

with consumer interests and are recommended by either a consortium of consumer-oriented organizations or other interested persons.

Representatives of industry interests will serve as liaisons to the regulated industry. The term of office is up to 4 years.

Nomination Procedures

Interested persons may nominate one or more qualified persons for membership on the Committee. Nominations shall state that the nominee is willing to serve as a member of the Committee and appears to have no conflict of interest that would preclude Committee membership. Additionally, the nominee's mailing address, telephone number, and curriculum vitae must accompany the nominations. Potential candidates will be asked by FDA to provide detailed information concerning such matters as financial holdings, employment, consultancies, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

Criteria for Consumer-Nominated Members

Selection of representatives of consumer interests will be conducted through procedures that include use of a consortium of consumer organizations which has the responsibility for screening, interviewing, and recommending candidates for the agency's selection. Candidates from this group, like all other candidates for membership on the Committee, should possess appropriate qualifications to understand and contribute to the Committee's work.

Industry Representatives

Regarding nominations for members representing industry interests, a letter will be sent to each person or organization that has made a nomination and to other organizations that have expressed an interest in participating in the selection process together with a complete list of all such organizations and the nominees. The letter will state that it is the responsibility of each nominator or organization that has expressed an interest in participating in the selection process to consult with the others and to provide a consensus slate of possible members representing industry interests within 60 days. In the event that a slate of nominees has not been provided within 60 days, the agency will select an industry representative for each such vacancy from the entire list of industry nominees to avoid delay or disruption of the work of the Committee. The

agency is particularly interested in nominees that possess the essential scientific credentials needed to participate fully and knowledgeably in the Committee's deliberations. In addition to this expertise, the agency believes that it would be an advantage to the Committee's work if the individual(s) had special insight and direct experience into specific industrywide issues, practices, and concerns that might not otherwise be available to others not similarly situated.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: April 17, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 95-10075 Filed 4-21-95; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 95E-0035]

Determination of Regulatory Review Period for Purposes of Patent Extension; LUVOX™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LUVOX™ 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, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

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 LUVOX™ (fluvoxamine maleate). LUVOX™ is indicated for the treatment of obsessions and compulsions in patients with obsessive compulsive disorder. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for LUVOX™ (U.S. Patent No. 4,085,225) from Duphar International, 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 1, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of LUVOX™ 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 LUVOX™ is 6,958 days. Of this time, 5,886 days occurred during the testing phase of the regulatory review period, while 1,072 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 became effective:* November 19, 1975. FDA has verified the applicant's claim that the date the investigational new drug application

(IND) became effective was on November 19, 1975.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* December 30, 1991. The applicant claims December 24, 1991, as the date the new drug application (NDA) for LUVOX™ (NDA 20-243) was initially submitted. However, FDA records indicate that NDA 20-243 was submitted and received on December 30, 1991.

3. *The date the applications was approved:* December 5, 1994. FDA has verified the applicant's claim that NDA 20-243 was approved on December 5, 1994.

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 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 23, 1995, 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 October 23, 1995, 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: April 17, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.
[FR Doc. 95-10073 Filed 4-21-95; 8:45 am]

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[Docket No. 95E-0038]

Determination of Regulatory Review Period for Purposes of Patent Extension; SERZONE®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SERZONE® 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, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

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 SERZONE® (nefazodone hydrochloride). SERZONE® is indicated for treatment of depression. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SERZONE® (U.S. Patent No. 4,338,317) from Bristol-Myers Squibb, 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 1, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SERZONE® 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 SERZONE® is 4,420 days. Of this time, 3,216 days occurred during the testing phase of the regulatory review period, while 1,204 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 became effective:* November 17, 1982. FDA has verified the applicant's claim that the date that the investigational new drug application (IND) became effective was on November 17, 1982.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* September 6, 1991. FDA has verified the applicant's claim that the date the new drug application (NDA) for SERZONE® (NDA 20-152) was initially submitted was on September 6, 1991.

3. *The date the application was approved:* December 22, 1994. FDA has verified the applicant's claim that NDA 20-152 was approved on December 22, 1994.

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 730 days of patent term extension.