SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#158) entitled ''Use of Material From Deer and Elk in Animal Feed.'' This draft guidance document, when finalized, will describe FDA's current thinking regarding the use in animal feed of material from deer and elk that are positive for chronic wasting disease (CWD) or are at high risk for CWD.

DATES: Submit written or electronic comments on the draft guidance at any time, however, comments should be submitted by June 16, 2003, to ensure their adequate consideration in preparation of the final document. FDA is requesting comments within 30 days, rather than within a longer period, because of the need to finalize the guidance in late August, prior to the start of the next deer hunting season.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit electronic comments on the draft guidance to http://www.fda.gov/dockets/ecomments. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Burt Pritchett, CVM (HFV–222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0177, e-mail: bpritche@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

CWD is a neurological (brain) disease of farmed and wild deer and elk that belong in the cervidae animal family (cervids). CWD belongs to a family of animal and human diseases called transmissible spongiform encephalopathies (TSEs). These include (1) Bovine spongiform encephalopathy (BSE or ''mad cow'' disease) in cattle; (2) scrapie in sheep and goats; and (3) classical and variant Creutzfeldt-Jakob diseases (CJD and vCJD) in humans. There is no known treatment for these diseases and there is no vaccine to prevent them. In addition, although validated postmortem diagnostic tests are available, there are no validated diagnostic tests for CWD that can be used to test for the disease in live animals.

Under FDA's BSE feed regulation (21 CFR 589.2000), most material from deer and elk is prohibited for use in feed for ruminant animals. This draft guidance document describes FDA's recommendations regarding the use in all animal feed of all material from deer and elk that are positive for CWD or are considered at high risk for CWD.

The potential risks from CWD to humans or noncervid animals such as poultry or swine are not well understood. However, because of recent recognition that CWD is spreading rapidly in white-tailed deer and because CWD's route of transmission is poorly understood, FDA is making recommendations regarding the use in animal feed of rendered materials from deer and elk that are CWD positive or that are at high risk for CWD.

II. Significance of Guidance

This draft level 1 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 the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IV. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this draft guidance document. Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the 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.

V. Electronic Access

Copies of the draft guidance document entitled ''Use of Material From Deer and Elk in Animal Feed'' may be obtained from the CVM home page (http://www.fda.gov/cvm) and from the Dockets Management Branch Web site (http://www.fda.gov/ohrms/dockets/default.htm).

Dated: May 6, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–12363 Filed 5–15–03; 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, DHHS.

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.

Method of Treating Ischemia/Reperfusion Injury with Nitroxyl Anion Donors

David Wink *et al.* (NCI).

DHHS Reference No. E–175–2002/0

Filed June 14, 2002, and DHHS Reference No. E–076–2003/0

Filed June 17, 2002.

Licensing Contact: Fatima Sayyid; 301/435–4521; *sayyidf@od.nih.gov.*

Ischemia/reperfusion injury refers to tissue damage caused by oxygen deprivation followed by reoxygenation causing oxidative stress.

The present invention relates to the administration of a nitroxyl anion donating compound prior to ischemia to attenuate ischemia/reperfusion injury. Accordingly, nitroxyl anion donating compounds such as Angeli's salt would be useful treatment agents to prevent or protect against such adverse conditions especially since the beneficial effect is a surprising result given that nitroxyl anion was previously reported to increase ischemia/reperfusion injury.

Preparation and Medical Uses of Novel Nitric Oxide Releasing Imidates, Amidines Derived Therefrom, and Enamines

Joseph Hrabie, Ernst Arnold, and Larry Keefer (NCI).

DHHS Reference Nos. E–149–2001

Filed June 13, 2001 and E–276–2002

Filed July 18, 2002.

Licensing Contact: Norbert Pontzer; 301/435–5502; *pontzern@od.nih.gov.*

Nucleophile/nitric oxide adducts (N_2O_2-diazeniumdiolates) spontaneously dissociate at physiological pH to release nitric oxide (NO) by stable first order kinetics. The bulk of the known and patented NIH compositions and methods using diazeniumdiolates are derived from amine nucleophiles. The formation of these amine-derived diazeniumdiolates requires exposure of the nucleophile to NO gas with the attendant occurrence of possible unwanted side reactions, or preparation of O_2 alkylated diazeniumdiolates that may release toxic by-products. Also, amine-derived diazeniumdiolates may dissociate into carcinogenic N-nitroso compounds and the primary amines may decompose into unstable diazotates. These inventors thus developed diazeniumdiolates in which the N_2O_2-functional groups are bonded to carbon atoms. This work has resulted in imidoester-, amidine- and enamine-derived diazeniumdiolates that spontaneously release NO under physiological conditions.

