mesalamine rectal suppositories, 500 mg.

FOR FURTHER INFORMATION CONTACT: S. Mitchell Weitzman, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5670.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Public Law 98–417), which authorized the approval of duplicate versions of drug products approved under an ANDA. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

On June 12, 2000, Able Laboratories, Inc., under 21 CFR 10.30, submitted a citizen petition (Docket No. 00P–1340/CP1) to FDA. The petition requested that the agency determine whether mesalamine Rectal Suppositories, 500 mg, was withdrawn from sale for reasons of safety or effectiveness. Mesalamine rectal suppositories, 500 mg, is the subject of NDA 19–919. FDA approved NDA 19–919, held by Solvay Pharmaceuticals, Inc. (Solvay), on December 18, 1990. On July 1, 1999, Solvay informed FDA that ROWASA Rectal Suppositories had been voluntarily recalled after repeated, sporadic dissolution specification failures were observed.

FDA has reviewed its records and, under § 314.161, has determined that Solvay's decision to recall and terminate marketing mesalamine rectal suppositories, 500 mg, was not for reasons of safety or effectiveness. Accordingly, the agency will continue to list mesalamine rectal suppositories, 500 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to mesalamine rectal suppositories, 500 mg, may be approved by the agency.

Dated: May 17, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–13169 Filed 5–23–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Oncology Subcommittee of the Oncologic 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: Pediatric Oncology Subcommittee of the Oncologic 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 June 28, 2001, 8 a.m. to 5 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee conference room 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research, (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or by e-mail: SomersK@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will discuss parameters used for extrapolation from the adult to the pediatric setting in solid tumors and malignancies of the central nervous system.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by June 18, 2001. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m., and 1 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 18, 2001, 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.

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

Dated: May 17, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–13168 Filed 5–23–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of June 2001.

Name: Advisory Commission on Childhood Vaccines (ACCV)

Date and Time: June 7, 2001; 10 a.m.–12 p.m.

Place: Audio Conference Call

The full Commission will meet on Thursday, June 7, from 10 a.m. to 12 p.m. (eastern standard time) via audio conference call. The meeting is open to the public. The public can join the conference call by calling 1–877–709–

5340 and providing the following information:

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

Password: ACCV

The agenda includes a briefing on the Institute of Medicine's Immunization Safety Review Committee Report on Measles-Mumps-Rubella Vaccine and Autism. Public comment will be permitted at the end of the presentation. Oral comments 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. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–46, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–2124. 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 do so at the end of the presentation. If time is available, these persons will be allocated time to make oral statements.

Anyone requiring information regarding the Commission should contact Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–46, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–2124.

Agenda items are subject to change as priorities dictate.

Dated: May 18, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–13139 Filed 5–23–01; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Neurological Disorders and Stroke Council, May 24, 2001, 10:30 am to May 25, 2001, 12 pm, 45 Center Drive, Natcher Building, Conference Room E1/2, Bethesda, MD, 20892 which was published in the **Federal Register** on May 2, 2001, 66 FR 21994.

The Training Sub. & Neuroinformatics, Computational Neurosci. & Infrastracture Sub. is changed to an open session; the time remains the same. The Clinical Trials Sub. will be open from 8:30 am to 9 am and closed from 9 am to 10 am. The meeting is partially Closed to the public.

Dated: May 17, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–13107 Filed 5–23–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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.

The meetings 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 contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel, NIH–ES–01–06.

Date: June 18, 2001.

Time: 8:30 a.m. to 11:30 a.m.

Agenda: To review and evaluate contract proposals.

Place: NIEHS—East Campus, Building 4401, Conference Room 122, 79 Alexander Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Zoe E. Huang, MD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institutes of Environmental Health Sciences, P.O. Box 12233, MD/EC–30, Research Triangle Park, NC 27709, 919/541–4964.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel, NIH–ES–01–07

Date: June 19, 2001.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: NIEHS, 79 T.W. Alexander Drive, Building 4401, Conference Room 3446, Research Triangle Park, NC 27709.

Contact Person: Zoe E. Huang, MD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institutes of Environmental Health Sciences, P.O. Box 12233, MD/EC–30, Research Triangle Park, NC 27709, 919/541–4964.

(Catalogue of Federal Domestic Assistance Program Nos. 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences, National Institutes of Health, HHS)

Dated: May 17, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–13108 Filed 5–23–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Communication Disorders Review Committee, June 20, 2001, 8 am to June 22, 2001, 5 pm, Governor's House, 1615 Rhode Island Avenue, NW., Washington, DC 20036 which was published in the **Federal Register** on May 2, 2001, 66 FR 21992.

The meeting has been changed to start on June 20, 2001 and end on June 21, 2001. The meeting is closed to the public.