

term maintenance of a complete State-based PbB surveillance system. In particular, specific activities that will be undertaken by the State during the project period to ensure that the surveillance program continues after completion of the project period.

4. Personnel (10 points).

The extent to which the qualifications and time commitments of project personnel are clearly documented and appropriate for implementing the proposal.

5. Use of Existing Resources (5 points).

The extent to which the proposal would make effective use of existing resources and expertise within the applicant agency or through collaboration with other agencies.

6. BUDGET (Not Scored).

The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of funds.

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Applicants should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC for each affected State. A current list of SPOCs is included in the application kit. If they have comments it should be sent to Lisa G. Tamaroff, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Atlanta, GA 30305, no later than 60 days after the application due date. The Program Announcement Number and Program Title should be referenced on the document. The granting agency does not guarantee to "accommodate or explain" State process recommendations it receives after that date.

Public Health System Reporting Requirement

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.197.

Other Requirements

*Paperwork Reduction Act*

Projects that involve the collection of information from 10 or more individuals and funded by the grant will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Application Submission and Deadline

The original and two copies of the PHS 5161-1 (OMB Number 0937-0189) must be submitted to Lisa G. Tamaroff, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Atlanta, GA 30305, on or before April 9, 1997.

1. *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 submission for the review process. 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.

2. *Late Applications*

Applications which do not meet the criteria in 1.A. or 1.B. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

A one-page, single-spaced, typed abstract must be submitted with the application. The heading should include the title of the grant program, project title, organization, name and address, project director and telephone number.

Where to Obtain Additional Information

To receive additional written information call (404) 332-4561. You will be asked to leave your name, address, and phone number and will need to refer to Announcement 721. You will receive a complete program description, information on application procedures and application forms.

If you have questions after reviewing the contents of all documents, business management technical assistance may be obtained from Lisa G. Tamaroff, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease

Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-13, Atlanta, GA 30305, telephone (404) 842-6796. Internet address lgt1.ops.cdc.gov.

This and other CDC announcements are also available through the CDC homepage on the Internet. The address for the CDC homepage is <http://www.cdc.gov>.

CDC will not send application kits by facsimile or express mail.

Please refer to Announcement Number 721 when requesting information and submitting an application.

Technical assistance on prevention activities may be obtained from Claudette A. Grant, Acting Chief, Program Services Section, Lead Poisoning Prevention Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop F-42, Atlanta, GA 30341-3724, telephone (770) 488-7330, Internet address [cag4@ceh.cdc.gov](mailto:cag4@ceh.cdc.gov).

Technical assistance on surveillance activities may be obtained from Carol Pertowski, M.D., Medical Epidemiologist, Surveillance and Programs Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop F-42, Atlanta, GA 30341-3724, telephone (770) 488-7330, Internet address [cap4@ceh.cdc.gov](mailto:cap4@ceh.cdc.gov).

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report, Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: January 30, 1997.

Joseph R. Carter,

*Acting Associate Director, Management and Operations, Centers for Disease Control and Prevention.*

[FR Doc. 97-2799 Filed 2-4-97; 8:45 am]

BILLING CODE 4163-18-P

**Food and Drug Administration**

[Docket No. 97F-0038]

**Alcide Corp.; Filing of Food Additive Petition**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Alcide Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of acidified sodium chlorite solutions for red meat disinfection in processing plants.

**DATES:** Written comments on the petitioner's environmental assessment by March 7, 1997.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3074.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 7A4532) has been filed by Alcide Corp., 8561 154th Ave. NE., Redmond, WA 98052. The petition proposes to amend part 173 (21 CFR part 173) of the food additive regulations to provide for the safe use of acidified sodium chlorite solutions for red meat disinfection in processing plants.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before March 7, 1997 submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the

notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: January 17, 1997.

Alan M. Rulis,  
*Director, Office of Premarket Approval,  
Center for Food Safety and Applied Nutrition.*  
[FR Doc. 97-2820 Filed 2-4-97; 8:45 am]  
**BILLING CODE 4160-01-F**

**Studies of Adverse Effects of Marketed Drugs, Biologics, and Devices; Availability of Grants (Cooperative Agreements); Request for Applications**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Drug Evaluation and Research, is announcing the availability of \$1.4 million in Fiscal Year 1997 funds for cooperative agreements to study adverse effects of marketed drugs, biologics, and devices. This amount is consistent with the level of funding in the President's budget. FDA expects to make four to six awards in the range of \$250,000 to \$350,000 for direct and indirect costs. The Government's obligation is contingent upon the availability of appropriated funds from which the cooperative agreements will be funded. The purpose of these agreements is to conduct drug, biologic, and device safety analysis for public health benefit; respond expeditiously to urgent public safety concerns; provide a mechanism for collaborative pharmacoepidemiological research designed to test hypotheses, particularly those arising from suspected adverse reactions reported to FDA; and enable rapid access to multiple data sources to ensure public safety when necessary.

**DATES:** Application receipt date is March 21, 1997.

**ADDRESSES:** Application kits are available from, and completed applications should be submitted to: Robert L. Robins, Grants Management Officer, Division of Contracts and Procurement Management (HFA-520), Food and Drug Administration, Park Bldg., rm. 3-40, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6170.

Note: Applications hand-carried or commercially delivered should be addressed to the Park Bldg., rm. 3-40, 12420 Parklawn Dr., Rockville, MD 20857. Please do NOT send applications to the Division of Research Grants, National Institutes of Health (NIH).

**FOR FURTHER INFORMATION CONTACT:**

Regarding the administrative and financial management aspects of this notice: Robert L. Robins (address above).

Regarding the programmatic aspects of this notice: Charles M. Maynard, Division of Pharmacovigilance and Epidemiology (HFD-733), Food and Drug Administration, 5600 Fishers Lane, rm. 15B-18, Rockville, MD 20857, 301-827-3187.

**SUPPLEMENTARY INFORMATION:** FDA's authority to fund research projects is set out in section 301 of the Public Health Service Act (the PHS Act) (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103. Applications submitted under this program are not subject to the requirements of Executive Order 12372.

**I. Background**

New drugs, biologics, and devices are required to undergo extensive testing before marketing. With the submission of adequate data on safety and effectiveness, FDA approves a new drug, biologic, and device application (NDA/PLA/PMA) that permits a manufacturer to market its product in the United States. Although the information provided before marketing is sufficient for approval, it is not adequate to anticipate all effects of a product once it comes into general use.

This request for applications (RFA) is intended to encourage collaboration between FDA and researchers with pharmacoepidemiological data bases to address postmarketing issues confronting the agency. FDA is also interested in the ability to measure and/or estimate incidence rates and test hypotheses based on signals of possible drug, biologic, and device safety problems originating from reports of adverse reactions received by FDA.

**II. Program Research Goals**

FDA would prefer to fund a variety of data bases representing, without overlap, different patient populations and/or types of patient care settings. The data bases maintained through these agreements must be able to: (1) Provide data on exposure to new chemical entities; (2) perform feasibility studies of multiple drugs and/or multiple outcomes; (3) identify adverse drug, biologic, and device events that occur infrequently; and (4) provide a substantive response within a very short timeframe.

The goal for these cooperative agreements is to investigate suspected associations between specific drug and