TABLE 2.—MEAN OXYTETRACYLINE LEVELS (PARTS PER MILLION) IN SKINLESS NORTHERN PIKE MUSCLE FOLLOWING DOSING FOR 10 DAYS WITH MEDICATED FEED AT 13.8 °C (N=40 FOR ALL SAMPLING TIMEPOINTS EXCEPT FOR DAY 10 SAMPLES, N=39)

Withdrawal Time (Days)	Fish Fed Biodiet Grower (Trout Feed) at 70.9 Milligrams Per Kilogram Per Day (mg/kg/day)	Fish Fed Walleye Grower (Walleye Feed) at 94.2 mg/kg/day
1	0.203±0.042	0.314±0.091
2	0.198±0.056	0.319±0.098
4	0.162±0.034	0.267±0.068
6	0.122±0.039	0.211±0.053
8	0.098±0.026	0.147±0.049
10	0.068±0.017	0.125±0.034

Data and information on safety are contained in PMF 5646. When you submit NADAs or supplemental NADAs, you may, without further authorization, reference the PMF to support approval of an application filed under 21 CFR 514.1(d). You must include a reference to the PMF and other information needed for approval when you submit an NADA or supplemental NADA. The information needed for approval in addition to the reference to the PMF includes effectiveness data; target animal safety data; data concerning manufacturing methods, facilities, and controls; animal drug labeling; and information addressing potential environmental impacts. If you need more information concerning the PMF or requirements for approval of an NADA or supplemental NADA, contact Julia A. Oriani (address above).

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety data and information provided in this PMF to support approval of an application may, upon approval of such application, be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 6, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–28680 Filed 11–15–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0475]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—ANDAs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—ANDAs.'' This draft guidance provides information for applicants on how to submit abbreviated new drug applications (ANDAs) in electronic format.

DATES: Submit written or electronic comments on the draft guidance by January 15, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ruth Warzala, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5845, e-mail: ESUB_OGD@CDER.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—ANDAs.'' In the Prescription Drug User Fee Act as amended by the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), the agency stated its plans to develop and update its information management capabilities to allow electronic submissions by 2002. In the **Federal Register** of January 28, 1999, the agency announced the availability of two guidances for industry entitled ''Providing Regulatory Submissions in Electronic Format—NDAs'' (64 FR 4432) and ''Providing Regulatory Submissions in Electronic Format—General Considerations'' (64 FR 4433). These guidances were the first two of a series of guidances for industry on making regulatory submissions in electronic format. In the 1999 guidance on general considerations, the agency stated that guidance would be forthcoming on other submission types and structured formats, including ANDAs, investigational new drug applications, and product licensing applications. When finalized, this draft guidance should be used in conjunction with the two previously issued guidances (64 FR 4432 and 4433, respectively).

CDER has encouraged the electronic submission of some types of data on a voluntary basis since 1997. However, these electronic submissions could not previously be archived and could only be made in addition to a complete paper submission. The electronic data submission program is now being expanded to include all parts of ANDA so that the electronic submission can replace the paper submission as the archival copy of ANDA.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

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)