carrier manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the consultation must occur before publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Health Care Financing Administration not later than December 31 of each year.

The Council consists of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under Medicare or Medicaid in the previous year. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members must be doctors of medicine or osteopathy authorized to practice medicine and surgery by the States in which they practice. Members have been invited to serve for overlapping 4-year terms. In accordance with section 14 of the Federal Advisory Committee Act, terms of more than 2 years are contingent upon the renewal of the Council by appropriate action before the end of the 2-year term.

The Council held its first meeting on May 11, 1992.

The current members are: Richard Bronfman, D.P.M.; Wayne R. Carlsen, D.O.; Gary C. Dennis, M.D.; Catalina E. Garcia, M.D.; Mary T. Herald, M.D.; Ardis Hoven, M.D.; Sandral Hullett, M.D.; Jerilynn S. Kaibel, D.C.; Marie G. Kuffner, M.D.; Marc Lowe, M.D.; Katherine L. Markette, M.D.; Derrick K. Latos, M.D.; Susan Schooley, M.D.; Maisie Tam, M.D.; and Kenneth M. Viste, Jr., M.D. The chairperson is Kenneth M. Viste, Jr., M.D.

Council members will receive an update on documentation guidelines, physician practice expense, private contracting, physician self referral rules, privacy and confidentiality, regional labaratory carriers, and other issues related to implementation of the Balanced Budget Amendment.

Individuals or organizations that wish to make 5-minute oral presentations on the agenda issues should contact the Executive Director by 12 noon, December 4, 1997, to be scheduled. The number of oral presentations may be limited by the time available. A written copy of the oral remarks should be submitted to the Executive Director no later than 12 noon, December 10, 1997. Anyone who is not scheduled to speak may submit written comments to the Executive Director by 12:00 noon, December 10, 1997. The meeting is open to the public, but attendance is limited to the space available.

(Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, section 10(a)); 45 CFR Part 11)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 27, 1997.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 97–31594 Filed 12–2–97; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Scientific and Commercial Development of Transgenic Mice That Express Human Cytochrome P450 Genes

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (DHHS) seeks an agreement with a pharmaceutical or biotechnology company to effectively pursue the development and characterization of transgenic mice that express human cytochrome P450 genes CYP2D6 and CYP3A4. The National Cancer Institute has data suggesting that these animals may be useful in drug development, carcinogen bioassays for risk assessment, and the determination of genetic regulatory mechanisms.

ADDRESSES: Proposals and questions about this opportunity may be addressed to Robert Dell'Orco, Ph.D., Technology Development and Commercialization Branch, National Cancer Institute, Executive Plaza South, Suite 450, 6120 Executive Blvd., Rockville, MD 20852, tel: 301–496–0477, fax: 301–402–2117.

DATES: In view of the important priority of developing new drugs for the treatment of cancer and methods for determining carcinogenic risk, interested parties should notify this office in writing not later that January 2, 1998. Respondents will then be provided an additional 30 days for filing of formal proposals.

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 April 10, 1987 as amended by the National Technology Transfer Advancement Act of 1995 to collaborate on the specific research project described below.

The National Cancer Institute seeks an agreement with a pharmaceutical or biotechnology company for joint development and evaluation of transgenic mice that express human cytochrome P450 genes CYP2D6 and CYP3A4 in a tissue specific manner that reflects the expression in humans. These two human P450 enzymes are involved in the metabolism of over 75% of the drugs that are now on the market; however, these two enzymes are poorly conserved between rodents and humans. This poor conservation precludes the use of unmodified rodent model systems for the analysis of new drugs with respect to their metabolism by these two enzymes. The development of a human P450 transgenic mouse system will allow for the determination of human metabolism and toxicity of new drugs, the prediction of drug interactions, and the definition of pharmacokinetic parameters in an intact animal system. Additionally, such a system would avoid the utilization of human liver tissue samples which forms the basis of the current methods used in the pharmaceutical industry. The animal model would also form the basis of carcinogen bioassays for human risk assessment and allow for the analysis of P450 gene regulation. In the proposed studies, the animals will be used to determine the tissue specific degradation of drugs. Drugs known through in vitro metabolism studies to be metabolized by CPY2D6 and CYP3A4 will be administered to the transgenic mice, and their pharmacokinetics will be studied.

