document provides guidance for industry on how FDA interprets the Federal Advisory Committee Act (FACA) with respect to the disclosure of materials provided to advisory committees convened by the Center for Drug Evaluation and Research (CDER).

DATES: Written comments may be submitted on the guidance document by February 28, 2000. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000.'' The document provides guidance on how FDA interprets the FACA (5 U.S.C. App. 2) and § 314.430 (21 CFR 314.430) with respect to the disclosure of materials provided to advisory committees and how FDA will exercise its discretion under § 314.430(d)(1) in connection with open advisory committee meetings convened by CDER beginning on January 1, 2000.

FDA construes the FACA to require that, with respect to any open advisory committee meeting convened pursuant to the FACA, whenever practicable and subject to any applicable exemptions of the Freedom of Information Act (FOIA) (5 U.S.C. 552), those materials that are provided to the members of an advisory committee in connection with that meeting must be made available for public inspection and copying before or at the time of the advisory committee meeting. FDA interprets § 314.430 to be consistent with the FACA and therefore will exercise its discretion under § 314.430(d)(1) in a manner consistent with the FACA and the FOIA as described in the previous sentence to make available for public inspection and copying materials provided to the members of an advisory committee in connection with open advisory committee meetings convened by CDER, beginning on January 1, 2000.

FDA will issue further guidance on what sponsors may expect concerning the disclosure of the materials they submit to advisory committees in connection with open advisory committee meetings convened by CDER beginning on January 1, 2000.

This level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It is being implemented immediately without prior public comment because the guidance is needed to implement a court-approved settlement agreement. However, the agency wishes to solicit comment from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

The guidance represents the agency's current thinking on the disclosure of materials provided to advisory committees in connection with open advisory committee meetings convened by CDER beginning on January 1, 2000. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 22, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–30955 Filed 11–29–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Antitumor and Antimicrobial Lead—Discovery and Development From Natural Products

Opportunities for Cooperative Research and Development Agreements (CRADAs) are available for collaborations with the NCI intramural Laboratory of Drug Discovery Research and Development (LDDRD) to discover and identify novel antitumor and antimicrobial leads from natural products. Collaborative projects will focus upon cancer and/or areas of infectious diseases of high public health significance and high national and international priority.

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

ACTION: Notice of opportunities for Cooperative Research and Development Agreements (CRADAs).

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 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 one or more Cooperative Research and Development Agreements (CRADAs) with pharmaceutical or biotechnology companies to discover and develop new potential antitumor and/or antimicrobial drug leads from natural products. 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.

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 inquires should be submitted to Dr. Michael R. Boyd, Chief, Laboratory of Drug Discovery Research & Development, National Cancer Institute—Frederick Cancer Research & Development Center, Bldg. 1052, Rm 121, Frederick MD, 21702–1201 (phone: 301–846–5391; Fax: 301–846–6919; e-mail boyd@dtpax2.ncifcrf.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 January 31, 2000. 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:

The LDDRD is an NCI intramural research laboratory dedicated to the discovery of new potential lead molecules for antitumor and/or antimicrobial drug development. Some general background and contact information for the LDDRD are available on the Internet at http://dtp.nci.nih.gov/docs/branches/lddrd/lddrd__home.html.

The primary starting materials for LDDRD's discovery research principally comprise the remarkable library of natural product extracts residing in the NCI Natural Products Repository (NPR).

The NPR contains the largest and most diverse natural products extracts collection in the world, derived during the past 15 years from an NCI contracts-based collections consortium led by renowned botanical, marine science and microbial research professionals and organizations globally. Most of these collections have been performed subject to legally-binding agreements between the NCI and relevant Source Country organizations or government agencies which commit the NCI to terms of collaboration and compensation in the event of discovery of a compound which meets the criteria for drug development. Even in instances where no agreement has been signed, the NCI still considers itself bound to the same policies of collaboration and compensation. Therefore, CRADA partners will be subject to similar requirements to those governing the NCI. (Further information may be obtained from the NCI—Developmental Therapeutics Program website, http://dtp.nci.nih.gov).

The LDDRD also engages in selected lead-discovery collaborations based upon natural product extracts originating directly from specific collaborating researchers or organizations rather than from the NCI–NPR. In such cases, collaborative projects are undertaken based both upon unique and mutual scientific and drug discovery and development interests, expertise and resources of the collaborating parties.

