

This draft guidance, when finalized, will represent the agency's current thinking on providing ANDAs in electronic format. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests are to be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: November 7, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-28681 Filed 11-15-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the

Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Diacylglycerol Compounds Useful as Protein Kinase C Activators and Apoptosis Inducers

Victor E. Marquez, Peter M. Blumberg, Jeewoo Lee, Marcelo Kazanietz (NCI) DHHS Reference No. E-088-01/0 filed 06 Aug 2001

Licensing Contact: Jonathan Dixon; 301/496-7056 ext. 270; dixonj@od.nih.gov

This invention discloses new diacylglycerol (DAG) compounds that may be useful as chemotherapeutic agents. DAG activates many of the isozymes in the Protein Kinase C (PKC) family, a phospholipid-dependent serine/threonine-specific kinase that plays an important role in cellular growth and differentiation. The activation of PKC by DAG is important in mediating the actions of a variety of hormones, neurotransmitters, and other biological control factors. This new class of DAG compounds is proving to be superior at inducing apoptosis in androgen-sensitive LNCaP prostate cancer cells by specifically activating the alpha isozyme. The compounds are believed to receive their superior properties from the replacement of the ester oxygen with a nitrogen attached to a hydroxyl group (N-OH). The presence of the hydroxamate functionality endows the molecule with improved solubility properties making these compounds the most potent and least lipophilic DAG analogues known to date.

Differentiation of Stem Cells to Pancreatic Endocrine Cells

Nadya Lumelsky et al. (NINDS) Serial No. 60/266,917 filed 06 Feb 2001 Licensing Contact: Norbert Pontzer; 301/496-7736 ext. 284; e-mail: np59n@nih.gov

Diabetes, which effects 16 million people in the United States alone, results at least in part from decreased production of insulin by the pancreas. In the pancreas, insulin is produced by specialized structures called the islets of Langerhans. Adult mammalian islets are composed of four major cell types: The α , β , δ and PP cells which produce glucagons, insulin, somatostatin, and pancreatic polypeptides respectively. The physical proximity and resulting interaction of each of these modulators of carbohydrate metabolism may be

necessary for the proper control of insulin secretion. The lack of tight feedback control of insulin secretion is thought to be responsible for pathologies arising after the long-term injection of insulin for diabetics.

This invention provides a method for differentiating stem cells into endocrine cells that produce insulin and other pancreatic hormones. The cells self-assemble to form three-dimensional clusters similar in topology to normal pancreatic islets. Glucose triggers insulin release from these cell clusters by mechanisms similar to those employed *in vivo*. When injected into experimental animals, the insulin producing cells undergo rapid vascularization and maintain an islet-like organization. These cells could provide both a model system for *in vitro* study of pancreatic islets and a potential therapy for replacing lost pancreatic function through transplantation.

Dated: November 6, 2001.

Jack Spiegel,

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

[FR Doc. 01-28705 Filed 11-15-01; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing: Method of Treating HIV With 2', 3'-Dideoxyinosine (ddi; didanosine)

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for nonexclusive licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for non-exclusive licensing.

- (1) U.S. Patent No. 4,861,759, issued August 29, 1989, entitled "Antiviral Compositions and Methods" (PHS Reference No. E-081-87/1)
- (2) U.S. Patent No. 5,254,539, issued October 19, 1993, entitled "Antiviral Compositions and Methods" (PHS Reference No. E-081-87/4)

- (3) U.S. Patent No. 5,616,566, issued April 01, 1997, entitled "Method of Inhibiting HIV Replication with 2', 3'-Dideoxyadenosine" (PHS Reference No. E-081-87/6)
- (4) U.S. Patent Application No. 08/246,916, filed May 20, 1994, entitled "Antiviral Compositions and Methods" (PHS Reference No. E-081-87/7)
- (5) U.S. Patent No. 5,026,687, issued June 25, 1991, entitled "Treatment of Human Retroviral Infections with 2', 3'-Dideoxyinosine" (PHS Reference No. E-051-90/0)
- (6) U.S. Patent No. 5,376,642, issued December 27, 1994, entitled "Treatment of Human Retroviral Infections with 2', 3'-Dideoxyinosine" (PHS Reference No. E-051-90/2)

ADDRESSES: Licensing information may be obtained by contacting Sally Hu, Ph.D., M.B.A., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; Telephone: 301/496-7056 ext. 265; Fax: 301/402-0220; E-mail: hus@od.nih.gov.

SUPPLEMENTARY INFORMATION: Human Immunodeficiency Virus (HIV) and other retroviruses need three viral enzymes for replication: reverse transcriptase (RT), protease and integrase. The current focus for treatment of acquired immune deficiency syndrome (AIDS) is the development of antiviral drugs that target the infection and replication of HIV. The patents and patent applications describe group novel compounds discovered by Dr. Hiroaki Mitsuya, Dr. Robert Yarchoan and Dr. Samuel Broder at the National Cancer Institute. It has been shown that the drugs 2', 3'-dideoxyinosine (ddI), 2', 3'-dideoxyadenosine (ddA), and 2', 3'-dideoxyguanosine (ddG), and their triphosphate derivatives are useful for treatment of retroviral infections, particularly HIV-infection and AIDS. ddI, ddA, and ddG are metabolized *in vivo* to active triphosphate derivatives that inhibit HIV and retroviral reverse transcriptase, an enzyme required for retroviral replication. Liposomal encapsulated dideoxynucleosides, salts and esters are also claimed since triphosphates ordinarily do not penetrate cell membranes and the triphosphate derivatives of this invention are delivered by liposomes, small particles that serve as intracellular transport systems. ddI (didanosine) is licensed for human use in the U.S. and around the world as a treatment for HIV infections.

Dated: November 6, 2001.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 01-28706 Filed 11-15-01; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group, Subcommittee D—Clinical Studies.

Date: December 4-5, 2001.

Time: 7 pm to 4 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: William D. Merritt, PhD, Scientific Review Administrator, Grants Review Branch, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8129, MSC 8328, Bethesda, MD 20892-8328, 301-496-9767.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 6, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-28694 Filed 11-15-01; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Neurological Disorders and Stroke; 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.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel.

Date: November 27, 2001.

Time: 2 pm to 5 pm.

Agenda: To review and evaluate grant applications.

Place: 6001 Executive Blvd., Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Raul A. Saavedra, PhD., Scientific Review Administrator Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: November 7, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01-28696 Filed 11-15-01; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as