with hazardous waste sites and other environmental releases. An important step in ATSDR's assessment process is examining exposures to contaminants under site-specific conditions and determining whether people are being exposed to harmful levels. In most of the agency's evaluations, the environmental concentration serves as a surrogate for ''exposure.''

To refine its assessments and to fill data gaps, ATSDR sometimes identifies ways to more precisely quantify exposures, such as measuring body burdens of a particular contaminant or its metabolites (e.g., lead in blood). On a site-by-site basis, ATSDR evaluates what additional exposure data might be practical and useful to obtain to further support public health evaluations and ultimately to help determine the disease potential of a particular exposure. ATSDR seeks to determine the overall utility of hair analysis as one such exposure assessment tool. ATSDR's overall goal is to receive expert opinion on the following four general questions related to hair analysis. A number of specific questions related to these issues will also be discussed.

- When is it appropriate to consider hair analysis in assessing human exposures to environmental contaminants?
- When is it inappropriate to consider hair analysis in assessing human exposures to environmental contaminants?
- What data gaps exist that limit the interpretation and use of hair analysis in the assessment of environmental exposures? What research is needed to fill these data gaps?
- For what substances do reliable hair analysis methods exist?

Contact Person for More Information: Dr. Allan Susten, Assistant Director for Science, Division of Health Assessment and Consultation, ATSDR, at 404–639–0625 or Dr. Deanna Harkins, Medical Officer, Commissioned Corps of the U.S. Public Health Service, Division of Health Education and Promotion, ATSDR, at 404–639–4669. For questions about logistics, contact ERG at 781–674–7374.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 18, 2001.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01–13128 Filed 5–23–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01066]

Applied Research on Antimicrobial Resistance; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a grant program for Applied Research on Antimicrobial Resistance (AR). This program addresses the ''Healthy People 2010'' focus area Immunization and Infectious Diseases.

The purpose of the program is to provide assistance for applied research aimed at prevention and control of the emergence and spread of antimicrobial resistance in the U.S. This AR research program will focus on two areas: (1) AR in rural areas; and (2) Microbiologic mechanisms of dissemination of AR genes and relationship to antimicrobial drug use, including (a) in health care settings and (b) from food animals to humans. This program's design will implement Part 1 of the Public Health Action Plan to Combat Antimicrobial Resistance, Domestic Issues. For more information visit the internet site: *www.cdc.gov/drugresistance/actionplan/index.htm.*

1. AR in Rural Areas (See Attachment II for additional information)

This research includes four components that will provide information needed to prevent and control AR in rural areas in the U.S.: Surveillance of antimicrobial infections, promoting appropriate antimicrobial drug prescribing, preliminary assessment of environmental impact of antimicrobials, and development of new antimicrobial products.

2. Microbiologic Mechanisms of Dissemination of AR Genes and Relationship to Antimicrobial Drug Use (See Attachment III for additional information)

This research will develop information necessary to prevent and control the emergence and spread of resistance in selected bacteria in health care settings and from food animals to humans, including mechanisms of resistance, dissemination of resistance, and the impact of antimicrobial use on dissemination of resistance.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau, federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Applicants may apply for either Antimicrobial Resistance in Rural Areas or Microbiologic Mechanisms of Dissemination of AR Genes and Relationship to Antimicrobial Drug Use or both. Proposals for Antimicrobial Resistance in Rural Areas must address all four components: Surveillance, Promoting Appropriate Antimicrobial Drug Prescribing, Assessment of Environmental Impact of Antimicrobials (environmental sampling or sentinel human populations), and New Antimicrobial Products.A separate application is required for each research area (rural health and microbiologic mechanisms).

Note: Title 2 of the United States Code, Chapter 26, Section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

C. Availability of Funds

Approximately $3,100,000 is available in FY 2001 as follows: Approximately $2,200,000 will be available for one award in focus area (1) and approximately $900,000 will be available for five awards in focus area (2), for an average award of $100,000 to $500,000. It is expected that the awards will begin on or about September 30, 2001, and will be made for a 12-month budget period within a project period of up to three years. The funding estimates may change.

A continuation award within an approved project period will be made on the basis of satisfactory progress as

evidenced by required reports and the availability of funds.

D. Program Requirements

Projects must meet the following requirements

1. AR in Rural Areas (See Attachment II for additional information)

Develop and implement comprehensive intervention projects to prevent and control AR in rural areas in the U.S.

a. Surveillance

Implement a practical, cost-effective system for monitoring antimicrobial drug resistance and use patterns that is operationally useful for prevention and control efforts in rural areas.

Taking into account factors relevant in rural settings, implement an epidemiologically representative, clinical laboratory based surveillance network for acute bacterial infections of public health importance that are commonly acquired in one or more of three settings: The community, health-care system, and/or the food supply.

b. Promoting Appropriate Antimicrobial Drug Prescribing

Measure antimicrobial drug prescribing and assess factors that influence such prescribing in rural areas. Use these data to conduct and evaluate appropriate use programs. Promote appropriate antimicrobial drug prescribing in human medicine and optionally in veterinary medicine.

c. Preliminary Assessment of Environmental Impact of Antimicrobials

Through pilot studies, assess the likelihood of environmental impact of antimicrobial drug use in modern agriculture and/or aquaculture.

d. New Antimicrobial Products

Identify and Investigate compounds, particularly naturally occurring substances, that may be useful in combating antimicrobial resistance in rural settings.

2. Microbiologic Mechanisms of Dissemination of AR Genes and Relationship to Antimicrobial Drug Use (See Attachment III for additional information)

Develop information necessary to prevent and control the emergence and spread of resistance in selected bacteria (see below) through better understanding the mechanisms through which resistance develops and spreads in field settings.

Projects should address one or more of the following: (1) Vancomycin resistance in staphylococci; (2) Cephalosporin resistance in *Klebsiella pneumoniae, Salmonellae,* or other Enterobacteriaceae through extended-spectrum β-lactamases, AmpC, or other β-lactamases; (3) Streptogramin (e.g., quinupristin/dalfopristin) resistance in enterococci; or (4) Fluoroquinolone resistance in *Escherichia coli.*

E. Application Content

Letter of Intent (LOI)

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter of intent shall be submitted on or before June 15, 2001 to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement. The letter should identify the announcement number, name the principal investigator, and briefly describe the scope and intent of the proposed research work. The letter of intent does not influence review or funding decisions, but the number of letters received will enable CDC to plan the review more effectively and efficiently.

Application

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. The application will be evaluated on the evaluation criteria listed below. The Research Plan for each research area should be no more than 25 pages, printed on one side, with one inch margins, and letters must not be smaller than 10 point font.

F. Submission and Deadline

Application

Submit the original and five copies of PHS–398 (OMB Number 0925–0001) (adhere to the instructions on the Errata Instruction Sheet for PHS–398).

On or before July 16, 2001, submit the application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Deadline: Applications shall be considered as meeting the deadline they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Background and Need (10 points)

Extent to which applicant's discussion of the background for the proposed project demonstrates a clear understanding of the purpose and objectives of this grant program. Extent to which applicant illustrates and justifies the need for the proposed project that is consistent with the purpose and objectives of this grant program.

2. Capacity (40 points total)

a. Extent to which applicant describes adequate resources and facilities (both technical and administrative) for conducting the project. (10 points)

b. Extent to which applicant documents that professional personnel involved in the project are qualified and have past experience and achievements in research related to that proposed as evidenced by curriculum vitae, publications, etc. (20 points)

c. Extent to which applicant includes letters of support appropriate non-applicant organizations, individuals, etc. Extent to which the letters clearly indicate the author's commitment to participate and/or collaborate as described in the operational plan. (10 points)

3. Objectives and Technical Approach (50 points total)

a. Extent to which applicant describes specific objectives of the proposed project which are consistent with the purpose and goals of this grant program and which are measurable and time-phased. (10 points)

b. Extent to which applicant presents a detailed operational plan for initiating and conducting the project, which clearly and appropriately addresses all Program Requirements. Extent to which applicant clearly identifies and describes appropriate study sites (per Program Requirements 1.a and 3.a). Extent to which applicant clearly identifies specific assigned responsibilities for all key professional personnel. Extent to which the plan clearly describes applicant's technical approach/methods for conducting the

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