for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: October 12, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95–25766 Filed 10–12–95; 4:41 pm]

BILLING CODE 4160–01–P

[Docket No. 95N–0281]

''Proceedings of the 1994 Vibrio Vulnificus Workshop;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of ''Proceedings of the 1994 *Vibrio vulnificus* Workshop.'' The workshop was a scientific forum that was cosponsored by FDA, the National Marine Fisheries Service (NMFS), and the Interstate Shellfish Sanitation Conference (ISSC) to: Review the current information available on the epidemiology, ecology, and pathogenicity of *Vibrio vulnificus*, as well as industry practices affecting the levels of this pathogen in seawater and shellfish, ongoing educational efforts, and other related technical information obtained since the last *Vibrio vulnificus* workshop, held in March 1988; identify further critical information needs; and identify the kind of research that will best address these needs using available government and nongovernment resources most effectively.

ADDRESSES: Submit written requests for single copies of ''Proceedings of the 1994 *Vibrio vulnificus* Workshop'' to the Program and Enforcement Branch, Office of Seafood (HFS–417), Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your requests. ''Proceedings of the 1994 *Vibrio vulnificus* Workshop'' is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20875, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Jeanette B. Lyon, Center for Food Safety and Applied Nutrition, Office of Seafood (HFS–417), 200 C St. SW., Washington, DC 20204, 202–418–3177.

SUPPLEMENTARY INFORMATION: *Vibrio vulnificus* is a naturally-occurring marine bacterium which has been associated with human illness and death from the consumption of raw shellfish, primarily raw oysters. Federal and State government agencies, the ISSC, academia, and the shellfish industry have been monitoring these illnesses and deaths and have focused their research efforts on the development of effective controls to prevent *Vibrio vulnificus*-related illnesses from the consumption of shellfish. In 1988, a jointly sponsored *Vibrio vulnificus* workshop was held in Washington, DC, to identify the current state of knowledge and research needs at that time.

At the 1994 workshop, experts were invited to present scientific and technical updates on the epidemiology, pathogenicity, and ecology of *Vibrio vulnificus*; the effects of time-temperature factors on outgrowth; depuration, irradiation, and other intervening control measures; and the use and effectiveness of consumer education and health advisories. In addition to the invited speakers and representatives of the sponsors, other attendees included state public health officials, industry, consumer representatives, epidemiologists, and researchers. The workshop concluded with several panel discussions during which panel members discussed their views on unresolved information and research needs and mechanisms by which these might be attained.

A draft of the proceedings was published and distributed to the participants for comment in August, 1994. The current publication incorporates their comments.

Dated: September 28, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–25621 Filed 10–16–95; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Cancer Institute; Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Scientific and Commercial Development of Homoharringtonine as an Anticancer Agent

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (DHHS) seeks a pharmaceutical company that can effectively pursue the clinical development of Homoharringtonine for the treatment of cancer. The National Cancer Institute has established that this agent may be effective in treating several types of cancers. The selected sponsor will be awarded a CRADA for the development of this agent.

The term of the CRADA is anticipated to be three (3) to five (5) years.

ADDRESSES: Questions about this opportunity may be addressed to Mike Christini, J.D. or Michelle Rhyu, Ph.D., Office of Technology Development, NCI, Building 31, Bethesda, Maryland 20892 (301) 496–0477, from whom further information including a summary copy of the preclinical and clinical data may be obtained.

DATES: In view of the important priority of developing new drugs for the treatment of cancer, proposals must be received at the above address by 5 pm December 18, 1995.

SUPPLEMENTARY INFORMATION:

Cooperative Research and Development Agreement or ''CRADA'' means the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of October 10, 1987 to collaborate on the specific research project described below. Under the present proposal, the Government is seeking a pharmaceutical company, which in accordance with the requirements of the regulations governing the transfer of technology that the Government has taken an active role in developing (37 CFR 404.8), can further develop Homoharringtonine to a marketable status to best meet the needs of the public. The government does not hold any active patents for this compound.