The Laboratory of Metabolism has many years of experience in cloning and characterizing human P450 genes. More recently, the laboratory has developed a series of knockout and transgenic mice to study various aspects of the role of cytochrome P450 enzymes in carcinogenesis and drug metabolism; and the development of transgenic mice with the human CYP2D6 and CYP3A4 enzymes is a continuation of the laboratory's commitment to this research area. The Laboratory of Metabolism is interested in establishing a CRADA with a company to assist in the continuing development of transgeic animals containing human cytochrome P450 enzymes to study known drug substrates and proprietary drug candidates. The Government will

provide all available expertise and information to date giving the company full access to existing data and data developed pursuant to the CRADA.

The successful company will provide the necessary scientific, financial and organizational support to characterize and test the animals.

Background information is available from the above-referenced address. Patent applications and pertinent information not yet publicly described can be obtained under a Confidential Disclosure Agreement.

The CRADA aims include the rapid publication of research results and the timely exploitation of commercial opportunities. The CRADA partner will enjoy rights of first negotiation for licensing Government rights to any inventions arising within the scope of the agreement. The license option and commercialization of inventions shall not conflict with NIH Guidelines for the availability of transgenic/knockout animals (http://www1.od.nih.gov/wals/transgen.html).

The expected duration of the CRADA will be 2 years.

The role of the Laboratory of Metabolism in this CRADA will be as follows:

1. Isolate and characterize genomic clones of human CYP2D6 and CYP3A4.

2. Generate mice by standard injections of oocyte pronuclei and screen founders.

3. Characterize tissue specificity of expression.

4. Jointly publish research results.

The role of the Collaborator will be:

1. Characterize in vitro metabolism using hepatic microsomal fractions.

2. Evaluate in vivo pharmacokinetics with probe substrates and proprietary compounds.

3. Analyze the role of CYP2D6 and CYP3A4 on bioavailability and efficacy of test compounds.

4. Jointly publish research results.

Selection criteria for choosing the CRADA partner will include but not be limited to:

1. Ability to collaborate with NCI on further research and development of this technology. Demonstration of experience and expertise in this or related areas of technology and the ability to provide intellectual contribution to the ongoing research and development. Ability to accomplish objectives according to an appropriate timetable to be outlined in the Collaborator's proposal.

2. Willingness to comply with NIH IRP Guidelines for the Availability of Transgenic/Knockout Animals (http://www1.od.nih.gov/wals/transgen.html). The proposal should specifically address the methods by which the animals will be made available.

3. Demonstration of the resources (facilities, personnel and expertise) necessary to perform research, development and commercialization of this technology.

4. Commitment of reasonable effort and resources on research, development and commercialization of this technology.

5. Expertise in the commercial development, production, marketing and sales of products related to this area of technology.

6. The level of financial support the Collaborator will supply for CRADA-related Government activities.

7. A willingness to cooperate with the National Cancer Institute in the publication of research results.

8. An agreement to be bound by the DHHS rules involving human subjects, patent rights and ethical treatment of animals.

9. A willingness to accept the legal provisions and language of the NIH model CRADA with modifications to address selection criteria #2 and other minor modifications.

10. Provisions for 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 negotiate an exclusive or nonexclusive license to the company on terms that are appropriate (when the Government employee is the sole inventor).

Dated: November 21, 1997.

Kathleen Sybert,

Acting Director, Technology Development and Commercialization Branch, National Cancer Institute, NIH.

[FR Doc. 97–31638 Filed 12–2–97; 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 National Cancer Institute Special Emphasis Panel (SEP) meeting:

Name of SEP: Cancer Genetics Network—Informatics and Information Technology Group.

Date: December 9–10, 1997.

Time: December 9–7:30 p.m. to Recess. December 10—8:00 a.m. to Adjournment.

Place: Ramada Inn—Rockville, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Gerald Lovinger, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 630C, 6130 Executive Boulevard, MSC 7405, Bethesda, MD 20892–7405, Telephone: 301/496–7987.

Purpose/Agenda: To review, discuss and evaluate grant applications.

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

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

(Catalog of Federal Domestic Assistance Program Numbers: 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)

Dated: November 25, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–31636 Filed 12–02–97; 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 of the National Cancer Institute Special Emphasis Panel (SEP):

Name of SEP: Informatics Support for Breast and Colon Cancer Cooperative Family Registries.

Date: December 8, 1997.

Time: 9:00 a.m. to Adjournment.

Place: Executive Plaza North, Conference Room C, 6130 Executive Boulevard, Bethesda, MD 20892.

Contact Person: Courtney M. Kerwin, Ph.D., M.P.H., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 630I, 6130