National Heart, Lung, and Blood Institute; Notice of a 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 Heart, Lung, and Blood Special Emphasis Panel (SEP) meeting:

Name of SEP: Refinement on Clinical Use of New Assays for Direct Detection of Viral Nucleic Acids in Donated Blood, Organs and Tissues (Teleconference Call).

Date: June 15, 1995.

Time: 11:00 a.m.

Place: 6701 Rockledge Drive, Room 7178, Bethesda, Maryland.

Contact Person: David M. Monsees, Jr., Ph.D., 6701 Rockledge Drive, Room 7178, Bethesda, Maryland 20892–7294, (301) 435–0270.

Purpose/Agenda: To review and evaluate contract proposals.

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/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

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

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health.)

Dated: May 30, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–13713 Filed 6–5–95; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Dental Research; 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 of Dental Research Special Emphasis Panel (SEP) meetings:

Name of SEP: National Institute of Dental Research Special Emphasis Panel—Trigeminal Pain Mechanisms & Control Center.

Dates: June 14–15, 1995.

Time: 8:00 a.m.

Place: Hyatt Hotel Dulles, 2300 Dulles Corner Boulevard, Herndon, VA.

Contact Person: Dr. Yong Shin, Scientific Review Administrator, 4500 Center Drive, Natcher Building, Room 4AN–38J, Bethesda, MD 20892, (301) 594–2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

Name of SEP: National Institute of Dental Research Special Emphasis Panel—Advanced Dental Restorative Systems Program Project.

Date: July 18, 1995.

Time: 8:00 a.m.

Place: National Institutes of Health, 4500 Center Drive, Natcher Building, Conf. Room A, Bethesda, MD 20892.

Contact Person: Dr. Yong Shin, Scientific Review Administrator, 4500 Center Drive, Natcher Building, Room 4AN–38J, Bethesda, MD 20892, (301) 594–2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

Name of SEP: National Institute of Dental Research Special Emphasis Panel—Dentin Characterization Program Project.

Date: July 19, 1995.

Time: 8:00 a.m.

Place: National Institutes of Health, 4500 Center Drive, Natcher Building, Conf. Room A, Bethesda, MD 20892.

Contact Person: Dr. Yong Shin, Scientific Review Administrator, 4500 Center Drive, Natcher Building, Room 4AN–38J, Bethesda, MD 20892, (301) 594–2372.

Purpose/Agenda: To evaluate and review grant applications and/or contract proposals.

Name of SEP: National Institute of Dental Research Special Emphasis Panel—Facial Profile SBIR.

Dates: August 22, 1995.

Time: 8:00 a.m.

Place: Wellesley College Club Inn, 44 Commonwealth Avenue, Boston, MA.

Contact Person: Dr. George Hausch, Chief, Review Section, 4500 Center Drive, Natcher Building, Room 4AN-38J, Bethesda, MD 20892, (301) 594–2372.

Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research.)

Dated: May 30, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–13714 Filed 6–5–95; 8:45 am]

BILLING CODE 4140–01–M

Opportunity for a Cooperative Research and Development Agreement (CRADA) and Licensing Opportunity for Testosterone Bucyclate

AGENCIES: National Institute of Child Health and Human Development, National Institutes of Health, Public Health Service, DHHS; and UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (WHO/HRP).

ACTION: Notice.

SUMMARY: The National Institutes of Health and the World Health Organization are seeking (a) partner(s) for the further development, evaluation and commercialization of testosterone bucyclate and pharmaceutical compositions thereof. The invention claimed in the issued U.S. patent referenced below is available for either exclusive or non-exclusive licensing. Licensing by NIH is subject to 35 U.S.C. 207 and 37 CFR part 404.

Long-Acting Androgenic Compounds and Pharmaceutical Compositions Thereof

Inventors: Sydney Archer, Gabriel Bialy, Richard P. Blye, Pierre Crabbe, Egon R. Diczfalusy, Carl Djerassi, Josef Fried and Hyun K. Kim

Assignees: National Institutes of Health and the World Health Organization

Issued: August 14, 1990

Patent Number: 4,948,790

To expedite the research, development and commercialization of testosterone bucyclate, the National Institutes of Health and the World Health Organization are seeking one or more CRADA and/or license agreements with pharmaceutical or biotechnology companies in accordance with the regulations governing the transfer of Government-developed agents and WHO's public sector objectives, as outlined below. Any proposal to use or develop these drugs will be considered.

SUPPLEMENTARY INFORMATION:

Androgens are principally employed in therapeutic medicine for replacement or supplementation in androgen deficiency states but also find use in hypopituitarism, menstrual disorders, anemia, promotion of anabolism, suppression of lactation and as a palliative measure in recurrent and metastatic carcinoma of the breast. NIH's and WHO's interest is to develop testosterone bucyclate for use as a hormonal method of male contraception and for androgen replacement in other methods of male contraception which usually compromise the endocrine as well as the gametogenic function of the testis. Long-term androgen therapy is complicated by the side effects and/or poor bioavailability of oral preparations and the need for frequent injections of parenteral products. Two of the most commonly used injectable androgens, testosterone enanthate and testosterone cypionate, must be administered about every two weeks. There is thus a crucial need for longer-acting injectable androgens.

