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 Trovan (trovafloxacin mesylate). Trovan is indicated for the treatment of infections caused by susceptible strains of microorganisms. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Trovan (U.S. Patent No. 5,164,402) from Pfizer, 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 September 28, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Trovan 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 Trovan is 1,967 days. Of this time, 1,613 days occurred during the testing phase of the regulatory review period, while 354 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*: August 1, 1992. The applicant claims July 2, 1992, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 1, 1992, 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 of the act*: December 30, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Trovan (NDA 20–759) was initially submitted on December 30, 1996.

3. *The date the application was approved*: December 18, 1997. FDA has verified the applicant's claim that NDA 20–759 was approved on December 18, 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 761 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 19, 1999, 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 November 15, 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: May 4, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–12526 Filed 5–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0779]

Determination of Regulatory Review Period for Purposes of Patent Extension; Monostrut™ Cardiac Valve Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Monostrut™ Cardiac Valve Prosthesis 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 medical device.

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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device Monostrut™ Cardiac Valve Prosthesis. Monostrut™ Cardiac Valve Prosthesis is indicated for the replacement of malfunctioning native or prosthetic mitral (sizes 27, 29, 31, and 33 millimeters (mm)) or aortic (sizes 21, 23, 25, 27, 29, 31, and 33 mm) heart valves. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Monostrut™ Cardiac Valve Prosthesis (U.S. Patent No. 4,343,049) from Alliance Medical Products Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this

patent's eligibility for patent term restoration. In a letter dated September 29, 1998, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period, and that the approval of Monostrut™ Cardiac Valve Prosthesis 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 Monostrut™ Cardiac Valve Prosthesis is 5,620 days. Of this time, 1,729 days occurred during the testing phase of the regulatory review period, while 3,891 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: May 14, 1982. FDA has verified the applicant's claim that the date the investigational device exemption required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective May 14, 1982.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: February 5, 1987. The applicant claims May 8, 1986, as the date the premarket approval application (PMA) for Monostrut™ Cardiac Valve Prosthesis (PMA P970002) was initially submitted. However, FDA records indicate that PMA P970002 was submitted on February 5, 1987.

3. *The date the application was approved*: September 30, 1997. FDA has verified the applicant's claim that PMA P970002 was approved on September 30, 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 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 19, 1999, 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 November 15, 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: May 4, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–12528 Filed 5–18–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–99–2001]

Memorandum of Understanding Between the Food and Drug Administration and the United States Department of Agriculture

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the FDA and the United States Department of Agriculture, Food Safety and Inspection Service. The purpose of the MOU is to facilitate an exchange of information between the agencies about establishments and operations that are subject to the jurisdiction of both agencies.

DATES: The agreement became effective February 23, 1999.

FOR FURTHER INFORMATION CONTACT: Gary L. Pierce, Office of Regulatory Affairs (HFC–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5655.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20. 108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: May 11, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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