LDDRD's principal lead-discovery strategy employs bioassay-guided fractionation, isolation, purification and structural elucidation of bioactive molecules. The sought-for bioactivity is defined by the specific type(s) of assay and/or target(s) employed in the primary screen(s) used for bioassay support of the process.

The LDDRD comprises an interdisciplinary research team, and appropriate resources, expertise and experience, to carry out all essential aspects of natural products lead-discovery, including high-throughput screening, cell-based bioassays, chemical isolation, purification and structural determinations.

Technology Sought

LDDRD now seeks potential collaborators with expertise or resources in several areas including but not limited to: novel screening technologies, bioassays, reagents or targets; synthetic chemistry capabilities pertinent to the specific collaboration; novel or distinctive extract and/or compound collections; preclinical and/or clinical drug research and development expertise and experience; proven track record in moving preclinical lead-discoveries through lead-optimization, drug candidate selection, preclinical and clinical development, regulatory approvals, and commercialization.

Collaborators Sought:

Accordingly, DHHS now seeks collaborative arrangements for the joint LDDRD and collaborator discovery research and development of novel, natural product lead-derived, clinically useful, antitumor and/or antimicrobial drugs of high public health priority. For collaborations 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 any commercial opportunities.

As a minimum, the successful Collaborator should either possess broad experience in most if not all of the following areas; or possess highly specialized, unique expertise in one or more of the following areas, as particularly pertinent to natural products lead-discovery and development: (a) Preclinical and clinical drug development; (b) ability to carry out or direct chemical synthetic studies supporting lead-optimization, drug candidate selection and development; (c) application of automation and robotics technologies to antitumor and/or antimicrobial high-throughput screening (HTS) assays; (d) experience with other pertinent enzyme-based, biochemical, cellular *in vitro* and/or *in vivo* assays; (e) application of database and bioinformatics technologies for the manipulation, storage and analysis of high-throughput assay data, including the development of software as required; (f) the use of high-throughput assay methods to support antitumor and/or antimicrobial lead-discovery from natural products; (g) elucidation and validation of novel antitumor and/or antimicrobial molecular targets; and, (h) specific experience in development and applications of lead-discovery HTS assays addressing novel antitumor and/or antimicrobial molecular targets.

NCI and Collaborator Responsibilities

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 isolated lead-molecules 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. Providing essential research materials, such as extracts, enzymes or other reagents, compounds, hardware or software.

3. Planning research studies and interpreting research results,

4. Providing technical expertise and/or financial support (*e.g. facilities, personnel and expertise) for CRADA-related research as outlined in the CRADA Research Plan.*

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 research and development of this technology involving lead discovery/optimization and biological evaluation.

This ability can be demonstrated through experience, expertise, and the ability to contribute intellectually in this or related areas of drug developmental research and development.

2. The demonstration of adequate resources to perform the research, development and commercialization of this lead discovery/optimization and biological evaluation 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, development and commercialization of this technology as defined above.

4. The demonstration of expertise in the commercial development, production, marketing and sales of antitumor and/or antimicrobial natural products.

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

6. 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.

7. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the equitable 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 non-exclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated: November 19, 1999.

Kathleen Sybert,

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

[FR Doc. 99–30996 Filed 11–29–99; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(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 Cancer Institute Initial Review Group, Subcommittee E—Cancer Epidemiology, Prevention & Control.

Date: December 6–7, 1999.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Georgetown Holiday Inn, 2101 Wisconsin Ave, NW, Washington, DC 20007.

Contact Person: Mary C. Fletcher, PhD., Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard, EPN-Room 643G, Bethesda, MD 20814, 301/496–7413.

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

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 23, 1999.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 99–31002 Filed 11–29–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(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 Cancer Institute Special Emphasis Panel, Trustees of Indian University.

Date: December 13, 1999.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: 6116 Executive Boulevard, 8th Floor, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Ray Bramhall, PhD, Scientific Review Administrator, Special Review, Referral and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Blvd, Rockville, MD 20892, (301) 496–3428.

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

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 23, 1999.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 99–31003 Filed 11–29–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Alternative Medicine; 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 the Cancer Advisory Panel for Complementary and Alternative Medicine (CAPCAM) meeting on Monday, December 13, 1999. The meeting will be held at the Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, Maryland 20814.

The meeting will be open to the public, with attendance limited to space available. The agenda includes: Remarks from the Director, NCCAM; CAPCAM Chair; and Director, OCCAM, NCI,