AR–14 Accounting System Requirements

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) [42 U.S.C. 241(a)] and 317(k)(2) [42 U.S.C. 247b(k)(2) of the Public Health Service Act, 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 Program 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, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone number: 770–488–2753, E-mail address: gcg4@cdc.gov.

For program technical assistance, contact: Dr. John Roehrig, Division of Vector-Borne Infectious Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention, P. O. Box 2087 (Foothills Campus), Fort Collins, CO 80522, Telephone number: 970–221–6442, E-mail address: jtr1@cdc.gov.

Dated: May 17, 2001.

John L. Williams,

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

[FR Doc. 01–12982 Filed 5–22–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Program Announcement No. ACF/ACYF/CB FY 2001–01A; Announcement of the Availability of Financial Assistance and Request for Applications to Support Adoption Opportunities Demonstration Projects, Child Abuse and Neglect Discretionary Activities, Abandoned Infants Assistance Awards, and Project To Build the Analytical Capacity of State Child Welfare Programs

AGENCY: Administration on Children, Youth and Families (ACYF), ACF.

ACTION: Correction.

SUMMARY: This document contains a correction to the Notice that was published in the **Federal Register** on Tuesday, May 1, 2001 (66 FR 21760). On page 21761, Column three, the information in the ''Project Duration'' section of priority area 2001B.1 National Resource Center on Child Maltreatment is in error. The correct information is as follows: The cooperative agreement will be awarded for a project period not to exceed 36 months. The initial grant award will be awarded for a 12-month budget period. The award of continuation funding beyond the 12-month budget period will be subject to the availability of funds, satisfactory progress on the part of the grantee, and a determination that continued funding would be in the best interest of the government.

FOR FURTHER INFORMATION CONTACT: The ACYF Operations Center at 1–800–351–2293 or send an email to *cb@cgnet.com.* You may also contact Sally Flanzer, Children's Bureau, at 202–215–8914.

Dated: May 18, 2001.

James A. Harrell,

Acting Commissioner, Administration on Children, Youth and Families.

[FR Doc. 01–13044 Filed 5–22–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01F–0233]

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 as an antimicrobial agent in processing waters applied to processed fruits and vegetables.

DATES: Submit written comments on the petitioner's environmental assessment by June 22, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 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 1A4729) has been filed by Alcide Corp., 8561 154th Ave. NE., Redmond, WA 98052. The petition proposes to amend the food additive regulations in § 173.325 *Acidified sodium chlorite solutions* (21 CFR 173.325) to provide for the safe use of acidified sodium chlorite solutions as an antimicrobial agent in processing waters applied to processed fruits and vegetables.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued 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 submit to the Dockets Management Branch written comments by June 22, 2001. 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 Dockets Management Branch 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: May 4, 2001.

Alan M. Rulis,

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

[FR Doc. 01–13068 Filed 5–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products 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: Vaccines and Related Biological Products 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 11, 2001, 11:30 a.m. to 2:30 p.m.

Location: Food and Drug Administration, 8800 Wisconsin Ave., Bldg. 29–B, conference room 1NN06, Bethesda, MD. This meeting will be held via telephone conference call. A speaker phone will be provided in the conference room to allow public participation in the meeting.

Contact: Nancy T. Cherry or Denise H. Royster, 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 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the intramural scientific research program of the Laboratory of Pediatric and Respiratory Viral Diseases.

Procedure: On June 11, 2001, from 11:30 a.m. to 1:30 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 May 31, 2001. Oral presentations from the public will be scheduled between approximately 12:20 p.m. and 1:25 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 31, 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.

Closed Committee Deliberations: On June 11, 2001, from 1:30 p.m. to 2:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The meeting will be closed to discuss personal information concerning individuals associated with the research program.

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. 01–13070 Filed 5–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1195]

Guidance for Industry on Bioanalytical Method Validation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Bioanalytical Method Validation.'' This guidance provides assistance to sponsors of investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), and their supplements in developing validation information on bioanalytical methods for pharmacokinetic (PK) evaluation of human clinical pharmacology, bioavailability (BA), and bioequivalence (BE) studies. The guidance also applies to bioanalytical methods used for nonhuman pharmacology/toxicology studies and preclinical studies. For studies related to the veterinary drug approval process, this guidance applies only to blood and urine BA, BE, and PK studies.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Vinod P. Shah, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5635.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Bioanalytical Method Validation.'' This guidance provides recommendations to sponsors of INDs, NDAs, ANDAs, and their supplements in developing validation information for bioanalytical methods for PK evaluations of human clinical pharmacology, BA studies, and BE studies. The information in this guidance generally applies to bioanalytical procedures such as gas chromatography (GC), high-pressure liquid chromatography (LC), combined GC and LC mass spectrometric (MS) procedures such as LC–MS, LC–MS–MS, GC–MS, GC–MS–MS, and immunological and microbiological procedures performed for quantitative determination of drugs and or metabolites in biological matrices such as serum, plasma, or urine. The guidance also applies to other bioanalytical matrices such as tissue and skin samples.

In the **Federal Register** of January 5, 1999 (64 FR 517), FDA announced the availability of a draft guidance entitled ''Bioanalytical Methods Validation for Human Studies.'' This January 1999 document gave interested persons an opportunity to comment through March 8, 1999. The agency received a total of 36 comments. All comments received