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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Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance.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 The draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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 polypeptide 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)