II. Request for Data and Information

FDA is preparing for presentation of this issue to the NACMCF by developing a white paper, i.e., a summary of current information from scientific literature and other sources, that identifies and evaluates both the risks related to microbiological contamination of ready-to-eat food by food preparation workers and the effectiveness of different interventions to prevent or minimize that risk (e.g., hand washing, hand sanitizers, disposable gloves, no bare hand contact). In order to ensure that this white paper contains all available data relating to the risks and effectiveness of interventions to prevent or minimize contamination of ready-to-eat food, FDA is requesting scientific data, studies, or other information related to the following questions and issues:

1. FDA seeks scientific data or information on the risk of transmitting bacterial, viral, or parasitic pathogens from food preparation workers, via ready-to-eat food, to consumers, including scientific data and information relating to:

a. The amount of hand contact that can result in the transfer of pathogens;

b. Whether transient contact, such as might occur when placing a garnish on a plate or glass, can transfer pathogens;

c. Whether pathogens can be transferred to raw produce while washing it, if bare hands are used; and

d. Whether bare hands can transmit pathogens to dry food like toast or rolls.

2. FDA seeks scientific data or information on the effectiveness of alternative interventions, either alone or in combination, including scientific data and information relating to:

a. Hand washing with soap:

i. What constitutes a properly done hand wash;

- How long should the hand-washing process last;
- What is the optimum temperature of the water;
- Whether the use of a nailbrush increases removal of pathogens;
- Whether it is likely that a nailbrush would become a fomite, that is, become contaminated, and transmit bloodborne or enteric pathogens to subsequent users;
- How long before subdermal pathogens recontaminate the skin's surface; and
- Whether hand-drying methods have an impact on microbial reduction.

ii. Whether a double hand wash is significantly better than a properly done single wash.

b. Hand-washing machines; whether the use of a hand-washing machine can be the ''equivalent'' to a properly done hand wash, and if so, under what conditions.

c. Use of ''hand sanitizers:''

i. Whether human skin can be ''sanitized;''

ii. Whether chemical hand sanitizers are effective against all pathogens of concern;

iii. Whether subdermal pathogens can recontaminate the skin and, if so, how long it would take; and

iv. Whether the use of hand sanitizers can increase the number of pathogens on hands.

d. Use of disposable gloves:

i. Whether pathogens can increase in numbers on gloved hands;

ii. Whether gloves are likely to become fomites themselves even when properly used, e.g., as they are being put on; and

iii. Whether glove use procedures used in other venues are applicable in retail food establishments.

e. Whether there are other interventions that should be considered to prevent or minimize microbial contamination of ready-to-eat food by food preparation employees.

Finally, FDA is also interested in views on whether additional studies, either microbiological or epidemiological, are needed to fill existing knowledge gaps; and, if so, what kind of studies should be done.

Interested persons may, on or before June 1, 1999, submit to the Dockets Management Branch (address above) the required data and information. Two copies of the data and information should be submitted, except that individuals may submit one copy. Data and information are to be identified with the docket number found in brackets in the heading of this document. Received data and information may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 25, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–8095 Filed 4–1–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Grants and Cooperative Agreements Availability

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

ACTION: Notice for CRADA Opportunities.

SUMMARY: New HIV treatments and diagnostic methods: Opportunities for Cooperative Research and Development Agreements (CRADAs) for the joint evaluation and development of inhibitors for multidrug resistant HIV and of methods to measure the biological and biochemical fitness of HIV protease mutants, and to assay new protease inhibitors using these methods.

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 by the National Technology Transfer and Advancement Act of 1995), 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 Cooperative Research and Development Agreements (CRADAs) with pharmaceutical or biotechnology companies to evaluate and develop new treatments and diagnostic methods for the multidrug resistant HIV-infected population. Any CRADA for the biomedical use of this technology will be considered. 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, diagnostics and treatments that result from the research. The CRADA Collaborator will have an option to elect a non-exclusive or exclusive commercialization license to subject inventions arising under the CRADA and which are subject of the CRADA Research Plan.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Dr. Bjarne Gabrielsen, Technology Development & Commercialization 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—Dr. John Erickson, Director, Structural Biochemistry Program, National Cancer Institute—Frederick Cancer Research & Development Center, P.O. Box B, Building 560, Room 12–68, Frederick MD, 21702–1201 (phone: 301–846–1979; FAX: 301–846–6066).

