(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.

* * * * *

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

September 10–11. These persons will be allocated time as time permits.

Anyone requiring information regarding the Commission should contact Ms. Palmer.

* * * * *

Name: National Advisory Committee on Rural Health.

Dates and Time: September 15, 1996—3:00 p.m.

Place: The Historic Inns of Annapolis, 16 Church Circle, Annapolis, MD 21401, Phone: (410) 263–2641, FAX: (410) 268–3813.

The meeting is open to the public.

Agenda: The meeting will begin at 3 p.m. on Sunday, September 15, with an orientation. A reception is planned following the orientation.

The plenary session on Monday, September 16, will convene at 8:30 a.m. with a legislative update and an overview of the Office of Rural Health Policy activities. Committee members will review the American Public Health Association's resolution, ''Rural Health Goals: Guaranteeing a Future.'' The remainder of the day and Tuesday, September 17, will be devoted to formulating Committee recommendations to the Secretary of Health and Human Services. Committee members will meet in their workgroups—Education and Health Services and Health Care Financing—to draft these recommendations. The meeting will convene at 8:30 a.m. on Wednesday, September 18. Adjournment is anticipated by 12:30 p.m.

Anyone requiring information regarding the subject Committee should contact Dena S. Puskin, Executive Secretary, National Advisory Committee on Rural Health, Health Resources and Services Administration, Room 9–05, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–0835, FAX (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Ms. Arlene Granderson or Lisa Shelton, Office of Rural Health Policy, Health Resources and Services Administration, Telephone (301) 443–0835.

Agenda Items are subject to change as priorities dictate.

Dated: August 5, 1996.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 96–20269 Filed 8–8–96; 8:45 am]

BILLING CODE 4160–15–P

Request for Comments on Legal Issues Related to Telemedicine

AGENCY: Health Resources and Services Administration (HRSA), Health and Human Services (HHS).

ACTION: Request for comments.

SUMMARY: In the Telecommunications Act of 1996 (Pub.L. 104–104), Congress directs the Secretary of Commerce, in consultation with the Secretary of Health and Human Services, to submit a report highlighting the activities of the Joint Working Group on Telemedicine (JWGT) and other Federal activities to promote the cost-effective use of telemedicine (Section 709). The JWGT is a Federal interagency working group that examines issues and makes recommendations regarding national policy on telemedicine. The Office of Rural Health Policy, Health Resources and Services Administration, provides staff support to the JWGT. Telemedicine is defined as the use of modern telecommunications and information technologies for the provision of clinical care to individuals at a distance.

In this notice, we seek comments identifying the legal barriers to the cost-effective use of telemedicine and specific suggestions for overcoming these barriers. In particular, we seek suggestions for easing licensure barriers to physicians and other health professionals providing telemedicine services across state lines, and comments on specific alternatives, such as those recently proposed by the Federation of State Medical Boards and the Institute of Electrical and Electronics Engineers. Respondents are encouraged to explore the advantages and disadvantages of a wide range of options such as various types of limited state licensure, registration of out-of-state physicians as proposed in California, regional and national initiatives to expand reciprocity among states, national licensure in terms of their impact on access and quality of health care services, and feasibility and cost of implementation. In addition to addressing cross-state licensure issues, respondents are encouraged to provide comments and suggestions on other legal issues associated with telemedicine such as liability/malpractice. Finally, we are asking respondents to identify the particular challenges in assuring privacy, confidentiality, and security in the conduct of telemedicine and provide suggestions for addressing those challenges. Comments will be reviewed and considered for incorporation into the final report to Congress.

DATES: Comments should be filed on or before August 30, 1996.

ADDRESSES: Copies of comments should be sent to: Dena S. Puskin, Sc.D., Office of Rural Health Policy, Health Resources and Services Administration, Room 9–05, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Dena S. Puskin, Sc.D., 301–443–0835, dpuskin@hrsa.ssw.dhhs.gov.

Dated: August 8, 1996.

Ciro V. Sumaya,

Administrator.

[FR Doc. 96–20270 Filed 8–8–96; 8:45 am]

BILLING CODE 4160–15–U

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–3778–N–97]

Office of the Assistant Secretary for Community Planning and Development; Federal Property Suitable as Facilities to Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: August 9, 1996.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, Department of Housing and Urban Development, Room 7256, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708–1226; TDD number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless v. Veterans Administration*, No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: August 2, 1996.

Jacquie M. Lawing,

Deputy Assistant Secretary for Economic Development.

[FR Doc. 96–20170 Filed 8–8–96; 8:45 am]

BILLING CODE 4210–29–M