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.