DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Safety Issues Pertaining to the Use of Flow Cytometry to Sort Human Cells for Clinical Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), is announcing the following public meeting: ''Safety Issues Pertaining to the Use of Flow Cytometry to Sort Human Cells for Clinical Applications.'' The public meeting is cosponsored by the International Society for Analytical Cytology (ISAC). The topics to be discussed are the scientific and technological issues related to developing voluntary safety protocols, which will be used to help ensure the safety of human cells that are sorted using flow cytometry for clinical applications.

Date and Time: The meeting will be held on April 20, 2001, from 9 a.m. to 5 p.m.

Location: The public meeting will be held in Wilson Hall, Building 1, National Institutes of Health, Bethesda, MD 20892.

Contact: Michele Keane-Moore, Center for Biologics Evaluation and Research (HFM–594), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–5102, FAX 301–827–5395, or e-mail to: keane-moore@cber.fda.gov.

Registration and Requests for Oral Presentations: Send or fax your registration information (including name, title, organization name, address, telephone, fax number, and e-mail address) and written material and requests to make oral presentations, to Michele Keane-Moore (address above) by Friday, April 13, 2001. There is no registration fee for the public meeting. Due to limited seating, interested parties are encouraged to register early. Registration at the site will be done on a space-available basis on the day of the workshop, beginning at 8 a.m.

If you need special accommodations due to a disability, contact Michele Keane-Moore at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The meeting on ''Safety Issues Pertaining to the Use of Flow Cytometry to Sort Human Cells for Clinical Applications'' will provide a forum for members of the public to discuss issues about maintaining the safety of cells prepared using flow cytometry.

The meeting is cosponsored by CBER and ISAC. The meeting will be of primary interest to public health professionals developing clinical protocols that use flow cytometry to sort human cells for readministration to patients and to manufacturers of these instruments. The objectives of the public meeting are to identify the safety issues related to using flow cytometry to sort populations of human cells and to establish a working group to formulate voluntary safety protocols that will help investigators ensure the safety and quality of cell-sorted products. The public meeting will specifically address: (1) The protection of flow cytometer operators from potential human pathogens, (2) the protection of the cellular product from contamination, (3) the cleaning and sterilization of the flow cytometer to help ensure a viable cellular product, and (4) other issues related to the development and adoption of these voluntary safety protocols.

Transcripts: Transcripts of the public meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the public meeting at a cost of 10 cents per page. The transcript will also be available on the Internet at http://www.fda.gov/cber/minutes/workshop-min.htm.

Dated: April 3, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–8641 Filed 4–6–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; a Follow-Up Survey of National Cancer Institute Science Enrichment Program Students

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the Nation Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: *Title:* A Follow-up Survey of National Cancer Institute Science Enrichment Program Students. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* This survey will investigate the long-term effects of the National Cancer Institute's Science Enrichment Program. The primary objective of the survey is to determine if past NCI SEP student participants are pursuing science education and science careers. The findings will provide information regarding the effectiveness of the program and will inform decisions about continuing and expand the program. *Frequency of Response:* One time. *Affected Public:* Individuals. *Type of Respondents:* Young adults (18–23 years old). The annual reporting burden is as follows: Estimated Number of Respondents: 930; *Estimated Number of Responses per Respondent:* 1; Average Burden Hours *Per Response:* .2500; and *Estimated Total Annual Burden Hours Requested:* 233. The annualized cost to respondents is estimated at $583. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Mr. Frank Jackson, Office of Special Populations Research, National Cancer Institute, National Institutes of Health, Executive Plaza South, Room 320, 6120 Executive Boulevard, Rockville, MD 20852, or call non-toll-free number (301) 496–8589, or E-mail your request, including your address to: *fj12i@nih.gov*

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before June 8, 2001.

Dated: April 2, 2001.

Reesa L. Nichols,

NCI Project Clearance Liaison.

[FR Doc. 01–8677 Filed 4–6–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute

Development of SH2 Domain Antagonists

An opportunity is available for a Cooperative Research and Development Agreement (CRADA) for the purpose of collaborating with the NCI intramural Laboratory of Medicinal Chemistry (LMC) on further research and development of U.S. government-owned technology encompassed within U.S. Patent Application Serial Nos. 60/126,047 entitled ''Phenylalanine Derivatives'' 60/226,671 entitled ''SH2 Domain Binding Inhibitors''; and, 60/221,525 entitled ''Inhibition of Cell Motility and Angiogenesis''.

