

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (REGISTERED LICENSE HOLDERS)^{1 2}—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Total burden hours					550

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Mixer-feeders.

³ There is no burden because medicated feeds are consumed on site (§ 225.110 *Distribution records*; § 225.115 *Complaint files*).

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (NONREGISTERED)^{1 2}

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
225.142	13,000	24	316,800	0.41	132,000
225.158	13,000	24	316,800	0.25	79,200
225.180	13,000	24	316,800	0.16	52,800
225.202	13,000	24	316,800	1.5	475,200
Total burden hours					739,200

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Commercial feed mills.

TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (NONREGISTERED)^{1 2}

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
225.142	45,000	3	135,000	0.16	22,500
225.158	45,000	3	135,500	0.16	22,500
225.180	45,000	3	135,500	0.083	11,250
225.202	45,000	3	135,500	0.5	67,500
Total burden hours					123,750

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Mixer-feeders.

The estimate of the times required for record preparation and maintenance is based on agency communications with industry. Other information needed to calculate the total burden hours (i.e., number of recordkeepers, number of medicated feeds being manufactured, etc.) is derived from agency records and experience.

Dated: June 30, 1998.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96E-0452]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VERLUMA™ 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 biological 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biological product VERLUMA™ (nofetumomab). VERLUMA™ is indicated for the detection of extensive stage disease in patients with biopsy confirmed, previously untreated small cell lung cancer. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for VERLUMA™ (U.S. Patent No. 4,897,255) from NeoRx 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 July 9, 1997, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of VERLUMA™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for VERLUMA™ is 3,360 days. Of this time, 925 days occurred during the testing phase of the regulatory review period, 2,435 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:* June 11, 1987. The applicant claims September 4, 1987, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 11, 1987, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act:* December 21, 1989. FDA has verified the applicant's claim that the Product License Application (PLA) for VERLUMA™ (PLA 90-0150) was initially submitted on December 21, 1989.

3. *The date the application was approved:* August 20, 1996. FDA has verified the applicant's claim that PLA 90-0150 was approved on August 20, 1996.

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 1,298 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 8, 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 January 6, 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: June 29, 1998.

Thomas J. McGinnis,
Deputy Associate Commissioner for Health Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E-0061]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for STROMEKTOL® 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 STROMEKTOL® (ivermectin). STROMEKTOL® is indicated for treatment of strongyloidiasis and onchocerciasis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for STROMEKTOL® (U.S. Patent No. 4,199,569) from Merck & Co., 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 March 7, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the