

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).

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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.

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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