AGENCY: National Cancer Institute, National Institutes of Health, PHS, DHHS.

ACTION: Notice of opportunity for Cooperative Research and Development Agreement (CRADA).

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; and Executive Order 12591 of April 10, 1987, as amended, the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks a Cooperative Research and Development Agreement (CRADA) with a pharmaceutical or biotechnology company to develop SH2 domain antagonists potentially useful for the treatment of cancers wherein the role of hepatocyte growth factor (HGF) in stimulating tumor invasiveness and metastasis is well-established. The CRADA would have an expected duration of one (1) to five (5) years. The goals of the CRADA include the rapid publication of research results and timely commercialization of products, methods of treatment or prevention that may result from the research. The CRADA Collaborator will have an option to negotiate the terms of an exclusive or non-exclusive commercialization license to subject inventions arising under the CRADA and which are subject of the CRADA Research Plan, and can apply for background licenses to the existing patent described above, subject to any pre-existing licenses already issued for other fields of use.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Dr. Bjarne Gabrielsen, Technology Transfer Branch, National Cancer Institute-Frederick Cancer Research & Development Center, Fairview Center, Room 502, Frederick, MD 21701 (phone: 301–846–5465, fax: 301–846–6820).

Scientific inquiries should be directed to Dr. Terrence Burke, Jr., Principal Investigator, Laboratory of Medicinal Chemistry, National Cancer Institute-Frederick, Bldg. 376, Rm 210, Frederick, MD 21702–1201 (phone: 301–846–5906; fax: 301–846–6033; e-mail tburke@helix.nih.gov).

EFFECTIVE DATE: Inquiries regarding CRADA proposals and scientific matters may be forwarded at any time. Confidential preliminary CRADA proposals, preferably two pages or less, must be submitted to the NCI on or before May 9, 2001. Guidelines for preparing final 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

DHHS scientists within the LMC, NCI, have discovered a novel class of compounds that bind with high affinity to Grb2 SH2 domains in extracellular assays and block Grb2-associated signaling in whole cell systems. These agents have been shown to inhibit Met-dependent growth factor-stimulated cell migration at low nanomolar concentrations. Details are in U.S. Patent Application Serial Nos. 60/126,047, 60/226,671 and 60/221,525 available under an appropriate Confidential Disclosure Agreement.

Technology Sought

Accordingly, DHHS now seeks collaborative arrangements to provide more extensive biological evaluation of both current and new inhibitors to Grb2-associated signaling under development within the Laboratory of Medicinal Chemistry, NCI. The ultimate purpose of the collaboration would be to develop the most promising agents into clinical trials against Met-dependent cancers. For collaboration with the commercial sector, a Cooperative Research and Development Agreement (CRADA) will be established to provide for equitable distribution of intellectual property rights developed under the CRADA. CRADA aims will include rapid publication of research results as well as full and timely exploitation of commercial opportunities.

NCI and Collaborator Responsibilities

The role of the LMC, NCI in this CRADA will include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience to the research project.
2. Providing the Collaborator with pertinent available compounds for investigation/evaluation.
3. Planning research studies and interpreting research results.
4. 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 technical expertise and/or financial support for CRADA-related research as outlined in the CRADA Research Plan.
4. 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 further 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 on-going research and development.
2. Expertise and experience in the following areas: Conducting extracellular ligand binding assays and providing IC_{50} values against a wide panel of relevant SH2 domains, including Grb2 SH2 domain, as well as protein-tyrosine binding domains and other potentially relevant signal transduction targets; conducting thorough examinations in whole cell assays of effects of inhibitors on intracellular signaling phenomena; examination of effects of inhibitors on cellular mitogenesis, motility, invasiveness and anti-angiogenic properties; conducting animal studies using relevant tumor model systems.
3.The demonstration of adequate resources to perform the research, development and commercialization 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.
4. The willingness to commit best effort and demonstrated resources to the research, development and commercialization of this technology.