DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99131]

Active Sentinel Hospital Surveillance and Epidemiologic Studies for Rotavirus Gastroenteritis; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement for Active Sentinel Hospital Surveillance and Epidemiologic Studies for Rotavirus Gastroenteritis. This program addresses the ''Healthy People 2000'', Immunization and Infectious Diseases.

The purpose of the program is to provide assistance to recipients to develop, maintain, and evaluate surveillance for hospitalizations among children <5 years of age due to rotavirus gastroenteritis and to conduct case-control studies (enrolling patients hospitalized with rotavirus gastroenteritis and appropriate control subjects) to evaluate vaccine effectiveness and risk factors for severe rotavirus disease and hospitalization due to rotavirus gastroenteritis.

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, and federally recognized Indian tribal governments, Indian tribes, or Indian Tribal Organizations.

Note: Public Law 104–65 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 $250,000 is available in FY 1999 to fund four cooperative agreement awards. It is expected that there will be two awards at an average of $105,000 (direct and indirect costs) for sites which conduct active surveillance and epidemiologic studies and two awards at an average of $20,000 (direct and indirect costs) for sites which only conduct active surveillance. It is expected that the awards will begin on or about September 30, 1999, and will be made for a 12-month budget period within a project period of up to 2 years. Funding estimates may change.

Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Applicants may request Federal personnel, equipment, or supplies (such as rapid antigen EIA test kits for testing hospitalized patients with gastroenteritis) as direct assistance, in lieu of a portion of financial assistance.

D. Program Requirements

In conducting the activities to achieve the purpose of this program, the recipient will be responsible for the activities listed under A. (Recipient Activities) and CDC will be responsible for the activities listed under B. (CDC Activities).

A. Recipient Activities

1. Meet three or four times each year with other funded sites to develop standardized research protocols (surveillance and epidemiologic studies).
2. Establish, maintain, and evaluate a surveillance system for hospitalizations due to rotavirus gastroenteritis among children <5 years of age in the hospital(s) affiliated with recipient institution.
3. Collect and analyze data.
4. Collaborate with a clinical laboratory to ensure: (1) Cases of pediatric gastroenteritis in the surveillance population are examined for rotavirus; and (2) cases of rotavirus gastroenteritis are strain typed.
5. Summarize the data and disseminate findings in peer-reviewed journals and at professional meetings.
6. For sites conducting both active surveillance and epidemiologic studies only: Conduct case-control studies. Enroll and interview hospitalized case-patients and age-matched control subjects from appropriate groups of children in order to examine vaccine effectiveness and identify risk factors for severe rotavirus disease and hospitalization due to rotavirus disease.

B. CDC Activities

1. Provide scientific and technical assistance and coordination, as requested, for all phases of the study.
2. As needed, participate in the analysis of data gathered from research projects and the reporting of results.
3. Facilitate group meetings with the sites to allow for the exchange of information and for input into the development and refinement of the research and intervention protocol.
4. Assist in the development of a research protocol for IRB review by each institution participating in the research project as well as the CDC IRB. CDC IRB will review the projects on at least an annual basis until the research is complete.
5. As needed, provide clinical laboratory services, at no charge, to ensure cases of rotavirus gastroenteritis are strain typed.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application. Your application will be evaluated on the criteria listed, so it is important to follow them in preparing your research plan.

Applicants must indicate whether they are applying to be a site where active surveillance will be performed (''surveillance site''), or to be a site where active surveillance and case-control studies will be performed (''combined study site''). Applicants may apply to be considered for either one or both study sites, but must submit separate applications for each type—one for funding to conduct active surveillance only and one to conduct surveillance and case-control studies only.

