**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 NAROPIN™ (ropivacaine hydrochloride monohydrate). NAROPIN™ is indicated for the production of local or regional anesthesia for surgery, for postoperative pain management and for obstetrical procedures. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for NAROPIN™ (U.S. Patent No. 4,870,086) from Astra Lakemedel Aktiebolag, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 21, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of NAROPIN™ 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 NAROPIN™ is 3,147 days. Of this time, 2,603 days occurred during the testing phase of the regulatory review period, while 544 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 (21 U.S.C. 355(i)) became effective*: February 14, 1988. The applicant claims February 15, 1988, as the date the investigational new drug application (IND) for NAROPIN™ (IND 31,121) became effective. However, FDA records indicate that the effective date for IND 31,121 was February 14, 1988, 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(b) of the Federal Food, Drug, and Cosmetic Act*: March 31, 1995. The applicant claims March 29, 1995, as the date the new drug application (NDA) for NAROPIN™ (NDA 20–533) was initially submitted. However, FDA records indicate that NDA 20–533 was submitted on March 31, 1995.

3. *The date the application was approved*: September 24, 1996. FDA has verified the applicant's claim that NDA 20–533 was approved on September 24, 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 1,400 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 16, 1997, 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 14, 1998, 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, 1997.

**Allen B. Duncan,**

*Acting Associate Commissioner for Health Affairs.*

[FR Doc. 97–18917 Filed 7–17–97; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97E–0110]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; MONUROL™

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for MONUROL™ 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, 12420 Parklawn Dr., rm. 1–23, 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 MONUROL™ (fosfomycin tromethamine). MONUROL™ is indicated only for the treatment of uncomplicated urinary tract infections (acute cystitis) in women due to susceptible strains of *Escherichia coli* and *Enterococcus faecalis*. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for MONUROL™ (U.S. Patent No. 4,863,908) from ZAMBON GROUP, S.p.A., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 1, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of MONUROL™ 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 MONUROL™ is 2,241 days. Of this time, 1,428 days occurred during the testing phase of the regulatory review period, while 813 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 (21 U.S.C. 355(i)) became effective*: November 2, 1990. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on November 2, 1990.

2. *The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357)*: September 29, 1994. The applicant claims September 28, 1994, as the date the new drug application (NDA) for MONUROL™ (NDA 50–717) was initially submitted. However, FDA records indicate that NDA 50–717 was submitted on September 29, 1994.

3. *The date the application was approved*: December 19, 1996. FDA has verified the applicant's claim that NDA 50–717 was approved on December 19, 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 1,525 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 16, 1997, 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 14, 1998, 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, 1997.

**Allen B. Duncan,**

*Acting Associate Commissioner for Health Affairs.*

[FR Doc. 97–18919 Filed 7–17–97; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 96D–0137]**

### Medical Device Reporting, Guidance Document for Manufacturers; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Medical Device Reporting (MDR) for Manufacturers.'' The guidance describes the new medical device reporting requirements for manufacturers, and it is intended for both domestic and foreign medical device manufacturers. The MDR regulations provide a mechanism for FDA to identify and monitor significant adverse events involving medical devices so that problems may be detected and corrected in a timely manner.

**ADDRESSES:** Submit written requests for single copies of the ''Medical Device Reporting (MDR) for Manufacturers'' guidance document to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. Requestors will be sent a floppy diskette with a Microsoft Word document file containing the guidance document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:** Bryan H. Benesch, Center for Devices and Radiological Health, HFZ–220, 1350 Piccard Dr., Rockville, MD 20850, 301–443–7491, ext. 131.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

In the **Federal Register** of May 31, 1996 (61 FR 27361), FDA announced the availability of a draft guidance entitled ''Medical Device Reporting for Manufacturers.'' The guidance document contained information to help manufacturers comply with the new MDR regulations. The purpose of the guidance document was to: (1) Provide domestic and foreign manufacturers with a thorough description of the current MDR regulations; (2) give a clear