racemates. The agency believes that this issue would benefit from a more focused consideration than it was subject to in the rulemaking process for the regulations implementing the 1984 amendments, where there were many complicated and contentious regulatory matters under consideration, and where this issue was raised by one comment submitted very late in the rulemaking process. Accordingly, FDA is requesting comments on the appropriate period of marketing exclusivity for drug products whose active ingredient is a single enantiomer of a racemate that is an active ingredient of a previously approved drug product. Among the issues that the agency is interested in receiving comment on are as follows:

(1) What period of marketing exclusivity would best effectuate the 1984 amendments' dual policy goals of increasing drug price competition and providing incentives for the development of innovative drug products?

(2) Would granting a 5-year period of exclusivity to enantiomers of previously approved racemates encourage medically significant pharmaceutical innovation?

(3) If the pharmacological action of each enantiomer is described in the approved NDA for the racemate, should a subsequently submitted application for an enantiomer of the racemate receive different treatment for exclusivity purposes than if the pharmacological action of each enantiomer is not described in the approved NDA for the racemate drug product?

(4) If the agency were to assess requests for exclusivity for enantiomers of previously approved racemates on a case-by-case basis, what criteria should the agency apply?

(5) Compared with other drug products, what are the costs of and technical barriers to obtaining safety and efficacy data for a drug product whose active ingredient is a single enantiomer of a previously approved racemate?

(6) How many drug products (whether approved, the subject of pending NDA's, or in development) are likely to be affected by this policy?

After considering comments received in response to this notice, FDA will publish a Federal Register notice setting forth its policy on exclusivity for a drug product whose active ingredient is an enantiomer of a previously approved racemate.

Interested persons may, on or before March 17, 1997, submit to the Dockets Management Branch (address above) written comments regarding this notice. 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. Copies of the comment on exclusivity for enantiomers submitted to the docket for the July 10, 1989, proposed rule; FDA's Stereoisomeric Drug Policy; and other correspondence and documents relating to the subject matter of this notice have been placed in the docket for this notice. Received comments and other material placed in the docket may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Persons considering submitting a 505(b)(2) application or an ANDA for a drug product that may be affected by any change in FDA's policy on marketing exclusivity for enantiomer drug products should contact the Center for Drug Evaluation and Research's (CDER's) Office of Generic Drugs or the appropriate review division within CDER before submitting the application.

Dated: January 10, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–944 Filed 1–10–97; 12:29 pm]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Program Announcement for Grant Programs Administered by the Division of Associated, Dental and Public Health Professions, Bureau of Health Professions for Fiscal Year 1997

Correction

In notice document 96–28112 appearing on page 56550 on the issue of Friday, November 1, 1996 make the following correction:

On page 56550, in the table on the fourth line titled ''Public Health Special Projects'' in the fourth column under the column heading ''Available for competing awards'', the amount should read ''$2,500,000''.

Dated: January 7, 1997.

Ciro V. Sumaya,

Administrator.

[FR Doc. 97–943 Filed 1–14–97; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

National Cancer Institute; Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Scientific and Commercial Development of Monoclonal Antibodies to a Tumor-Specific Growth Factor for the Diagnosis and Prognosis of Premalignant Lesion and Cancer

AGENCY: National Institutes of Health, DHHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks a pharmaceutical or biotechnology company that can effectively pursue the scientific and commercial generation and development of a panel of monoclonal antibodies against an epidermal growth factor (EGF)-related peptide, cripto-1 (CR–1) and its novel receptor. The project is of scientific importance because CR–1 is a protein that exhibits structural homology to the EGF / transforming growth factor α (TGFα) gene family of peptides. As such, CR–1 might function as a growth or survival factor. Therefore, CR–1 may be important as an autocrine or paracrine modulator in such processes a tumor cell growth, wound repair, neovascularization, inflammation, and apoptosis.

NCI has successfully isolated and cloned the gene that encodes CR–1, an EGF-related peptide growth factor that does not bind to the EGF receptor or other type 1 receptor tyrosine kinases. The NCI has also obtained a rabbit anti-peptide polyclonal antibody that can detect the expression of CR–1 in formalin-fixed, paraffin-embedded human tissue sections. CR–1 has been shown to be preferentially and differentially expressed in several different human premalignant lesions and cancers. The selected sponsor will purify a recombinant CR–1 protein and use this material as an immunogen to generate anti-CR–1 monoclonal antibodies for use in the diagnosis and prognosis of human cancers.

ADDRESSES: Inquiries and proposals regarding this opportunity should be sent to Richard I. Kohn, J.D., M.S., Office of Technology Development, National Cancer Institute, as follows: (a) *by U.S. Mail to:* Executive Plaza South, Room 450, 6120 Executive Blvd., MSC 7182, Bethesda MD 20892–7182; (b) *By messengers and express delivery to:* 6120 Executive Blvd, Suite 450, Rockville, MD 20852; (c) *by telephone at* (301) 496–0477; (d) *by fax at* (301) 402–2117.

DATES: Written proposals must be received at the above address by 5:00 p.m. on March 17, 1996.