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

3, 1999. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents who have been selected.

SUPPLEMENTARY INFORMATION:

Technology Available

DHHS scientists in the Structural Biochemistry Program, NCI-Frederick Cancer Research and Development Center (SBP) have developed certain structural and biochemically-based technologies that are believed to be of value in the diagnosis and treatment of drug resistant HIV. Using these technologies, SBP scientists have developed strategies for designing inhibitors to multidrug resistant HIV, and for predicting resistance-potentials of HIV protease inhibitors. Recent evidence indicates that multidrug resistant HIV strains are appearing in the drug-naïve population at an increasing rate. Thus, the SBP research is believed to be at a stage that is ripe for the development of new treatments and diagnostic methods for the multidrug resistant HIV-infected population. SBP is interested in a multi-disciplinary but highly focussed approach to the biochemical and virologic evaluation of protease inhibitors against clinically-derived drug resistant mutant viruses, as well as in the structure-based design and chemical synthesis of new protease inhibitors for testing.

The successful Collaborator should possess experience in the following areas at a minimum: Experience with pre-clinical and clinical drug development for antiretroviral compounds; ability to generate site-directed mutant viruses for measurement of phenotypic resistance with specific expertise in HIV; application of automation and robotics technologies to cell culture-based antiviral assays and to enzyme-based biochemical assays with specific expertise in HIV; application of automation and robotics technologies to cell culture-based assays designed to measure phenotypic resistance; application of database and bioinformatics technologies for the manipulation, storage and analysis of high throughput assay data, including the development of software as required; and, the use of high throughput assay methods to evaluate protease inhibitors against multidrug resistant HIV mutants.

DHHS now seeks collaborative arrangements for the joint evaluation and development of methods to biochemical and virologic evaluate protease inhibitors against clinically-derived drug resistant mutant viruses, as well as in the structure-based design and chemical synthesis of new protease inhibitors for further analysis. For collaborations with the commercial sector, a Cooperative Research and Development Agreement (CRADA) will be established to provide 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 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 to the research project.
2. Providing the Collaborator with HIV drug resistant gene sequences and protease inhibitors for 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 (e.g. facilities, personnel and expertise) for CRADA-related Government activities.
4. Accomplishing objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.
5. The willingness to commit best effort and demonstrated resources to the research, development and commercialization of this technology.
6. The demonstration of expertise in the commercial development, production, marketing and sales of products related to this area of technology.
7. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.
8. 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.
9. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern patent rights to CRADA inventions.

Dated: March 25, 1999.

Kathleen Sybert,

Director, Technology Development & Commercialization Branch, National Cancer Institute, National Institutes of Health.

[FR Doc. 99–8097 Filed 4–1–99; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting of the Working Group To Advise the ACD on Guidelines and Oversight Process for Research Involving Human Pluripotent Stem Cells

Notice is hereby given that the Working Group of the Advisory Committee to the Director (ACD), NIH to advise the ACD on guidelines and oversight for research involving human pluripotent stem cells, will meet in public session at the Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, Maryland 20814, on April 8, 1999. The meeting will begin at approximately 9:00 a.m. and end at approximately 5:30 p.m.

The goal of the Working Group is to provide advice to the ACD about the scientific, ethical, legal, and social issues relevant to guidelines for the conduct of research utilizing human pluripotent stem cells (cells that can form most of the cells and tissues of the body) and to consider oversight options for this research.

A limited amount of meeting time will be allotted for public testimony. Individuals who wish to give five minute public testimony may sign up at the meeting site the morning of the meeting on a first come, first served basis. Written testimony may be submitted to: the Office of Science Policy, Bldg. 1, Room 218, NIH, 9000 Rockville Pike, Bethesda 20892.

Attendance may be limited to seat availability.

Ruth L. Kirschstein,

Deputy Director, NIH.

[FR Doc. 99–8096 Filed 4–1–99; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Center for Scientific Review Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should