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 DYNABAC® (dirithromycin). DYNABAC® is indicated for the treatment of individuals age 12 years and older with mild-to-moderate infections caused by susceptible strains of designated microorganisms in the specific conditions: (1) Acute Bacterial Exacerbations of Chronic Bronchitis due to *Moraxella catarrhalis* or *Streptococcus pneumoniae*; (2) Secondary Bacterial Infection of Acute Bronchitis due to *M. catarrhalis* or *S. pneumoniae*; (3) Community-Acquired Pneumonia due to *Legionella pneumophila*, *Mycoplasma pneumoniae*, or *S. pneumoniae*; (4) Pharyngitis/Tonsiletis due to *S. pyogenes*; or (5) Uncomplicated Skin and Skin Structure Infections due to *Staphylococcus aureus* (methicillin-resistant strains). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for DYNABAC® (U.S. Patent No. 4,048,306) from Boehringer Ingelheim GmbH, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 28, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of DYNABAC® 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 DYNABAC® is 2,469 days. Of this time, 1,687 days occurred during the testing phase of the regulatory review period, while 782 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*: September 16, 1988. The applicant claims February 28, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 16, 1988, the date the IND was removed from clinical hold via telephone conversation.

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)*: April 29, 1993. The applicant claims April 27, 1993, as the date the new drug application (NDA) for DYNABAC® (NDA 50–678) was initially submitted. However, FDA records indicate that NDA 50–678 was submitted on April 29, 1993, the date the resubmission for NDA 50–678 was received by FDA following a refusal to file letter.

3. *The date the application was approved*: June 19, 1995. FDA has verified the applicant's claim that NDA 50–678 was approved on June 19, 1995.

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 1,726 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 8, 1996, 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 6, 1997, 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 26, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–20340 Filed 8–8–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0114]

Determination of Regulatory Review Period for Purposes of Patent Extension; CORVERT

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CORVERT 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 CORVERT (ibutilide fumarate). CORVERT is indicated for the rapid conversion of atrial fibrillation or atrial flutter of recent onset to sinus rhythm. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CORVERT (U.S. Patent No. 5,155,268) from the Upjohn Co. and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 13, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of CORVERT 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 CORVERT is 2,292 days. Of this time, 1,865 days occurred during the testing phase of the regulatory review period, while 427 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: September 20, 1989. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was on September 20, 1989.

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: October 28, 1994. FDA has verified the applicant's claim that the new drug application (NDA) for CORVERT (NDA 20–491) was initially submitted on October 28, 1994.

3. The date the application was approved: December 28, 1995. The applicant claims December 29, 1995, as the date NDA 20–491 was approved. However, FDA records indicate that NDA 20–491 was approved on December 28, 1995.

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 application seeks 73 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 8, 1996, 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 Februar 6, 1997, 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 26, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–20342 Filed 8–8–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0112]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for MAXIPIME® 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 MAXIPIME® (cefepime hydrochloride). MAXIPIME® is indicated for the treatment of the following infections when caused by susceptible strains of the designated microorganisms: Uncomplicated and complicated urinary tract infections, including pyelonephritis, uncomplicated skin and skin structure infections, and pneumonia. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for MAXIPIME®