medication. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Rescula (U.S. Patent No. 5,221,763) from R-Tech Veno, Ltd./Novartis, 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 3, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Rescula 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 Rescula is 1,347 days. Of this time, 1,186 days occurred during the testing phase of the regulatory review period, while 161 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 (the act) (21 U.S.C. 355(i)) became effective*: November 27, 1996. The applicant claims October 25, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 27, 1996, 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 act*: February 25, 2000. The applicant claims February 14, 2000, as the date the new drug application (NDA) for Rescula (NDA 21–214) was initially submitted. However, FDA records indicate that NDA 21–214 was submitted on February 25, 2000.

3. *The date the application was approved*: August 3, 2000. FDA has verified the applicant's claim that NDA 21–214 was approved on August 3, 2000.

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 774 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written comments and ask for a redetermination by November 20, 2001. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 20, 2002. 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. Three copies of any information are to be submitted except that individuals may submit one copy. Comments are to be 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: September 5, 2001.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

[FR Doc. 01–23702 Filed 9–20–01; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 01E–1250]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; Synercid

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for Synercid 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 that claims that human drug product.

**ADDRESSES:** Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

**FOR FURTHER INFORMATION CONTACT:** Claudia Grillo, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 Synercid (quinupristin and dalfopristin). Synercid is indicated for the treatment of patients with complicated skin and skin structure infections caused by Staphylococcus aureus (methicillin susceptible) or Streptococcus pyogenes. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Synercid (U.S. Patent No. 4,798,827) from Rhone Poulenc Rorer S.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 26, 2000, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Synercid 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 Synercid is 2,793 days. Of this time, 2,046 days occurred during the testing phase of the regulatory review period, while 747 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 (the act) (21 U.S.C. 355(i)) became effective*: January 30, 1992. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 30, 1992.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: September 5, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for Synercid (NDA 50–748) was initially submitted on September 5, 1997.

3. *The date the application was approved*: September 21, 1999. FDA has verified the applicant's claim that NDA 50–748 was approved on September 21, 1999.

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 1,770 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written comments and ask for a redetermination by November 20, 2001. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 20, 2002. 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. Three copies of any information are to be submitted except thatindividuals may submit one copy. Comments are to be 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: September 5, 2001.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

[FR Doc. 01–23703 Filed 9–20–01; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 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 body scheduled to meet during the month of October 2001.

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

*Date and Time:* October 11, 2001; 3 p.m.—5:30 p.m.,October 12, 2001; 8:30 a.m.—5 p.m., October 13, 2001; 9 a.m. to 5 p.m.,October 14, 2001; 8 a.m.—11 a.m.

*Place:* Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852, Phone: (301) 468–1100.

The meeting is open to the public.

*Agenda:* The agenda will focus on meeting with the management team from the Agency and the Bureau of Health Professions regarding the Administration's vision and goals for the National Health Service Corps and the designation of health professional shortage areas.

For further information, call Ms. Eve Morrow, Division of National Health Service Corps, at (301) 594–4144.

Agenda items and times are subject to change as priorities dictate.

Dated: September 17, 2001.

**Jane M. Harrison,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. 01–23611 Filed 9–20–01; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Advisory Committee; 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 body scheduled to meet during the month of October 2001.

*Name:* Advisory Committee on Training in Primary Care Medicine and Dentistry.

*Date and Time:* October 29, 2001; 8:30 a.m.–5:00 p.m., October 30, 2001; 8:30 a.m.–4:00 p.m.

*Place:* The Holiday Inn, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.

The meeting is open to the public.

*Purpose:* The Advisory Committee shall (1) provide advice and recommendations to the Secretary concerning policy and program development and other matters of significance concerning activities under section 747 of the Public Health Service Act; and (2) prepare and submit to the Secretary, the Committee on Health, Education, Labor and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report describing the activities of the Advisory Committee, including findings and recommendations made by the Committee concerning the activities under section 747 of the PHS Act. The Advisory Committee will meet twice each year and submit its first report to the Secretary and the Congress by November 2001.

*Agenda:* Policy and program development issues will be discussed and recommendations for the future will be addressed.

Anyone interested in obtaining a roster of members or other relevant information should write or contact Crystal L. Clark, M.D., M.P.H., Acting Deputy Executive Secretary, Advisory Committee on Training in Primary Care Medicine and Dentistry, Parklawn Building, Room 9A–21, 5600 Fishers Lane, Rockville, Maryland 20857, phone (301) 443–6326, e-mail *cclark@hrsa.gov*. The web address for the Advisory Committee is *http://www.bhpr.hrsa.gov/dm/actpcmd.htm*.

Dated: September 17, 2001.

**Jane M. Harrison,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. 01–23612 Filed 9–20–01; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

### Program Exclusions: August 2001

**AGENCY:** Office of Inspector General, HHS.

**ACTION:** Notice of program exclusions.

During the month of August 2001, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any