Testosterone bucyclate emanated, in 1980, from a joint NIH–WHO-sponsored steroid synthesis program in which the

preparation of selected steroid esters was contracted by WHO and the resulting compounds screened by the Contraceptive Development Branch (CDB) of the National Institute for Child Health and Human Development at its Biological Testing Facility. Chemically, testosterone bucyclate is Testosterone 17β-(*trans*-4-*n*-butyl) cyclohexyl carboxylate. This ester of the natural hormone, testosterone, exhibits prolonged activity when administered intramuscularly as an aqueous crystalline suspension in all species studied, including man. The drug was evaluated, including pharmacokinetics and metabolic studies in both rodents and primates, by CDB. WHO supported studies in primates as well as the first clinical studies in hypogonadal and normal men. The patent is jointly held by NIH and WHO. NIH and WHO intend to continue joint development of testosterone bucyclate.

Although each patentee may proceed with granting a non-exclusive license independently, joint licensing is envisaged. Licensing will include use of testosterone bucyclate as a hormonal method of male contraception, use for androgen replacement in other methods of male contraception, which usually compromise the endocrine as well as the gametogenic function of the testis and use as a therapeutic androgen for patients with androgen deficiency syndromes. A ''Notice of Claimed Investigational Exemption For A New Drug'' (IND) is currently being prepared.

The National Institute of Child Health and Human Development and the World Health Organization seek partners for the further development and commercialization of testosterone bucyclate.

The role of the National Institute of Child Health and Human Development and the World Health Organization is expected to be as follows:

1. Provide the commercial partner with all biological data on testosterone bucyclate covered by the agreement.
2. Provide samples of the drug and clinical dosage forms.
3. Provide chemical data on testosterone bucyclate, including routes of synthesis, analytical methods employed, purity, stability and formulation.
4. Provide reports of all safety studies of the drug.
5. Continue studies on the pharmacokinetics and biological activity of testosterone bucyclate and formulations thereof.
6. Conduct appropriate studies to optimize formulations of testosterone bucyclate.
7. Prepare the IND.
8. Participate in meetings with the Food and Drug Administration for establishment of the protocols for Phase I, II and III clinical investigations and provide liaison with the FDA.

The role of the commercial partner is expected to be as follows;

1. Obtain a commercialization license from NIH and the WHO.
2. Participate in the development of the IND.
3. Assume responsibility for regulatory affairs.
4. Assume responsibility for preparation and formulation of the drug for pre-Phase III safety studies and Phase III clinical trials.
5. Undertake such additional safety studies as may be required for Phase III clinical trials and for NDA submission.
6. Undertake an orderly sequence of clinical investigations of testosterone bucyclate as a hormonal method of male contraception and for androgen replacement in other methods of male contraception.
7. Assume responsibility for preparation and filing of the NDA.
8. Assume responsibility for commercial manufacture and distribution of the final products.
9. Ensure availability of the final products to the public sector of developing countries in sufficient quantities, at a preferential price, in accordance with WHO's public sector objectives.

Selection criteria for choosing commercial partners will furthermore include, but will not be limited to the following:

1. The proposal must contain a clear statement of capabilities and experience with respect to the tasks to be undertaken. This would include experience in drug development, regulatory affairs and marketing.
2. The proposal must contain a clear and concise outline of the work to be undertaken, a schedule of significant events, an outline of objectives to be accomplished with individual and overall times frames, and details of experimental procedures and techniques to be employed.
3. The proposal must contain the level of financial support which will be supplied for the development of testosterone bucyclate.
4. Agreement to be bound by DHHS and WHO rules and regulations regarding patent rights, the ethical treatment of animals, the involvement of human subjects in clinical investigations and the conduct of randomized clinical trials.
5. Agreement with provisions for equitable distribution of patent rights to any inventions developed under the CRADA and license agreements.

EFFECTIVE DATE: In view of the high priority for developing and commercializing testosterone bucyclate, all proposals must be received no later than September 5, 1995 for priority consideration.

ADDRESSES: CRADA proposals and questions should be addressed to Dr. Gordon Guroff, Deputy Scientific Director, National Institutes of Child Health and Human Development, Building 49, Room 5A64, Bethesda, Maryland 20892 (Telephone: 301/496–4751); with a copy to Director, UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, World Health Organization, 20, Avenue Appia, CH–1211 Geneva 27, Switzerland. Responders interested in submitting a CRADA should simultaneously submit a license application concerning the above-mentioned patent rights to NIH and WHO for commercialization of products arising from the CRADA.

Requests for copies of the U.S. patent, license application forms, or questions about the licensing 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), with a copy to Office of the Legal Counsel, World Health Organization, 20 Avenue Appia, CH–1211 Geneva 27, Switzerland (Telephone: 00–41–22 7912685). Completed license applications should be submitted to the same addresses.

Pertinent information not yet publicly described can be obtained under a Confidential Disclosure Agreement with the appropriate agency.

Dated: May 24, 1995.

Barbara M. McGarey,

Deputy Director, Office of Technology Transfer.

[FR Doc. 95–13711 Filed 6–5–95; 8:45 am]

BILLING CODE 4140–01–P

National Institute of Nursing Research; Meetings of the National Advisory Council for Nursing Research and its Subcommittees

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the National Advisory Council for Nursing Research, National Institute of Nursing Research, National Institutes of Health; and its Subcommittees, June 16 and June 20–21, 1995.

The meetings will be open to the public as indicated below. Attendance will be limited to space available.