the bridge, then turn right; the hotel is on the left. From I–285 West, Exit 22, Chamblee-Dunwoody Road, continue through the intersection; the hotel is approximately one mile on the right.

Status: Open to the public for participation, comment, or observation, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: The VSP of CDC is responsible for overseeing the public health concerns on passenger cruise ships that enter the United States from foreign ports. These public health responsibilities include reviewing plans for new ships or remodeling old ships, inspecting ships while they are under construction, and monitoring the installation of facilities and equipment. The VSP is also responsible for ensuring that food service, portable water treatment, and care and maintenance of the recreational spas and pools are handled in accordance with the guidelines in the ''VSP Operations Manual.''

This meeting is one in a series on the ''Construction Specifications'' and the ''Spa Guidelines.'' The purpose of this meeting is to introduce the completed versions of the documents for final review and comments by the cruise ship industry and other interested parties.

Matters to be Discussed: Agenda items will include the final discussion on comments and suggested changes made by the cruise ship industry and other interested parties at the June 3, 1996, public meeting.

Agenda items are subject to change as priorities dictate.

For 15 days after the meeting, through October 11, 1996, the official record of the meeting will remain open so that additional material or comments may be submitted and made a part of the record.

Contact Person for More Information: Donald W. Turner, Chief, VSP, NCEH, CDC, 1015 North America Way, Room 107, Miami, Florida 33132, telephone 305/536–4307.

Dated: September 10, 1996.

Nancy C. Hirsch,

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

[FR Doc. 96–23590 Filed 9–13–96; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 96N–0169]

Midland County Hospital District; Revocation of U.S. License No. 961

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the establishment license (U.S. License No. 961) and the product licenses issued to Midland County Hospital District, now doing business as Permian Basin Regional Center, for the manufacture of Red Blood Cells, Plasma, and Platelets. In a letter to FDA dated November 1, 1995, the firm voluntarily requested that its establishment and product licenses be revoked.

DATES: The revocation of the establishment license (U.S. License No. 961) and the product licenses became effective March 14, 1996.

ADDRESSES: Copies of letters from FDA and Midland County Hospital District may be seen at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Annette A. Ragosta, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA conducted an inspection of Midland County Hospital District, 200 Airport Plaza, Midland, TX 79711–1650, from March 14 through April 11, 1995. The inspection also involved a concurrent investigation which included interviews with individuals knowledgeable about the firm's daily operations. The inspection and concurrent investigation revealed serious noncompliance with applicable standards and Federal regulations. Serious deficiencies were reported in interviews and observed by the investigators in several areas of the firm's operations. Deviations included, but were not limited to the following: (1) Failure to collect blood by aseptic methods in a sterile system to protect against contamination (21 CFR 640.4(f)) in that it was reported to our investigators that on numerous occasions employees broke the sterility barrier of blood containers and drained blood into vacutainer tubes or biohazard containers in order to conceal overbleeds; (2) failure to follow standard operating procedures for addressing adverse donor reactions (21 CFR 606.100(b)(9)) in that it was reported to our investigators that on several occasions employees continued to bleed donors while the donors were experiencing adverse reactions; and (3) failure to maintain records concurrently with the performance of each significant step in the collection, processing, storage, and distribution of each unit of blood and blood components so that all steps can be clearly traced (§ 606.160(a)(1) (21 CFR 606.160(a)(1))) in that: (a) important donor selection information, such as vital signs, answers to medical history and high risk behavior questions, and documentation of hemoglobin checks, was not obtained and recorded concurrently with each donor suitability determination; (b) it was reported to our investigators that on several occasions daily performance checks of equipment were not performed but the records were completed to indicate that these had been performed (§ 606.160(b)(5)(ii)); and (c) it was reported to our investigators that, on at least two occasions, maintenance records for the Cobe Spectra instrument were completed to give the appearance that maintenance had been performed, when in fact, it may not have been performed (§ 606.160(b)(7)(iv)).

FDA determined that these deviations from Federal regulations constituted a danger to public health warranting a suspension under 21 CFR 601.6(a). In a letter to Midland County Hospital District, dated April 20, 1995, FDA detailed the above-described violations and stated that the firm's management had not effectively fulfilled its responsibilities to exercise control in all matters relating to compliance and had not assured that personnel were adequately trained and had a thorough understanding of the procedures that they were to perform (21 CFR 600.10(a) and (b) and 606.20(a) and (b)). In the same letter, FDA suspended the firm's establishment and product licenses for the manufacture of Red Blood Cells, Plasma, and Platelets. In a letter dated November 1, 1995, Midland County Hospital District voluntarily requested that its licenses be revoked. The agency acknowledged the request for a voluntary revocation of the establishment and product licenses in a letter dated March 14, 1996.

The agency has placed copies of letters from FDA, dated April 20, 1995, and March 14, 1996, and a letter from Midland County Hospital District, dated November 1, 1995, on file under the docket number found in brackets in the heading of this document in the Dockets Management Branch (address above). These documents are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Accordingly, under section 351 of the Public Health Service Act (42 U.S.C. 262), 21 CFR 601.5, and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68), the establishment license (U.S. License No. 961), and the product licenses for the manufacture of Red Blood Cells, Plasma, and Platelets, issued to Midland County Hospital District, Midland, TX, now doing business as Permian Basin Regional

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