DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, May 25, 2004, 8:30 a.m. to May 25, 2004, 5 p.m., Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD, 20814 which was published in the **Federal Register** on April 29, 69 FR 23517.

The meeting will be held at The Latham Hotel, 3000 M Street, NW., Washington, DC 2007. The date and time remain the same. The meeting is closed to the public.

Dated: May 6, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–11096 Filed 5–14–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: 1,8-Naphthalimide Imidazo [4,5,1-de] Acridones With Anti-Tumor Activity

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

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in U.S. Patent 6,664,263 issued December 16, 2003, entitled ''1,8-Naphthalimide Imidazo [4,5,1-de] Acridones with Anti-Tumor Activity'' (DHHS Reference No. E–289–1999/0), and all related foreign patents/patent applications, to Reata Discovery, Inc., which is located in Richardson, TX. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory will be worldwide and the field of use may be limited to human pharmaceutical uses of 1,8-naphthalimide imidazo [4,5,1-de] acridones as anti-cancer agents.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before July 16, 2004 will be considered.

ADDRESSES: Requests for copies of the patent, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: George G. Pipia, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5560; Facsimile: (301) 402–0220; and e-mail: *pipiag@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The present invention relates to novel bifunctional molecules with anti-tumor activity. These agents are composed of an imidazoacridone moiety linked by a nitrogen containing aliphatic chain of various length and rigidity to another aromatic ring system capable of intercalation to DNA.

Previous studies on related symmetrical bis-imidazoacridones revealed that only one planar imidazoacridone moiety intercalates into DNA. The second aromatic moiety, which is crucial for biological activity, resides in a DNA groove, and is believed to interact with DNA-binding proteins. It is hypothesized that the action of bis-imidazoacridone constitutes a new paradigm of how small molecules can interfere with the gene transcription.

To enhance the biological activity, the inventors have developed asymmetrical compounds in which one imidazoacridone system, with relatively poor DNA-intercalating properties, was replaced with much stronger intercalators, such as 3-chloro-7-methoxyacridine or naphthalimide moieties. These new compounds, especially those containing a naphthalimide moiety, are extremely *cytotoxic in vitro* against variety of tumor cells (IC50 at low nanomolar range) and kill tumor cells by inducing apoptosis. *In vivo,* in nude mice xenografted with human tumors, the compounds significantly inhibited growth of such tumors as colon tumor HCT116 and Colo205 as well as pancreatic tumors.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 7, 2004.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 04–11088 Filed 5–14–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Public Comment on a Written Request Issued by the Food and Drug Administration in the Use of Azithromycin for the Treatment of *Ureaplasma urealyticum* Pneumonia in the Preterm Neonate and Prevention of Bronchopulmonary Dysplasia

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) is requesting public comment on the following Written Request issued by the Food and Drug Administration (FDA) for off-patent drugs as defined in the Best Pharmaceuticals for Children Act (BPCA). The Written Request was referred to NIH by FDA as required by the BPCA. The Written Request was developed following formulation of an NIH-generated priority list, which prioritizes certain drugs most in need of study for use by children. The priority list was produced in consultation with the FDA, other NIH Institutes and Centers, and pediatric experts, as mandated by the BPCA. The studies that are described in the Written Request are intended to characterize the safety, efficacy, and pharmacokinetics of the drug for optimum use in pediatric patients.

DATES: Comments are requested within 90 days of publication of this notice.

ADDRESSES: Submit comments to: Anne Zajicek, M.D., Pharm. D., National Institute of Child Health and Human Development, 6100 Executive Boulevard, Suite 4B–09, Bethesda, MD 20892–7510, telephone 301–435–6865 (not a toll-free number), e-mail *BestPharmaceuticals@mail.nih.gov.*