Studies of Adverse Effects of Marketed Drugs, Biologics, and Devices; Availability of Grants (Cooperative Agreements); Request for Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of February 5, 1997 (62 FR 5429). The document announced the availability of $1.4 million in Fiscal Year 1997 funds for cooperative agreements to study adverse effects of marketed drugs, biologics, and devices. The document was published with an incorrect application acceptance date. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Robert L. Robins, Grants Management Officer, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, Park Bldg., rm. 3–40, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6170.

In FR Doc. 97–2870, appearing on page 5429, in the Federal Register of Wednesday, February 5, 1997, the following correction is made:

1. On page 5432, in the first column, in the first full paragraph, in line four, ''March 14, 1997'' is corrected to read ''March 21, 1997''.

Dated: February 7, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–3660 Filed 2–12–97; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Institute of Child Health and Human Development: Licensing Opportunity and/or Opportunity for a Cooperative Research and Development Agreement (CRADA) for Novel Progesterone Antagonists and Pharmaceutical Compositions Thereof

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health is seeking licensees and/or CRADA partners for the further development, evaluation, and commercialization of novel progesterone antagonists and pharmaceutical compositions thereof. The invention claimed in U.S. Patent Application 60/016,628 entitled ''21-Substituted Progesterone Derivatives As New Antiprogestational Agents'' (HK Kim, RP Blye, PN Rao, JW Cessac, and CK Acosta), filed May 1, 1996, is available for either exclusive or non-exclusive licensing (in accordance with 35 U.S.C. 207 and 37 CFR part 404) and/or further development under a CRADA for clinical and research applications described below in **SUPPLEMENTARY INFORMATION.**

To expedite the research, development, and commercialization of this new class of drugs, the National Institutes of Health is seeking one or more license agreements and/or CRADAs with pharmaceutical or biotechnology companies in accordance with the regulations governing the transfer of Government-developed agents. Any proposal to use or develop these drugs will be considered.

DATES: There is no deadline by which license applications must be received. CRADA proposals must be received on or before May 14, 1997.

ADDRESSES: CRADA proposals and questions about this opportunity should be addressed to Dr. Diana Blithe, Contraceptive Development Branch, Center for Population Research, National Institute of Child Health and Human Development, 6100 Executive Boulevard, Room 8B13, Bethesda, Maryland 20892; Telephone: 301/496–1661.

Licensing proposals and questions about this opportunity should be addressed to Ms. Carol Lavrich, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; Telephone: 301/496–7735, ext. 287.

Information about the patent application and pertinent information not yet publicly described can be obtained under a Confidential Disclosure Agreement. Respondees interested in licensing the invention(s) will be required to submit an Application for License to Public Health Service Inventions. Respondees interested in submitting a CRADA proposal should be award that it may be necessary to secure a license to the above patent rights in order to commercialize products arising from a CRADA.

SUPPLEMENTARY INFORMATION: The discover of antiprogestational steroids can be traced back to the work of chemists at Roussel in the early 1970s who were trying to develop synthetic routes for some new glucocorticoids which require substitution at position 11 of the steroid nucleus. They found that the size of the substituent largely determined whether the compound exhibited agonist or antagonist activity. By extending this work to the sex steroids, Georges Teutsch and his colleagues prepared RU 38486 or mifepristone in 1980 which was subsequently shown to exhibit both antiprogrestational and antiglucocorticoid activity. Clinical studies showed that mifepristone could terminate pregnancy when it was administered prior to day 49 of gestation when the source of progesterone shifts from the corpus luteum to the placenta and could also prevent pregnancy when administered within 72 hours of unprotected intercourse.

As part of its steroid synthetic program, a novel antiprogestin, code named CDB–2914, was prepared by the Research Triangle Institute under contract to the Contraceptive Development Branch and subsequently evaluated by the Branch's Biological Testing Facility. Chemically, CDB–2914 is 17α-acetoxy-11β-(4-N,N-dimethylaminophenyl)-19-norpregna-4,9-diene-3,20-dione. It differs from mifepristone in that it is a derivative of progesterone rather than 19-nortestosterone. However, it shares many pharmacological properties with mifepristone, and is being developed as a postcoital contraceptive.

The compounds available for licensing under this notice are 21-substituted analogs of CDB–2914. Although they have not been studied as extensively as CDB–2914, they exhibit greater antiprogestational and reduced antiglucocorticoid activity and thus have substantial clinical potential as contraceptive agents and for a broad spectrum of therapeutic uses in gynecic medicine. While a licensee/CRADA partner may wish to pursue development of these antiprogestins for the most extensive clinical applications, contributions by the Government will be limited to contraceptive development. Development as abortifacients will be prohibited.

In an effort to expedite research, development, and commercialization of the novel antiprogestational steroids, the National Institute of Child Health and Human Development seeks a CRADA partner(s) for joint exploration and possible commercialization. Any CRADA proposed for these purposes will be considered.

The CRADA aims will include the rapid publication of research results consistent with protection of proprietary information and patentable inventions as well as the timely exploitation of commercial opportunities. The CRADA partner will enjoy the benefits of first negotiation for licensing Government