assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 6, 2001, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Menicon Z Rigid Gas Permeable Contact Lens 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 Menicon Z Rigid Gas Permeable Contact Lens is 1,917 days. Of this time, 1,435 days occurred during the testing phase of the regulatory review period, while 482 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: April 14, 1995. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective on April 4, 1995. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on April 14, 1995, which represents the IDE effective date.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: March 18, 1999. FDA has verified the applicant's claim that the premarket approval application (PMA) for Menicon Z Rigid Gas Permeable Contact Lens (PMA P990018) was initially submitted March 18, 1999.

3. *The date the application was approved*: July 11, 2000. FDA has verified the applicant's claim that PMA P990018 was approved on July 11, 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 1,205 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 or electronic comments and ask for a redetermination by April 26, 2002. Furthermore, any interested person may petition FDA by for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 26, 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: January 24, 2002.

Jane A. Axelrad,

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

[FR Doc. 02–4383 Filed 2–22–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Antiviral Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 19, 2002, from 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Tara P. Turner, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: TurnerT@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 21–245, Picovir (pleconaril), ViroPharma Inc., proposed for treatment of acute viral respiratory infection (the common cold) in adults.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 12, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 12, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Tara P. Turner at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 17, 2002.

Linda A. Suydam,

Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 02–4455 Filed 2–22–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Childhood Vaccines Advisory Commission; 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 March.

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: March 6, 2002; 9 a.m.–3 p.m., March 7, 2002; 9 a.m.–12 p.m.

Place: The Ramada Inn, Georgetown Conference Room, 1775 Rockville Pike, Rockville, Maryland 20852, and Audio Conference Call.

The full ACCV will meet on Wednesday, March 6, from 9 a.m. to 3 p.m., and Thursday, March 7, from 9 a.m. to 12 p.m. The public can join the meeting in person at the address listed above or by audio conference call by dialing 1–888–566–5772 on March 6, and dialing 1–888–458–9977 on March 7, and providing the following information on both days:

Leader's Name: Thomas E. Balbier, Jr.

Password: ACCV.

The agenda items for March 6 will include, but not limited to: comments from the public on the legislative proposals to change the National Vaccine Injury Compensation Program (VICP), such as the American Academy of Pediatrics' proposed revisions to the VICP, and the House Committee on Government Reform bill titled, ''National Vaccine Injury Compensation Program Improvement Act of 2002,'' an update on the Vaccine Safety Data Link, a presentation of the Institute of Medicine's Report entitled, ''Multiple Immunizations and Immune System Dysfunction,'' and updates from the Office of Special Programs, the VICP, the Department of Justice, and the National Vaccine Program Office.

The agenda items on March 7 will include, but not limited to: a discussion of recommendations from the ACCV Workgroup on Proposed Legislative Changes to the VICP, and a discussion of reversionary trusts.

Persons interested in obtaining a copy of the American Academy of Pediatrics' proposed revisions to the VICP, and the proposed bill titled, ''National Vaccine Injury Compensation Program Improvement Act of 2002'' may contact Ms. Cheryl Lee by telephone at (301) 443–2124 or by e-mail at *clee@hrsa.gov* prior to March 6.

Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Office of Special Programs, Health Resources and Services Administration, Room 8A–46, 5600 Fishers Lane, Rockville, MD 20857 or by e-mail at *clee@hrsa.gov.* 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 a presentation, but desire to make an oral statement, may sign-up in the Georgetown Conference Room on March 6 and March 7. These persons will be allocated time as time permits.

Anyone requiring information regarding the ACCV should contact Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Office of Special Programs, Health Resources and Services Administration, Room 8A–46, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443–2124 or e-mail: *clee@hrsa.gov.*

Agenda items are subject to change as priorities dictate.

Dated: February 19, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02–4458 Filed 2–20–02; 3:34 pm]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel.

Date: March 14–15, 2002.

Time: March 14, 2002, 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD 20814,

Time: March 15, 2002, 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Samuel Rawlings, PhD, Chief, Scientific Review Branch, Division of Extramural Research, National Eye Institute, Bethesda, MD 20892, 301–496–5561.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: February 19, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–4441 Filed 2–22–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel ''Develop New Technologies for Drug Abuse Prevention Delivery''.

Date: March 14, 2002.

Time: 9:00 AM to 5:00 PM.

Agenda: To review and evaluate contract proposals.

Place: Doubletree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 3158, MSC 9547, Bethesda, MD 20892–9547, (301) 435–1439.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: February 19, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–4442 Filed 2–22–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.