Previous amidine-linked NO releasing compounds were prepared using NO gas after acetamidation of amine groups. This invention provides a simple, robust method of preparing diazeniumdiolated imidates from cyano compounds. As with other imidoesters, these diazeniumdiolated imidoesters react with nucleophiles allowing formation of a wide range of NO releasing derivatives. For example, imidoesters are extensively used as protein crosslinking reagents because they react with primary amines to form amidine bonds. These already diazeniumdiolated and purified imidoesters can thus be used to directly attach amidine NO-releasing groups onto molecules such as peptides and medicinals without exposing them to NO gas or its potentially toxic by-products. Some of these compounds may also release nitroxyl (HNO, NO) in solution under physiological conditions. *See* Arnold *et al.*, Tetrahedron Lett., 41, 8421–8424(2000).

Postnatal Stem Cells and Uses Thereof

Drs. Songtao Shi and Pamela Robey (NIDCR).

DHHS Reference No. E–018–2003/0–PCT–01.

Licensing Contact: Marlene Shinn-Astor; 301/435–4426; *shinnm@od.nih.gov.*

Many individuals with ongoing and severe dental problems are faced with the prospect of permanent tooth loss. Examples of such dental problems include: dentinal degradation due to chronic dental disease (caries or periodontal); mouth injury; or through surgical removal, such as with tumors associated with the jaw. For many, a technology that offers a possible alternative to artificial dentures by designing and transplanting a set of living teeth fashioned from an individual's own pulp cells would greatly improve their quality of life.

The NIH announces a new technology wherein human postnatal deciduous dental pulp stem cells commonly known as ''baby teeth'', are used to create dentin and have been shown to differentiate into cells of specialized function such as neural cells, adipocytes, and odontoblasts. It is believed that these cells could be manipulated to repair damaged teeth, induce the regeneration of bone, and treat neural injury or disease.

This research is described, in part, in Miura *et al.*, ''SHED: Stem cells from human exfoliated deciduous teeth,'' Proc. Natl. Acad. Sci. USA, vol. 100 (no. 10; May 13, 2003) pp. 5807–5812.

Methanocarba Cycloalkyl Nucleoside Analogues

Dr. Kenneth Jacobson (NIDDK).

Serial No. 10/169,975

Filed July 12, 2002, (and related National Stage patent applications).

Licensing Contact: Marlene Shinn-Astor; 301/435–4426; *shinnm@od.nih.gov.*

Purines such as adenosine and ATP have been shown to play a wide array of roles in biological systems such as inter alia, modulator of vasodilation and hypotension, muscle relaxant, central depressant, inhibitor of platelet aggregation, regulator of energy supply/demand, responder to oxygen availability, neurotransmitter and neuromodulator. All P1 and P2 receptor nucleoside ligands suffer from chemical instability that is caused by the labile glycosidic linkage in the sugar moiety of the nucleoside. However, it has been found that relatively few ribose modifications are tolerated by the presently known agonists and antagonists of P1 and P2 receptors.

The NIH announces a new technology wherein a new class of nucleoside and nucleotide analogs has been identified that serve as selective agonists or antagonists for P1 and P2 receptors. The technology relates to a chemical modification of purines and pyrimidines, which provide enhanced therapeutic profile and potentially greater in vivo stability, because of the absence of a glycosidic bond. The P2Y receptor agonists and antagonists could potentially be used in immune modulation, inflammation, cardiovascular diseases, neurodegeneration, diabetes, and cancer. In addition, the A3 receptor agonists and antagonists could be useful in cardioprotection, neuroprotection, and asthma.

This research is described, in part, in J. Med. Chem., 2000, 43:2196–2203 and J. Med. Chem., 2002, 45:208–218.

Orally Active Derivatives of 1,3,5(10)-estratriene

H.K. Kim, *et al.* (NICHD).

U.S. Patent 5,554,603
Issued Sep. 10, 1996.

Licensing Contact: Marlene Shinn-Astor; 301/435–4426; *shinnm@od.nih.gov.*

The utility of estrogenic substances in the practice of medicine is well documented. Estrogens may be used for the replacement of the natural hormone, estradiol, in hypogonadism, and following the removal of the ovaries or cessation of ovarian activity during menopause. They are also widely employed as a component of oral contraceptives. However, the orally active synthetic estrogens are associate with a number of side effects such as enhanced risk of endometrial carcinoma; induction of malignant carcinoma especially in the cervix, breast, vagina and liver; promotion of gallbladder disease, thromboembolic and thrombotic diseases, myocardial infarction, hepatic adenoma, elevated blood pressure, and hypercalcemia; and a worsening of glucose tolerance can occur.

The NIH announces a new family of novel, active estrogens that are esters of estradiol. These esters possess enhanced estrogenic activity following oral administration in the absence of a 17-

ethynyl alcohol which has been implicated in many side effects. It is anticipated that these esters could be used in all instances where estrogen is prescribed as a treatment.