The research plan for each application should include the sections listed in the table of contents on page CC of form PHS 398:

1. Specific aims of the proposed rotavirus sentinel hospital surveillance system.
2. Background and Significance. This section should include the following:

—the demographic characteristics of the population served by the pediatric hospital including race, ethnicity, and socio-economic data,
—detailed characteristics of the hospital including size, number of admissions, academic affiliation, previous experience with pediatric research,
—information to demonstrate that the applicant has the appropriate organizational structure, administrative and laboratory support, and ability to access appropriate target populations, current hospital guidelines (if any) and information about hospital practice regarding testing for rotavirus in cases of gastroenteritis, and current laboratory testing procedures for rotavirus.

3. Preliminary studies. This section should include the following:

—number of admissions for gastroenteritis in children <5 years of age (by year of age)
—data on the number of admissions for laboratory confirmed rotavirus gastroenteritis for the target age group,

—other available data or previous studies on rotavirus gastroenteritis in the surveillance population,
—information on coverage with the current routine infant immunizations, including rotavirus vaccine, in this population.

4. Research Design and Methods. This section should include the following:

—the proposed operation of surveillance for rotavirus gastroenteritis in the hospital, to include details of how cases of gastroenteritis will be detected, how routine testing of each case for rotavirus will be organized, how the immunization status of case-patients will be verified, the type and format of data to be collected, mechanism for monitoring the system, and type of personnel required for obtaining and managing data.
—The proposed operation of case-control studies of cases of rotavirus gastroenteritis (if applying to perform epidemiologic studies). This should include a description of the populations from which control subjects will be selected, details of how case and control subjects will be selected and enrolled, possible sources of bias in selection of control subjects, how the immunization status of case-patients and control subjects will be verified, the type and format of data to be collected, and type of personnel required for obtaining, managing, and analyzing data.

5. Current letters of support should be included if applicant anticipates the participation of other organizations in conducting proposed activities.

F. Submission and Deadline

Letter of Intent

In order to assist CDC in planning and executing the evaluation of applications submitted under this announcement, all parties intending to submit an application are requested to submit a letter of intent. Your letter of intent should include the following information. (1) Name and address of institution, and (2) name, address, and telephone number of contact person, (3) identification of type site(s). On or before July 16, 1999, submit the letter of intent to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Application

Submit the original and five copies of PHS 398 (OMB Number 0925–0001) (adhere to the instructions on the Errata Instruction Sheet). Forms are in the application kit. On or before August 18, 1999, 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 if 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 orderly processing. (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. Applications for ''Surveillance Sites'' will be evaluated against Criteria A., and applications for ''Combined Sites'' will be Evaluated against Criteria B.

A. Surveillance sites

11. Specific aims: (5 percent)

The extent to which the applicant demonstrates an understanding of the purpose of the proposed rotavirus sentinel hospital surveillance system activity and the feasibility of accomplishing the outcomes described.

2. Background and Significance: (15 percent)

The extent to which background information and other data demonstrate that the applicant (a) has the appropriate organizational structure, administrative and laboratory support, and the ability to access and test cases of gastroenteritis admitted to the hospital and affiliated emergency department and (b) has experience with conducting pediatric research.

3. Preliminary Studies: (30 percent)

(a) The extent to which the applicant demonstrates that the participating hospital(s) will have sufficient rotavirus admissions among children <5 years of age to provide adequate statistical power for surveillance studies (i.e. >150 admissions per year due to gastroenteritis or >75 admissions per year due to rotavirus gastroenteritis),

(b) The extent to which background information and other data demonstrate that uptake of rotavirus vaccine is likely to be substantial in the population served by the hospital in the first 2 years of surveillance, and the extent to which the applicant demonstrates capacity for estimation of rotavirus immunization coverage rates during the study period,

(c) The extent to which previous studies demonstrate experience and expertise in conducting studies on rotavirus in this population.

4. Research Design and Methods: (35 percent)

The adequacy of the plan for detecting, testing for rotavirus, and obtaining and reporting information, including verified immunization histories on cases of childhood gastroenteritis, and the extent to which these proposed methods of testing will ensure complete monitoring for rotavirus of all cases of gastroenteritis admitted.

