BeneFIX™ is 749 days. Of this time, 583 days occurred during the testing phase of the regulatory review period, while 166 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 351 of the Public Health Service Act became effective*: January 26, 1995. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 26, 1995.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act*: August 30, 1996. The applicant claims August 29, 1996, as the date the Product License Application (PLA) for BeneFIX™ (PLA 96–1048) was initially submitted. However, FDA records indicate that PLA 96–1048 was submitted on August 30, 1996.

3. *The date the application was approved*: February 11, 1997. FDA has verified the applicant's claim that PLA 96–1048 was approved on February 11, 1997.

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 423 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 5, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 1, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–20742 Filed 8–3–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0292]

Determination of Regulatory Review Period for Purposes of Patent Extension; AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION 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 Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that food additive.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

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 food additives, the testing phase begins when a major health or environmental effects test involving the food additive begins and runs until the approval phase begins. The approval phase starts with the initial submission of a petition requesting the issuance of a regulation for use of the food additive and continues until FDA grants permission to market the food additive product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner 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 food additive will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(2)(B).

FDA recently approved for marketing the food additive AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION (2,2′-ethylidenebis(4,6-di-tertbutylpheny)fluorophosphonite). AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION is used as an antioxidant in adhesives and in the preparation of polymers intended for contact with food. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION (U.S. Patent No. 4,867,907) from Albemarle Corp., 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 21, 1997, FDA advised the Patent and Trademark Office that this food additive had undergone a regulatory review period and that the approval of AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION 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 AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION is 2,930 days. Of this time, 935 days occurred during the testing phase of the regulatory review period, 1,995 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a major health or environmental effects test was begun*: January 9, 1989. The applicant claims July 21, 1986, as the date the test was begun. However, FDA records indicate that the test was begun on January 9, 1989.

2. *The date the petition requesting the issuance of a regulation for use of the food additive under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348) was initially submitted*: August 1, 1991. The applicant claims August 1, 1991, as the date the petition for AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION was initially submitted.

3. *The date the regulation for the food additive petition became effective*: January 15, 1997. FDA has verified the applicant's claim that the regulation for the food additive became effective on January 15, 1997.

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 1,268 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 5, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 1, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 8, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–20707 Filed 8–3–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0152]

Determination of Regulatory Review Period for Purposes of Patent Extension; Dostinex® Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Dostinex® Tablets 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 Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

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 Commissioner 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 Dostinex® Tablets (cabergoline). Dostinex® Tablets is indicated for the treatment of hyperprolactinemic disorders, either idiopathic or due to pituitary adenomas. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Dostinex® Tablets (U.S. Patent No. 4,526,892) from Upjohn & Pharmacia, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 31, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Dostinex® Tablets 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 Dostinex® Tablets is 2,188 days. Of this time, 1,825 days occurred during the testing phase of the regulatory review period, 363 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: December 29, 1990. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 29, 1990.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: December 27, 1995. FDA has verified the applicant's claim that the new drug application (NDA) for Dostinex® Tablets (NDA 20–664) was initially submitted on December 27, 1995.

3. *The date the application was approved*: December 23, 1996. FDA has verified the applicant's claim that NDA 20–664 was approved on December 23, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension.