proposed studies and extent to which the plan is adequate to accomplish the objectives. Extent to which applicant describes specific study protocol(s), the roles of partners or collaborators or plans for the development of study protocols that are appropriate for achieving project objectives. (30 points)

c. If the proposed project involves human subjects, the degree to which the applicant has met the CDC policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation. (2) The proposed justification when representation is limited or absent. (3) A statement as to whether the design of the study is adequate to measure differences when warranted. (4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits will be documented. (see Other Requirements for additional information regarding this requirement for research projects). (5 points)

d. Extent to which applicant provides a detailed and adequate plan for evaluating study results and for evaluating progress toward achieving project objectives. (5 points)

4. Budget (not scored)

Extent to which the proposed budget is reasonable, clearly justifiable, and consistent with the intended use of grant funds.

5. Human Subjects (not scored)

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with an original plus two copies of the following:

1. Annual progress reports;

2. Financial status report, no more than 90 days after the end of the budget period; and

3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit.

AR–1 Human Subjects Requirements

AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR–9 Paperwork Reduction Act Requirements

AR–10 Smoke-Free Workplace Requirements

AR–11 Healthy People 2010

AR–12 Lobbying Restrictions

AR–15 Proof of Non-Profit Status

AR–22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a) and 317(k)(2) of the Public Health Service Act, [42 U.S.C. Sections 241(a) and 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—http://www.cdc.gov Click on ''Funding'' then ''Grants and Cooperative Agreements.''

To receive additional written information and to request an application kit, call 1–888-GRANTS4 (1–888 472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Gladys Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Mailstop K75, Atlanta, GA 30341–4146, Telephone number: 770–488–2753, Email address: gcg4@cdc.gov.

For program technical assistance, contact: Marsha Jones, Health Scientist, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Mailstop C–12, Atlanta, GA 30333, Telephone number: 404–639–2603. Email address: maj4@cdc.gov.

Dated: May 17, 2001.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–13127 Filed 5–23–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Planning, Research and Evaluation; Grant to the Institute for Responsible Fatherhood and Family Revitalization

AGENCY: Office of Planning, Research and Evaluation, ACF, DHHS.

ACTION: Award announcement.

SUMMARY: Notice is hereby given that a noncompetitive grant award is being made to the Institute for Responsible Fatherhood and Family Revitalization to build the Institute's capacity and infrastructure and expand the provision of direct services to reunite fathers and families. As a Congressional setaside, this one-year project is being funded noncompetitively. The Institute has community-based service centers in several states and has successfully served so far more than 7000 fathers and their families. The cost of this one-year project is $500,000.

FOR FURTHER INFORMATION CONTACT: K. A. Jagannathan, Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Phone: 202–205–4829.

Dated: May 18, 2001.

Howard Rolston,

Director, Office of Planning, Research and Evaluation.

[FR Doc. 01–13143 Filed 5–23–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–1340]

Determination That ROWASA (mesalamine) Rectal Suppositories, 500 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that ROWASA (mesalamine) Rectal Suppositories, 500 milligrams (mg) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for

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–