5. Qualifications of Key Personnel: (15 percent)

Qualifications, including training and experience, of key project personnel and the projected level of effort by each toward accomplishment of the proposed activities.

6. Budget (not scored)

Extent to which the line-item budget is detailed, clearly justified, and consistent with the purpose and objectives of this program.

7. Human Subjects (not scored)

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

8. Inclusion of Women and Racial and Ethnic Minorities in Research (not scored)

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:

A. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

B. The proposed justification when representation is limited or absent.

C. A statement as to whether the design of the study is adequate to measure differences when warranted.

D. 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.

B. Combined Study Sites

1. Specific Aims: (5 percent)

The extent to which the applicant demonstrates an understanding of the purpose of the proposed rotavirus sentinel hospital surveillance system activity and the feasibility of accomplishing the outcomes described.

2. Background and Significance: (10 percent)

The extent to which background information and other data demonstrate that the applicant (a) Has the appropriate organizational structure, administrative and laboratory support, and the ability to access and test cases of gastroenteritis admitted to the hospital and affiliated emergency department and (b) has experience with conducting pediatric research.

3. Preliminary studies: (25 percent)

(a) The extent to which the applicant demonstrates that the participating hospital(s) will have sufficient rotavirus admissions among children <5 years of age to provide adequate statistical power for surveillance studies (i.e., >150 admissions per year due to gastroenteritis or >75 admissions per year due to rotavirus gastroenteritis),

(b) The extent to which background information and other data demonstrate that uptake of rotavirus vaccine is likely to be substantial in the population served by the hospital in the first 2 years of surveillance, and the extent to which the applicant demonstrates capacity for estimation of rotavirus immunization coverage rates during the study period,

(c) The extent to which previous studies demonstrate experience and expertise in conducting studies on rotavirus in this population.

4. Research design and methods: (45 percent)

(a) The adequacy of the plan for detecting, testing for rotavirus, and obtaining and reporting information, including verified immunization histories on cases of childhood gastroenteritis, and the extent to which these proposed methods of testing will ensure complete monitoring for rotavirus of all cases of gastroenteritis admitted.

(b) Ability to enroll and interview an adequate (>50 per year) number of hospitalized children with cases of rotavirus gastroenteritis.

(c) Adequacy of the plan for selecting, enrolling, and interviewing suitable controls, including the plan for obtaining a suitable number of controls per case to obtain a study with adequate power to assess vaccine effectiveness and risk factors; adequacy of the plan to minimize potential sources of bias in the selection of control populations.

5. Qualifications of key personnel: (15 percent)

Qualifications, including training and experience, of key project personnel and the projected level of effort by each toward accomplishment of the proposed activities.

6. Budget (not scored)

Extent to which the line-item budget is detailed, clearly justified, and consistent with the purpose and objectives of this program.

7. Human Subjects (not scored)

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

8. Inclusion of Women and Racial and Ethnic Minorities in Research (not scored)

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:

A. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

B. The proposed justification when representation is limited or absent.

C. A statement as to whether the design of the study is adequate to measure differences when warranted.

D. 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.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semiannual progress reports.

2. Financial Status Report (FSR), no more than 90 days after the end of the budget period

3. Final FSR and performance report, 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 Addendum I in the application kit.

AR 98–1 Human Subjects Requirements
AR 98–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR 98–7 Executive Order 12372 Review
AR 98–9 Paperwork Reduction Act Requirements
AR 98–10 Smoke-Free Workplace Requirements
AR 98–11 Healthy People 2000
AR 98–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a) and 317(k)(1) and (K)(2) of the Public Health Service Act [42 U.S.C. 241(a), 247b(K)(1) and (k)(2)].

The Catalog of Federal Domestic Assistance Number is 93.185.

J. Where To Obtain Additional Information

This and other CDC announcements may be viewed and downloaded from the CDC homepage on the Internet, at: http://www.cdc.gov. Click on ''funding opportunities.''

