Center, were revoked, effective March 14, 1996.

This notice is issued and published under 21 CFR 601.8 and the redelegation at 21 CFR 5.67.

Dated: August 28, 1996.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 96–23550 Filed 9–13–96; 8:45 am]

BILLING CODE 4160–01–F

Cooperative Agreement for Shellfish and Seafood Safety Assistance Project; Intent to Supplement for Fiscal Year 1996

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of intent.

SUMMARY: The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition, Office of Seafood, is announcing its intention to supplement the current year of the cooperative agreement with the Interstate Shellfish Sanitation Conference (ISSC) in the amount of $165,000. This money will provide for research of *Vibrio vulnificus* which, although not normally a threat to healthy individuals, can cause serious illness and death in individuals with certain preexisting conditions. The research is intended to provide information to establish science-based controls to protect at-risk consumers from *V. vulnificus* infection.

ADDRESSES: An application form is available from, and the completed form should be submitted to Robert L. Robins, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, Park Bldg., 5600 Fishers Lane, rm. 3–40, Rockville, MD 20857, 301–443–6170. Applications hand-carried or commercially delivered should be addressed to the Park Bldg., 12420 Parklawn Dr., rm. 3–40, Rockville, MD 20857.

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: Paul W. DiStefano, Office of Seafood, Center for Food Safety and Applied Nutrition (HFS–417), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3177.

SUPPLEMENTARY INFORMATION: This project is authorized under section 301 of the Public Health Service Act (42 U.S.C. 241). This activity is generally described in the Catalog of Federal Domestic Assistance at 93.103. This application is not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Program (45 CFR 100). Under this supplement, the ISSC will make funds available to State agencies, academic institutions, and private and public organizations for *V. vulnificus* research through a competitive process.

I. Restricted Eligibility

On October 20, 1995, the Commissioner of Food and Drugs, as authorized by the Public Health Service (PHS) Grants Administration Manual, Part 144.3, determined that a single source cooperative agreement could be awarded to the ISSC without competition. This supplemental application will provide for the implementation and enhancement of activities associated with *V. vulnificus* described and authorized under the original application, FD–U–000891–01 dated January 4, 1996.

II. Availability of Funds

FDA will fund this supplement to the cooperative agreement at a total level of $165,000. The original cooperative agreement has an additional 4 years of support which are contingent upon the availability of fiscal year appropriations, continued support from other government agencies, and successful performance. FDA anticipates that this supplement to the cooperative agreement will commence on or before September 30, 1996.

III. Background

V. vulnificus is a pathogen found in the estuarine environment. *V. vulnificus* bacteria are not normally a threat to healthy individuals. However, in individuals with preexisting chronic medical conditions such as liver disease, alcoholism, and hemochromatosis, *V. vulnificus* can cause serious illness and death. Each year, between 12 and 31 cases of *V. vulnificus* illness associated with consumption of raw molluscan shellfish are reported to public health authorities in the United States.

The paucity of scientific data associated with *V. vulnificus* has hindered efforts by public health officials, including FDA, to establish science based controls to protect at-risk consumers from *V. vulnificus* infection.

IV. Purpose

This supplement to FDA's current cooperative agreement will enable the ISSC to award, through a competitive process, *V. vulnificus* research projects. Research efforts made possible by this supplement will complement existing efforts under FDA's current cooperative agreement with the ISSC and provide public health officials with better science and an enhanced understanding of *V. vulnificus*. Innovative research efforts will contribute significantly to the ISSC's and to FDA's ability to identify scientifically defensible controls that will help to reduce the incidence of *V. vulnificus* illness.

V. Substantive Involvement by FDA

FDA will collaborate with the ISSC in the preparation of the Requests For Application and any other solicitation materials. FDA will review and comment on the methods of solicitation as proposed by the ISSC, provide technical assistance in the form of guidance and participation in the competitive review of all applications, and collaborate with the ISSC in the final selection of subgrantees.

In the event that the ISSC does not have written policies governing the objective review for awarding subgrants, the ISSC has agreed to adhere to the PHS Grant Policy Statement governing ''Objective Review'' to the extent that it is applicable. All decisions by the objective review panel are final and are not appealable.

VI. Review Procedure and Evaluation Criteria

A. Review Procedure

The application submitted by the ISSC will undergo a noncompetitive dual peer review. The application will be reviewed for scientific and technical merit by a panel of experts based upon applicable evaluation criteria. If the application is recommended for approval, it will then be presented to the National Advisory Environmental Health Sciences Council.

B. Evaluation Criteria

The application will be reviewed and evaluated according to the following criteria:

1. The application must clearly present an understanding of the purpose and objectives of the supplement to the cooperative agreement in conducting *V. vulnificus* research and set out the steps, with a proposed schedule for planning, implementing, and accomplishing the activities, to be carried out under this project.