Homoharringtonine is a cephalotaxine ester isolated from the cephalotaxus evergreen indigenous to China. It has shown promising activity in patients with chronic myelogenous leukemia (CML). Clinical development directed toward licensing includes confirmatory phase 2 trials of HHT in combination with other agents with demonstrated activity in CML and a phase 3 trial of HHT against standard therapy in refractory CML.

The Division of Cancer Treatment, NCI, is interested in establishing a CRADA with a pharmaceutical company to assist in the continuing development of the agent. The Government will provide all available expertise and information to date and will jointly pursue new clinical studies as required, giving the pharmaceutical company full access to existing data and data developed pursuant to the CRADA.

The successful pharmaceutical company will provide the necessary financial and organizational support to complete further development of this agent to establish clinical efficacy and possible commercial status.

The role of the Division of Cancer Treatment, NCI, includes the following:

1. The Government will provide information concerning pharmaceutical manufacturing and controls including dosage development data.

2. The Government will allow the pharmaceutical company to review and cross-file the Division's IND for the agent; it is likely that the pharmaceutical company would wish to undertake clinical studies independently, as well as jointly under the CRADA.

3. The Government will make the Division's IND for the agent proprietary under the terms of the CRADA and the IND data will be offered exclusively to the selected pharmaceutical company.

4. The DCT, NCI will make the collaborator its sole and exclusive commercialization partner for the development of this compound.

5. The Government will continue the preclinical and clinical development of this agent under its extramural clinical trials network.

The role of the successful pharmaceutical company for the agent under a CRADA will include the following:

1. Provide and implement plans to independently secure future supplies of the agent to assure continued preclinical and clinical development. The pharmaceutical company will provide for the costs of production of Homoharringtonine produced from the date of this Notice until such time as the company shall assume responsibility for satisfying the supplies required by the Division of Cancer Treatment, NCI.

2. Generate a plan and provide financial and regulatory support for the clinical development leading to FDA approval for marketing.

3. In the development of compounds derived from natural products, the NCI is concerned that the utilization of the plant material comport with all applicable laws and policies in the source country related to biodiversity. It is the responsibility of the CRADA partner to negotiate and enter into agreements with source country agencies as appropriate to address these concerns.

Criteria for choosing the pharmaceutical company include the following:

1. Experience in the preclinical and clinical development of anticancer agents.

2. Experience and ability to produce, package, market and distribute pharmaceutical agents in the United States.

3. Experience in the monitoring, evaluation and interpretation of the data from investigational agent clinical studies under an IND.

4. A willingness to cooperate with the Public Health Service in the collection, evaluation, publication and maintenance of data from clinical trials of investigational agents.

5. A willingness to cost share in the development of the agent. This includes the acquisition of bulk material and formulation of clinical products in adequate amounts as needed for future clinical trials and marketing, as well as the partial funding of regulatory costs and personnel dedicated to completion of the CRADA research project.

6. An agreement to be bound by the DHHS rules involving human and animal subjects.

7. Formulation of an aggressive clinical development plan, including appropriate milestones and deadlines.

8. Provisions for equitable distribution of patent rights to any inventions. Generally the rights of ownership are retained by the organization which is the employer of the inventor, with (1) an irrevocable, nonexclusive, royalty-free license to the Government (when a company employee is the sole inventor) or (2) an option to an exclusive or nonexclusive license to the company on terms that are appropriate (when the Government employee is the sole inventor).

9. Willingness and ability to acquire any necessary background patent rights.

10. Submission of an initial response to the NIH Model Clinical Trial CRADA boilerplate provisions.

Dated: October 6, 1995.

Thomas D. Mays,

Director, Office of Technology Development, National Cancer Institute, National Institutes of Health.

[FR Doc. 95–25731 Filed 10–16–95; 8:45 am]

BILLING CODE 4140–01–P

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.