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 you will be instructed to identify the Announcement number of interest. If you have questions after reviewing the contents of all documents, business management technical assistance may be obtained from: Sharron Orum, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone: (770) 488–2716, E-Mail: spo2@cdc.gov.

Programmatic technical assistance may be obtained from:

Charles Vitek, M.D., Medical Epidemiologist, Epidemiology and Surveillance Division, National Immunization Program, Mailstop E–61, Centers for Disease Control and Prevention (CDC), Telephone: (404) 639–8715, E-Mail: cxv3@cdc.gov

OR

Rebecca Prevots, Ph.D., Epidemiologist, Epidemiology and Surveillance Division, National Immunization Program, Mailstop E–61, Centers for Disease Control and Prevention (CDC), Telephone (404) 639–8255, E-Mail: ryp0@cdc.gov

OR

Joseph Bresee, M.D., Medical Epidemiologist, Viral and Rickettsial Diseases, Natl. Center for Infectious

Diseases, Mailstop A–34, Centers for Disease Control and Prevention (CDC), Atlanta, GA 30333, Telephone: (404) 639–4651, E-Mail: jsb6@cdc.gov

Dated: June 23, 1999.

John L. Williams,

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

[FR Doc. 99–16473 Filed 6–28–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98C–0431]

EM Industries, Inc.; Filing of Color Additive Petition; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a color additive petition filed by EM Industries, Inc., to clarify that the petitioner's request is to amend the color additive regulations to provide for the safe use of composite pigments made from synthetic iron oxide, titanium dioxide, and mica to color ingested drugs.

FOR FURTHER INFORMATION CONTACT: Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3076.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 22, 1998 (63 FR 33934), FDA announced that a color additive petition (CAP 8C0257) had been filed by EM Industries, Inc., 7 Skyline Dr., Hawthorne, NY 10532. The petition proposed to amend the color additive regulations to provide for the safe use of synthetic iron oxide to color ingested drugs at levels higher than the current limit and to provide for the safe use of mica to color ingested drugs.

The data in the petition indicated that the petitioner manufactured color additives, to color ingested drugs, by combining synthetic iron oxide, mica, and titanium dioxide. Based on these data, at the time of the filing of the petition, FDA considered the color additive combinations the petitioner prepared from synthetic iron oxide, mica, and titanium dioxide to be color additive mixtures. Titanium dioxide was already listed as a color additive for ingested drug use and the petition did not propose to amend the existing regulation.

To more accurately describe the pigments that are the subjects of this petition, FDA is amending the filing notice of June 22, 1998, to indicate that the petition proposes to amend the color additive regulations to provide for the safe use of composite pigments prepared from synthetic iron oxide, mica, and titanium dioxide to color ingested drugs.

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 2, 1999.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–16527 Filed 6–28–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biological Response Modifiers 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Biological Response Modifiers 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 July 15, 1999, 8 a.m. to 5:45 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Gail M. Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 15, 1999, the committee will discuss the following issues: (1) An update of FDA's regulatory policy concerning the implications on biological product development of fast track and the recent pediatric rule, (2) a scientific discussion concerning immune reactions to therapeutic and diagnostic biological products, (3) the report of the June 3 through 4, 1999, meeting of the xenotransplantation subcommittee, and (4) an update of research programs in the Laboratory of Cytokine Research, Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research.

Procedure: On July 15, 1999, from 8 a.m. to approximately 1 p.m., and from 1:30 p.m. to approximately 5 p.m., the meeting is open to the public. 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 July 8, 1999. Oral presentations from the public will be scheduled between approximately 8:10 a.m. to 9:10 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 8, 1999, 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.

Closed Committee Deliberations: On July 15, 1999, from 1 p.m. to 1:30 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The meeting will be closed to discuss issues relating to pending or proposed investigational new drug applications. The meeting will also be closed from 5 p.m. to 5:45 p.m., to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of this information.

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

Dated: June 21, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–16442 Filed 6–28–99; 8:45 am]

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