2. The application must describe the ISSC's ability to perform its responsibilities under this project by providing qualified staff. The

application must also demonstrate that the ISSC has the financial and other resources required for this project.

3. The application must specify the approach that the ISSC will use to solicit proposals for *V. vulnificus* research.

4. The ISSC application must explain how the ISSC will monitor the progress of selected research projects, and how it will keep FDA informed of any significant advances in the understanding of or control of *V. vulnificus*.

In addition, FDA will determine whether the estimated cost of the project is reasonable. The application must include a detailed budget that shows: (1) Anticipated costs for personnel, travel, communications and postage, equipment, and supplies; and (2) the sources of funds to meet those needs.

VII. Reporting Requirement

All terms and conditions of the current award shall remain in full force and effect for the supplemental award.

As a result of this supplemental award, annual project progress reports must also include the following:

1. Listing of research projects funded.
2. Specific purpose of each project.
3. Cost of each project.
4. Anticipated completion and milestone dates for each project.
5. Year-to-date results/scientific findings/public health findings of each project.
6. Potential *V. vulnificus* control measures/strategies suggested by research efforts.

VIII. Mechanism of Support

Support for this project will be in the form of a supplement to FDA's cooperative agreement with the ISSC. This agreement will be subject to all policies and requirements that govern the research grant programs of the PHS, including provisions of 42 CFR part 52 and 45 CFR part 74.

Dated: September 10, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–23669 Filed 9–13–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0309]

Promotion of FDA-Regulated Medical Products on the Internet; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss issues related to the promotion of FDA-regulated medical products on the Internet. FDA is seeking participation in the public meeting and written comments from all interested parties, including, but not limited to, consumers, patient groups, information vendors, manufacturers of FDA-regulated medical products, and health care professionals. This meeting and the written comments are intended to help guide FDA in making policy decisions on the promotion of biologics, human and animal drugs, and medical devices on the Internet and the World Wide Web (the Web).

DATES: The public meeting will be held on Wednesday, October 16, 1996, from 8:30 a.m. to 5 p.m. and on Thursday, October 17, 1996, from 8:30 a.m. to 3 p.m. Registration for persons who wish to actively participate in the discussion groups is required by October 4, 1996. Registration is not required for persons who wish to be in the audience. Written comments will be accepted until December 16, 1996.

ADDRESSES: The public meeting will be held at the Quality Hotel, 8727 Colesville Rd., Silver Spring, MD. Individuals who wish to actively participate in the public meeting should mail, fax, or e-mail their registration information to Fay Fink (address below). There is no registration fee for this meeting, but registration is required for individuals who wish to actively participate in the group discussions. Seating for each discussion group is limited to 15 persons, on a first-come, first-serve basis. Information about the public meeting is also available on FDA's website at http://www.fda.gov. Submit written comments on the questions to the Dockets Management Branch (DMB) (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. After the meeting, a transcript will be available at DMB (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Regarding registration: Fay Fink, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, FAX 301–594–6777, e-mail: FFink@bangate.fda.gov.

Regarding this notice: Ilisa B.G. Bernstein, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380, e-mail: IBernste@bangate.fda.gov; or Melissa M. Moncavage, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2828, e-mail: moncavage@cder.fda.gov or Byron L. Tart, Center for Devices and Radiological Health (HFZ–302), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4639, e-mail: bxt@fdadr.cdrh.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

With the recent dramatic increases in the number of users of the Internet, including the Web, companies, including manufacturers and distributors of products regulated by FDA, are looking at the Internet as a medium for disseminating information about their products. FDA is evaluating how the statutory provisions, regulations, and policies concerning advertising and labeling should be applied to product-related information on the Internet and whether any additional regulations, policies, or guidances are needed. Although the agency believes that many issues can be addressed through existing FDA regulations, special characteristics of the Internet may require the agency to provide guidance to the industry on how the regulations should be applied.

The Internet is a global network of computers. The most widely used portion of the Internet is the Web. The Web permits the display of multimedia documents and objects, such as plain text, searchable indices, images, sounds, movies, and fill-in forms. Web pages can be linked to other sites on the Web using ''hypertext,'' which allows the user to jump to any other information page that is linked to the Web. The Web is where most promotion of FDA-regulated products is located on the Internet. In addressing promotional issues in this notice, FDA will use the broader term, Internet, which includes the Web.

Since late 1995, FDA has been gathering information about the Internet and its utility to promote FDA-regulated products. This is in an effort to facilitate the development of guidance to the industry on the promotion of regulated products on the Internet. As part of its fact finding process, FDA has been meeting with companies, third party providers, and other groups, to gain a better understanding of the nature of, and the technical aspects to, promotion on the Internet. FDA appreciates the time and effort that these individuals, companies, and associations have