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