revisions include changes in the following ways: (1) The text on the recommended reporting, identification, and qualification thresholds; (2) the recommended deletion of the exception to conventional rounding practice; (3) modification of the decision tree in Attachment 2, which sets out a recommended approach to identifying and qualifying degradation products; and (4) additions and revisions to the previous glossary including definitions for the terms ''unspecified degradation product,'' ''reporting threshold,'' and ''identification threshold.''

In addition, the guidance was updated to reference, where appropriate, other more recently published VICH guidances relevant to this topic. Finally, minor editorial changes were made to improve the clarity and consistency of the document.

III. Paperwork Reduction Act of 1995

This draft revised guidance contains information collection previsions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this draft revised guidance have been approved under OMB control number 0910–0032.

IV. Significance of Guidance

This draft revised document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than ''guideline.'' In addition, guidance documents must not include mandatory language such as ''shall,'' ''must,'' ''require,'' or ''requirement,'' unless FDA is using these words to describe a statutory or regulatory requirement.

The draft revised VICH guidance (#93) represents the agency's current thinking on impurities in new veterinary drug medicinal products. This draft revised guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

V. Comments

This draft revised guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft revised guidance document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft revised guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Electronic comments may also be submitted on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on this Internet site, select Docket No. 1999D–2245, entitled ''Draft Revised Guidance for Industry on Impurities in New Veterinary Medicinal Products (Revised)'' (VICH GL11(R)) and follow the directions.

Copies of the draft guidance document entitled ''Draft Revised Guidance for Industry on Impurities in New Veterinary Medicinal Products (Revised)'' VICH GL11(R) may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: December 30, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–90 Filed 1–9–06; 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 an agency 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.

Polysaccharide Derived Nitric Oxide Releasing Carbon Bound Diazeniumdiolates

Joseph A. Hrabie et al. (NCI)

U.S. Provisional Application No. 60/731,946 filed 31 Oct 2005 (HHS Reference No. E–279–20050–US–01)

Licensing Contact: John Stansberry; 301/435–5236; *stansbej@mail.nih.gov*

The invention discloses a method for producing nitric oxide(NO)-releasing derivatives of any material containing a reducing sugar component. It may be used to produce NO-releasing cotton bandages or surgical fabrics, cellulose filters or dialysis membranes, and drug formulating/compounding agents to prevent stomach irritation. The method involves incorporation of a diazeniumdiolate ($-N_2O_2$) group at one or more carbons via the base-catalyzed replacement of acidic hydrogens and is thus compatible with traditional polysaccharide processing techniques. Monosaccharides such as glucose may also be derivatized.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Hydropneumatic Fluid Control for a Cell Culturing System

Alexandr Chanturiya, Svetlana Glushakova, and Joshua Zimmerberg (NICHD)

U.S. Provisional Application No. 60/725,327 filed 12 Oct 2005 (HHS Reference No. E–166–2005/0–US–01)

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

Available for licensing and commercial development is a hydropneumatic fluid control system in which cell culture media is perfused through a bioreactor by gas pressure where the direction of the gas directs the direction of perfusion. The gas can also act to regulate the pH of the cell culture media. Containers holding the cell culture media are situated on either side of an axis of rotation of a platform. The weight of the container as it fills with media forces the platform to oscillate. The oscillation actuates a piston—also coupled to the platform—which regulates a valve that switches the flow of gas to the other container. This system does not use electricity and, with an appropriate gas mixture, saturates cell culture media with gas.

In addition to licensing, the technology is available for further

development through collaborative research opportunities with the inventors.

A Knockout Mouse for Transcription Factor Nurr1

Dr. Vera Nikodem (NIDDK)
HHS Reference No. E–024–1999/0—Research Tool
Licensing Contact: Marlene Shinn-Astor; 301/435–4426; *shinnm@mail.nih.gov*

Transcriptional factor Nurr1 is an obligatory factor for neurotransmitter dopamine biosynthesis only in ventral midbrain as demonstrated by the Nurr1 genomic locus inactivation using homologous recombination.

From a neurological and clinical perspective, it suggests an entirely new mechanism for dopamine depletion in a region where dopamine is known to be involved in Parkinson's disease. Clinically, our findings indicate that activation of Nurr1 may be therapeutically useful for Parkinson's disease patients; therefore, the mice would be useful in Parkinson's disease research.

Dated: January 3, 2006.

Steven M. Ferguson,

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

[FR Doc. E6–86 Filed 1–9–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Anthrax Lethal Factor Is a MAPK Kinase Protease

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

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Patent Nos. 6,485,925 B1, issued November 26, 2002, 6,893,835 B2, issued May 17, 2005, and 6,911,203 B1, issued June 28, 2005, and U.S. Patent App. No. 11/112,137, filed April 22, 2005 and published on September 8, 2005 as U.S. Pat. Pub. No. 2005/0196822 A1, all titled ''Lethal Factor is a MAPK Kinase Protease'' (HHS Ref. Nos. E–066–1998/0–US–06, –07, –08, and –10) to Van Andel Research Institute, of Grand Rapids, Michigan. The patent rights in these inventions have been assigned to the Government of the United States.

The prospective exclusive license territory will be worldwide. The field of use may be limited to the development and sale of Anthrax lethal factor, a MAPK kinase protease, as a therapeutic agent for the treatment of cancer.

DATES: Only license applications which are received by the National Institutes of Health on or before March 13, 2006 will be considered.

ADDRESSES: Requests for information, inquiries, comments, and other materials relating to the contemplated co-exclusive license should be directed to: Thomas P. Clouse, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: 301–435–4076; Facsimile: 301–402–0220; E-mail: *clouset@mail.nih.gov.* Copies of the U.S. patent publications can be obtained from *http://www.uspto.gov.*

SUPPLEMENTARY INFORMATION: The above-identified patents relates to the discovery that Mitogen Activated Protein Kinase (MAPK) signal transduction pathway is an evolutionarily conserved pathway for effecting gene regulation that controls cell proliferation and differentiation in response to extracellular signals and also plays a crucial role in regulating oocyte meiotic maturation. The above-identified patent discloses in vitro and in vivo methods of screening for modulators, homologues, and mimetics of LF mitogen activated protein kinase kinase (MAPKK) protease activity. Mos (i.e., an oncogene first identified as the transforming determinant of Moloney Murine Sarcoma Virus) is a serine/threonine kinase which phosphorylates and activates MAPK1 kinase which in turn phosphorylates and activates MAPK. The patent also discloses that LF prevents activation of MAPK in oocytes of Xenopus laevis and tumor derived NIH3T3 (490) cells expressing an effector domain mutant form of the human V12HaRas oncogene. The tumor derived NIH3T3 cells reverted to a more normal morphology after LF treatment. Therefore, LF directly inhibits the Mos/MAPK pathway. Tumor cells utilize MAPK kinases in a different way than normal cells as in tumor cells there is a constitutive MAPK kinase activity. Additionally, MAPKK1 was found to be a proteolytic substrate for the metalloprotease LF. By analysis of MAPKK2, a consensus sequence for LF activity was found. The disclosure is claimed in the above-identified patent and other patents in the same patent family.

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 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 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: January 3, 2006.

Steven M. Ferguson,

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

[FR Doc. E6–89 Filed 1–9–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on