

- Development of improved derivatives of minocycline.

Party Contributions

The role of NIA includes the following:

- (1) Develop and file, in consultation with Collaborator, any and all regulatory applications for the use of minocycline in the treatment of osteoporosis;
- (2) Provide staff, expertise, and materials for the development and execution of protocols, and for the development and testing of promising minocycline analogues;
- (3) Together with the Collaborator, evaluate the results of joint research, and to ensure progress toward meeting the CT-CRADA goals; and
- (4) Provide work space and equipment for testing of any prototype pharmaceutical compositions developed.

The role of the successful Collaborator will include the following:

- (1) Provide staff, expertise, and materials for the development and production of pharmaceutical compositions;
- (2) Purchase or manufacture an adequate supply of minocycline;
- (3) Together with NIA, evaluate the results of joint research, and to ensure progress toward meeting the CT-CRADA goals;
- (4) Provide funding in support of the clinical trials; and
- (5) Provide resource to develop and market any promising analogues to minocycline.

Selection Criteria

Proposals submitted for consideration should fully address each of the following qualifications:

(1) Expertise

The successful Collaborator should have the following expertise:

- A. Demonstrated expertise in developing and producing high quality pharmaceutical compositions;
- B. Demonstrated ability to secure national and/or international marketing and distribution of pharmaceutical compositions;
- C. Demonstrated expertise in overseeing all aspects of product development;
- D. Demonstrated intellectual ability to guide development of product line which addresses the requirements of NIA.

(2) Reputation

The successful Collaborator should be recognized in the pharmaceutical industry for each of the following:

- A. Producing quality pharmaceutical products;

B. Indications of high levels of satisfaction by industry experts with the Collaborator's products; and

C. Strong commitment to the research and development of new pharmaceuticals.

(3) Physical Resources

The successful Collaborator should be able to demonstrate it will have the following material resources as of the commencement of research under the CT-CRADA:

A. An established headquarters with offices, space, and equipment;

B. Adequate means for communication with the Collaborator during business hours, such as by telephone, mail, e-mail, the Internet, and other evolving technologies; and

C. Sufficient financial resources to support, at a minimum, the current activities of the CT-CRADA to meet the needs of NIA.

Dated: March 26, 1997.

Thomas D. Mays,

*Director, Office Technology Development,
National Cancer Institute, NIH.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; 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 Institute of Child Health and Human Development Special Emphasis Panel (SEP) meeting:

Name of SEP: Specialized Clinical Fellowships (Teleconference).

Date: May 5, 1997.

Time: 1:00 p.m.—adjournment.

Place: 6100 Executive Boulevard, 6100 Building Room 5E03, Rockville, Maryland 20852.

Contact Person: Hameed Khan, Ph.D., Scientific Review Administrator, NICHD, 6100 Executive Boulevard, 6100 Building, Room 5E01, Rockville, Maryland 20852, Telephone: 301-496-1485.

Purpose/Agenda: To evaluate and review grant applications.

The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. The discussions of these applications 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 Nos. [93.864, Population Research and No. 93.865, Research for Mothers and Children, National Institutes of Health].)

Dated: April 7, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke, Division of Extramural Activities; 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:

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel (Telephone Conference Call).

Date: April 23, 1997.

Time: 9:00 a.m.

Place: National Institutes of Health, 7550 Wisconsin Avenue, Room 9C10, Bethesda, MD 20892.

Contact Person: Dr. Howard Weinstein/Mr. Phillip Wiethorn, Scientific Review Administrator, National Institutes of Health, 7550 Wisconsin Avenue, Room 9C10, Bethesda, MD 20892, (301) 496-9223.

Purpose/Agenda: To review and evaluate an SBIR Phase II Contract Proposal.

The meeting will be closed in accordance with the positions set forth in sections 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 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program No. 93.853, Clinical Research Related to Neurological Disorders; No. 93.854, Biological Basis Research in the Neurosciences).

Dated: April 7, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

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