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®

(U.S. Patent No. 4,406,899) from Bristol-Myers Squibb Co. and the Patent and Trademark Office requested FDA's assistance in determining this patent's 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 MAXIPIME® 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 MAXIPIME® is 3,741 days. Of this time, 2,444 days occurred during the testing phase of the regulatory review period, while 1,297 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: October 23, 1985. The applicant claims November 22, 1985, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND's effective date was October 23, 1985, 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 507 of the Federal Food, Drug, and Cosmetic Act: July 1, 1992. The applicant claims June 30, 1992, as the date the new drug application (NDA) for MAXIPIME® (NDA 50–679) was initially submitted. However, FDA records indicate that NDA 50–679 was submitted on July 1, 1992.

3. The date the human drug was approved: January 18, 1996. FDA has verified the applicant's claim that NDA 50–679 was approved on January 18, 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, the applicant seeks 1,825 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 Commisioner for Health Affairs.

[FR Doc. 96–20343 Filed 8–8–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory bodies scheduled to meet during the month of September 1996.

Name: National Advisory Council on the National Health Service Corps.

Date and Time: September 5–8, 1996

Place: Marriott Residence Inn, 7335 Wisconsin Avenue, Bethesda, Maryland.

The meeting is open to the public.

Agenda: Agenda items include updates on the National Health Service Corps program, policies, and budget; meetings of the Council workgroups on new environment strategies, health system linkages, and mission coalition building; and site visits to community health centers in the area.

The opening meeting will be held on Thursday, September 5 from 6:00 p.m. to 8:30 p.m. On Friday, site visits will begin at 9:00 a.m. and will be followed by a business meeting which will conclude about 7:00 p.m. Saturday's meeting will begin at 9:00 a.m. and includes meetings of the Council workgroups. On Sunday, the meeting will begin at 9:00 a.m. and will adjourn around noon.

The meeting is open to the public; however, no transportation will be provided for the site visits. Anyone requiring information regarding the subject Council should contact Ms. Jewel Davis, National Advisory Council on the National Health Service Corps, Health Resources and Services Administration, 8th floor, 4350 East West Highway, Rockville, Maryland 20857, Telephone (301) 594–4144.

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Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: September 10–11, 9:00 am–5:00 pm.

Place: Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, Maryland 20857.

The meeting is open to the public.

The first day of the meeting, will consist of meetings of one of the Commission's workgroups and Subcommittees.

Name: Workgroup on Intent, Provisions and Process.

Date and Time: September 10, 1996; 9:00 a.m.–12:00 Noon.

Place: Parklawn Building, Potomac Room.

Agenda: Agenda items will include, but not be limited to, discussion of the following issues: Program and policy issues related to the operation of the Vaccine Injury Compensation Program.

Name: Joint ACCV/National Vaccine Advisory Committee (NVAC) Subcommittee on Vaccine Safety.

Time: September 10, 1996; 1:00 p.m.–5:00 p.m.

Place: Parklawn Building, Conference Rooms G & H.

Agenda: Agenda items will include, but not be limited to: discussion of the inclusion of adult vaccines under the National Vaccine Injury Compensation Program; and discussion of the Task Force on Safer Childhood Vaccines, Final Report and Recommendations.

The full Commission will meet on Wednesday, September 11 from 9:00 a.m. to 5:00 p.m. Agenda items will include, but not be limited to: a report on the Vaccine Safety Subcommittee; a report from the Workgroup on Intent, Provision and Process; and update on the Proposed Polio Immunization Schedule Changes; and an update on the Current Status of Licensure of Acellular Pertussis Vaccines and routine Program reports.

Public comment will be permitted before the Workgroup and Subcommittee meetings adjourn on September 10; and before noon and at the end of the Commission meeting on September 11. Oral presentations will be limited to 5 minutes per public speaker.

Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to Ms. Mellissa Palmer, Principal Staff Liaison, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–35, 5600 Fishers Lane, Rockville, MD 20852; Telephone (301) 443–6593. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for presentation, but desire to make an oral statement, may sign up in Conference Room G and H on