

Dated: September 9, 1998.

Thena M. Durham,

Acting Associate Director for Management and Operations Centers for Disease Control and Prevention (CDC).

[FR Doc. 98-24660 Filed 9-14-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F-0749]

Rohm and Haas Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Rohm and Haas Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of the ion exchange resin, methylacrylate-divinyl benzene diethylene glycol divinyl ether terpolymer to treat water and aqueous foods without limits on the conditions of use, and with a specification for dimethylaminopropylamine, an impurity in the ion exchange resin.

FOR FURTHER INFORMATION CONTACT: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3078.

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 8A4609) has been filed by Rohm and Haas Co., 100 Independence Mall West, Philadelphia, PA 19106-2399. The petition proposes to amend the food additive regulations in § 173.25 *Ion exchange resins* (21 CFR 173.25) to provide for the safe use of the ion exchange resin, methylacrylate-divinyl benzene diethylene glycol divinyl ether terpolymer, identified in § 173.25(a)(16), to treat water and aqueous foods as described in § 173.25(b)(2), without limits on the conditions of use, and with a specification for dimethylaminopropylamine, an impurity in the ion exchange resin.

The agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: August 31, 1998.

Laura M. Tarantino,

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

[FR Doc. 98-24626 Filed 9-14-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: Opportunities for Cooperative Research and Development Agreements (CRADAs) for the Development and Evaluation of Chemokine or Chemokine Receptor Neutralizing Antibodies for Their Anti-Angiogenic Effects and Potential as Treatments for Cancer

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice of opportunities for cooperative research and development agreements.

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. § 3710; Executive Order 12591 of April 10, 1987 as amended by the National Technology Transfer and Advancement Act of 1995), the National Cancer Institutes (NCI) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks Cooperative Research and Development Agreements (CRADAs) with pharmaceutical or biotechnology companies.

Any CRADA for the biomedical use of this technology will be considered. The CRADAs would have an expected duration of one (1) to five (5) years. The goals of the CRADAs include the rapid publication of research results and timely commercialization of products, diagnostics and treatments that result from the research. The CRADA Collaborators will have an option to negotiate the terms of an exclusive or nonexclusive commercialization license to subject inventions arising under the CRADAs.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Dr. Thomas M. Stackhouse, Technology Development & Commercialization Branch, National Cancer Institute-Frederick Cancer Research and Development Center, P.O. Box B, Frederick, MD 21702-1201, Telephone: (301) 846-5465, Facsimile: (301) 846-6820.

EFFECTIVE DATE: Organizations must submit a confidential proposal summary preferably one page or less, to NCI on or before September 29, 1998. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents with whom initial confidential discussions will have established sufficient mutual interest.

SUPPLEMENTARY INFORMATION:

Technology Available

Recent publications show inhibition of angiogenic factors such as Interleukin-8 (IL-8) and another chemotactic cytokine GRO, reduce the growth of melanomas by interfering with the angiogenic effects of these tumors. DHHS scientists are working toward the identification and evaluation of other chemokines with angiogenic effects such as SDF-1alpha. DHHS would like to test the effect of neutralizing antibodies to these chemokines and chemokine receptors on the growth, in animal models, of human tumors such as breast, prostate or lung. Publications outlining these developments are available on request, and descriptions of other (unpublished) advances can be obtained under a Confidential Disclosure Agreement.

DHHS now seeks collaborative arrangements to test and develop such potential therapeutic antibodies. The successful CRADA collaborator will provide expertise and experience in the preparation of totally humanized anti-chemokine or anti-chemokine receptor antibodies, and will provide sufficient quantities of the humanized antibodies to complete the studies to be outlined under the Research Plan of the CRADA. NCI and the CRADA collaborator will perform tests using these humanized antibodies in various combinations, including combinations with other anti-tumor biologicals, such as humanized antibodies to epidermal growth factor receptors, which are known to have some anti-tumor activity. The Cooperative Research and Development Agreement (CRADA) will provide for distribution of intellectual property rights developed under the Agreement. CRADA aims will include rapid publication of research results as well as timely exploitation of any commercial opportunities.

The role of the National Cancer Institute in this CRADA will include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience related to chemokines and chemokine receptors to the research project.
2. Planning and conducting some of the research studies in cell lines and

animal models and interpreting research results.

