active ingredient for inclusion in the monograph for OTC laxative drug products (21 CFR part 334). Accordingly, FDA invites all interested persons to submit data and information, as described in § 330.14(f), on the safety and effectiveness of this active ingredient for this use so that FDA can determine whether it can be GRAS/E and not misbranded under recommended conditions of OTC use.

The TEA does not include an official or proposed United States Pharmacopeia-National Formulary (USP-NF) drug monograph. According to § 330.14(i) sponsors must include, an official or proposed USP-NF monograph for this ingredient as part of the safety and effectiveness data for this ingredient.

III. Comments

Interested persons should submit comments, data, and information to the Division of Dockets Management (see **ADDRESSES**). Submit three copies of all comments, data, and information. Individuals submitting written information or anyone submitting electronic comments may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting information. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Information submitted after the closing date will not be considered except by petition under (21 CFR 10.30).

IV. Marketing Policy

Under § 330.14(h), any product containing the condition for which data and information are requested may not be marketed as an OTC drug in the United States at this time unless it is the subject of an approved new drug application or abbreviated new drug application.

V. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. TEA for sodium picosulfate submitted by Ropes and Gray LLP on behalf of Boehringer Ingelheim on June 24, 2005.

2. FDA's evaluation and comments on the TEA for sodium picosulfate.

Dated: June 16, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-9896 Filed 6-21-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E-0444]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for BONIVA 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 that 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 application 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 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 BONIVA (ibandronate sodium). BONIVA is indicated for treatment and prevention of osteoporosis in postmenopausal women. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for BONIVA (U.S. Patent No. 4,927,814) from Hoffmann-La Roche 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 October 19, 2004, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of BONIVA 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 BONIVA is 2,559 days. Of this time, 2,254 days occurred during the testing phase of the regulatory review period,

while 305 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) became effective: May 15, 1996. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 15, 1996.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the act: July 16, 2002. The applicant claims July 15, 2002, as the date the new drug application (NDA) for BONIVA (NDA 21-455) was initially submitted. However, FDA records indicate that NDA 21-455 was initially submitted on July 16, 2002.

3. The date the application was approved: May 16, 2003. FDA has verified the applicant's claim that NDA 21-455 was approved on May 16, 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 application for patent extension, this applicant seeks 337 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 August 21, 2006. 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 19, 2006. 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: May 17, 2006.

Jane Axelrad,

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

[FR Doc. E6-9817 Filed 6-21-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E-0413]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CIALIS 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 that 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 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 CIALIS (tadalafil). CIALIS is indicated for treatment of erectile dysfunction. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CIALIS (U.S. Patent No. 5,859,006) from ICOS Corporation, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 19, 2004, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of CIALIS 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 CIALIS is 1,943 days. Of this time, 1,067 days occurred during the testing phase of the regulatory review period, while 876 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) became effective:* July 29, 1998. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 29, 1998.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* June 29, 2001. FDA has verified the applicant's claim that the new drug application (NDA) for CIALIS (NDA 21-368) was initially submitted on June 29, 2001.

3. *The date the application was approved:* November 21, 2003. FDA has verified the applicant's claim that NDA