Additional information about these esters may be found in U.S. Patent 5,554,603.

Dated: May 9, 2003.

Steven M. Ferguson,

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

[FR Doc. 03–12277 Filed 5–15–03; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

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Methods and Apparatus for Performing Multiple Simultaneous Manipulations of Biomolecules in a Two-Dimensional Array

Michael Emmert-Buck, *et al.* (NCI).

DHHS Reference No. E–339–2002/0

Filed Nov. 25, 2002.

Licensing Contact: Susan Ano; 301/435–5515; *anos@od.nih.gov.*

This technology concerns a method and apparatus for accomplishing and/or facilitating the analysis of multiple biomolecules separated in a two-dimensional array, such as gel, membrane, tissue biopsy, etc. The invention employs a separator, termed an External Movement Inhibitor Device, that allows biomolecules to be transferred from an array such as those listed above to another support system while maintaining the two-dimensional spatial relationship of the biomolecules as in the array. The biomolecules can subsequently be subjected to various manipulations such as amplification, reverse transcription, labeling, cloning, etc., after which multiple well-established methods for quantitative and qualitative analysis can be used. The technology allows detection/analysis of all molecules regardless of their abundance.

Methods for Assessing the Ability of HIV Patients to Restrict HIV Replication

Mark Connors, Stephen Migueles (NIAID).

DHHS Reference No. E–260–2002/0

Filed Sep. 20, 2002.

Licensing Contact: Susan Ano; 301/435–5515; *anos@od.nih.gov.*

One of the current obstacles for the design and testing of effective vaccines and immunotherapies of HIV is the lack of in vitro correlates that will predict the ability to restrict virus replication. This invention relates to methods for evaluating the effectiveness of HIV therapies and vaccines and methods for assessing the ability of HIV patients to restrict virus replication. Upon restimulation of $CD8^+$ T cells, the expression of perforin in these cells, and the cell cycle stage of these cells may be measured and used as in vitro markers for monitoring the patient's ability to restrict HIV replication and the effectiveness of the therapies and vaccines applied. Significant proliferation of $CD8^+$ T cells, the presence of perforin in these cells, and the ability of these cells to progress beyond the G_1 stage signify the patient's ability to restrict HIV replication and a favorable effect of the therapies or vaccines. These methods may be advantageously applied in conjunction with other measurements of HIV specific immune response such as HLA tetramers.

Safer Attenuated Virus Vaccines with Missing or Diminished Latency of Infection

Jeffrey Cohen (NIAID), Edward Cox (FDA), Lesley Pesnicak (NIAID).

DHHS Reference No. E–250–2002/0

Filed Nov. 5, 2002.

Licensing Contact: Susan Ano; 301/435–5515; *anos@od.nih.gov.*

This technology describes viruses that have weakened ability to establish and/or maintain latency and their use as live vaccines. The viruses have one or more genetic mutations that allow for continued replication but that inhibit latency. The vaccine materials and methods for their construction are exemplified with the virus that causes chickenpox and whose latent infection results in shingles, a condition that affects up to an estimated 1 million people per year in the United States alone. Specific examples of gene deletion are described. Furthermore, replacement of these deleted genes with other desirable viral antigen encoding sequence(s) and/or cytokine genes in order to enhance a desired immunological response is also described. Aspects of this technology are relevant to other live virus vaccines, thus increasing the safety of such vaccines.

HTLV–1 Cell Binding and Inhibition

Bishop Hague, Tong Mao Zhao, Thomas Kindt (NIAID).

DHHS Reference No. E–240–2002/0

Filed Oct 30, 2002.

Licensing Contact: Susan Ano; 301/435–5515; *anos@od.nih.gov.*

This technology describes methods for inhibiting human T-cell lymphotropic virus type I (HTLV–I) infection in cells and for reducing viral load or titer in infected individuals. As many as 20 million people worldwide are infected with HTLV–I, and approximately 1 million will develop adult T-cell leukemia/lymphoma, myelopathy, or tropic spastic paraparesis (a condition similar to multiple sclerosis) as a result of infection. Previous treatments have proven ineffective. The current invention relates to the surprising results that adenosine receptor antagonists specific for type A2A and A2B adenosine receptors prevent binding of HTLV–I to cells. Such antiviral use of adenosine receptor antagonists has not been suggested elsewhere. This technology also has veterinary application, as such treatment methods could be used against feline leukemia virus infections.

Flp-in T-Rex Jurkat Cell Line

Steven Zeichner, Naoto Yoshizuka (NCI).

DHHS Reference No. E–161–2003.

Licensing Contact: Michael Shmilovich; 301/435–5019; *mish@codon.nih.gov.*

This Flp-in T-Rex Jurkat cell line offers rapid and efficient generation of cell lines containing a gene of interest