3. Publishing research results.

The role of the CRADA Collaborator may include, but not be limited to:

1. Providing significant intellectual, scientific, and technical expertise or experience to the research project.

2. Planning research studies and interpreting research results.

3. Providing samples of the subject compounds to test, optimize and develop for their anti-angiogenic and anti-tumor potential.

4. Providing technical and/or financial support to facilitate scientific goals and for further design of applications of the technology outlined in the agreement.

5. Publishing research results.

Selection criteria for choosing the CRADA Collaborator may include, but not be limited to:

1. The ability to collaborate with NCI on the research and development of this technology. This ability can be demonstrated through experience and expertise in this or related areas of technology indicating the ability to contribute intellectually to ongoing research and development.

2. The demonstration of adequate resources to perform the research and development of this technology (e.g. facilities, personnel and expertise) and accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.

3. the willingness to commit best effort and demonstrated resources to the research and development of this technology, as outlined in the CRADA Collaborator's proposal.

4. The demonstration of expertise in the commercial development and production of products related to this area of technology.

5. The level of financial support the CRADA Collaborator will provide for CRADA-related Government activities.

6. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.

7. The agreement to be bound by the appropriate DHHS regulations relating to human subjects, and all PHS policies relating to the use and care of laboratory animals.

8. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the distribution of patent rights to CRADA inventions. Generally, the rights of ownership are retained by the organization that is the employer of the inventor, with (1) the grant of a license for research and other Government purposes to the Government when the CRADA

Collaborator's employee is the sole inventor, or (2) the grant of an option to elect an exclusive or nonexclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated: September 4, 1998.

Kathleen Sybert,

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

[FR Doc. 98-24810 Filed 9-11-98; 3:08 pm]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Alternative Medicine, Office of the Director; Notice of Meeting

Pursuant to Pub. L.92-463, notice is hereby given of the meeting of the Alternative Medicine Program Advisory Council on September 24-25, 1998 at the Doubletree Hotel, 1750 Rockville Pike, Rockville, Maryland.

The two-day meeting will be open to the public from 8:30 to 4:30 p.m. on September 24 and 8:30 a.m. to adjournment on September 25, 1998. Attendance by the public will be limited to space available. The purpose of the meeting will be to update and review the progress of the Office of Alternative Medicine and obtain Council's advice on research activities. Additional agenda items include: (1) a report on current AM initiatives; (2) future AM initiatives; (3) AM Cancer trials; and (4) other business of the Council.

A public comment session is scheduled for September 25 from 10:15 a.m. to 11:15 a.m. Only one representative of an organization may present oral comments. Each speaker will be permitted 5 minutes for their presentation. Interested individuals and representatives of organizations must submit a letter of intent to present comments and three (3) typewritten copies of the presentation, along with a brief description of the organization represented, to the attention of Dr. Geoffrey Cheung, Office of Alternative Medicine, NIH, 31 Center Drive, MSC 2182, Building 31, Room 5B37, Bethesda, MD 20892, (301) 594-2013, FAX: (301) 594-6757. Letters of intent and copies of presentations must be received no later than 5:00 p.m. on Friday September 18.

Any person attending the meeting who does not request an opportunity to speak in advance of the meeting may be considered for oral presentation, if time

permits, and at the discretion of the Chairperson.

Ms. Odessa Colvin, Program Assistant, Office of Alternative Medicine, 31 Center Drive, MSC 2182, Building 31, Room 5B37, Bethesda, MD 20892, (301) 594-2013, will provide a summary of the meeting and a roster of Council members as well as substantive program information. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Colvin no later than September 17, 1998.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meeting timing limitations imposed by the review and funding cycle.

Dated: September 4, 1998.

Ms. Anna Snouffer,

Acting Committee Management Officer, NIH.

[FR Doc. 98-24649 Filed 9-14-98; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(a)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel General Clinical Research Centers Committee

Date: November 16-18, 1998

Time: November 16, 1998, 2:00 PM to Adjournment

Agenda: To review and evaluate grant applications

Place: Johns Hopkins University, Ross Building, Room G007, 720 Rutland Avenue, Baltimore, MD 21205

Contact Person: John J. Ryan, PhD, Scientific Review Administrator, Office of Review, National Center For Research Resources, 6705 Rockledge Drive, MSC 7965,