SUPPLEMENTARY INFORMATION: The NCI is seeking a pharmaceutical or biotechnology company which, after obtaining a license in accordance with the requirements of the regulations governing the transfer of Government-developed rights, (37 CFR part 404), can purify a recombinant CR–1 protein (for which patents are pending or have been issued) and utilize this purified recombinant CR–1 protein as an immunogen to generate a panel of mouse monoclonal antibodies. The immunoreactive CR–1 protein has been detected by immunoperoxidase staining using a rabbit anti-peptide polyclonal CR–1 antibody in a majority of human colon cancers, breast cancers, gastric cancers, and pancreatic cancers. Little or no staining was detected in surrounding, noninvolved colon, breast or gastric epithelial cells. In addition, a majority of premalignant colonic adenomas, breast ductal carcinomas *in situ* and gastric intestinal metaplasia express immunoreactive CR–1.

A recombinant CR–1 protein has been generated using a baculovirus expression vector in Sf-9 insect cells and a partially purified protein obtained. This protein as well as synthetic, refolded peptides that correspond to the EGF-like domain in CR–1 are mitogenic for human breast cancer cells and can modulate milk protein expression, yet fail to bind to the EGF receptor or other type I receptor tyrosine kinases. Expression of CR–1 antisense mRNA using a recombinant, replication defective retroviral expression vector in colon cancer cells that expresses CR–1 inhibits the growth of these cells *in vivo* in nude mice. In order to utilize diagnostic and therapeutic potentials of CR–1, it will be necessary to purify a significant amount of the recombinant CR–1 protein to more fully define its biological properties and to identify the receptor through which it functions. In addition, mouse monoclonal antibodies against the purified CR–1 recombinant protein will expedite screening studies for CR–1 expression in other human premalignant lesions and cancers and should exhibit more specificity and sensitivity for the detection of CR–1 in tissues by immunocytochemistry (ICC) or in tissue extracts or serum samples by ELISA.

The United States Public Health Service owns the following issued patents which may be relevant to the subject technology:

1. United States Patent No. 5,264,557, issued November 23, 1993, ''Human CRIPTO-Related Gene.''

2. United States Patent No. 5,256,643, issued October 26, 1993, ''Cloned Human CRIPTO Gene and Applications Thereof.''

Questions regarding licensing should be directed to Joseph Hemby, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, #325, Rockville, MD 20852–3804, telephone (301) 496–7056.

The role of the National Cancer Institute, Division of Basic Sciences, includes:

1. NCI will provide vectors that encode CR–1 and can be used to produce CR–1 in *E. coli* and in Sf-9 insect cells.

2. NCI will provide a rabbit polyclonal anti-CR–1 antibody for monitoring CR–1 recovery during the purification from the yeast conditioned medium.

3. NCI will assay the purified recombinant CR–1 protein for bioactivity.

4. NCI will screen anti-CR–1 monoclonal antibodies for reactivity by Western blot analysis against native CR–1 protein from CR–1 positive human embryonal carcinoma or colon carcinoma cells.

The role of the successful collaborator will include:

1. Purify to homogeneity 30–50 milligrams of CR–1 from *E. coli* or Sf-9 insect cell conditioned medium.

2. Provide the purified recombinant CR–1 protein.

3. Utilize the purified recombinant CR–1 protein to generate mouse anti-CR–1 monoclonal antibodies.

4. Screen anti-CR–1 monoclonal antibodies for specificity, reactivity, and sensitivity towards the recombinant CR–1 protein.

5. Ascertain whether monoclonal anti-CR–1 antibodies can detect nature CR–1 protein in CR–1 positive human colorectal or embryonal carcinoma cells by radioimmunoprecipitation analysis and by ELISA.

6. Determine whether anti-CR–1 antibodies can be used for ICC on formalin-fixed, paraffin embedded tissues known for CR–1 expression.

7. Provide funds to support a postdoctoral fellow and associated expenses.

Criteria for choosing the collaborator will include:

1. Experience in producing and purifying recombinant proteins, particularly growth factors or cytokines.

2. Experience in generating and screening monoclonal antibodies.

3. Willingness to cooperate with the NCI in the collection and evaluation of data.

4. Willingness to cost share in laboratory expenses.

5. And agreement to be bound by the DHHS rules involving the use of human and animal subjects and human tissues.

6. Provisions for equitable distribution of patent rights to any inventions. Generally, the rights of ownership are retained by the organization(s) which is/are the employer(s) of the inventor. For inventions made solely by the collaborator's employees, there shall be a grant to the Government of a nonexclusive, nontransferable, irrevocable, paid up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government for research or other Government purposes. For inventions not made solely by the collaborator's employees, there shall be a grant to the collaborator of an option to elect an exclusive or nonexclusive commercialization license.

Dated: December 9, 1996.

Thomas Mays,

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

[FR Doc. 97–1004 Filed 1–14–97; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Drug Abuse; 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 National Institute on Drug Abuse (NIDA) Initial Review Group and Special Emphasis Panel meetings.

Purpose/Agenda: To review and evaluate grant applications.

Name of Committee: Human Development Research Subcommittee.

Date: February 11–12, 1997.

Time: 8:30 a.m.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Kesinee Nimit, M.D., Scientific Review Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10–22, Telephone (301) 443–9042.

Name of Committee: Neuropharmacology Research Subcommittee.

Date: February 11–12, 1997.

Time: 8:30 a.m.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Syed Husain, Ph.D, Scientific Review, Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10–22, Telephone (301) 443–2620.