

influenza vaccine manufactured by Sanofi Pasteur. In the afternoon, the committee will hear presentations and have discussions on clinical development of influenza vaccines for pre-pandemic uses. On February 28, 2007, in the morning, the committee will hear presentations and make recommendations on strain selections for the influenza virus vaccine for the 2007–2008 season. In the afternoon, the committee will hear presentations and have discussions on circulating lineages of influenza type B virus.

FDA intends to make background material available to the public no later than 1 business day before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2007 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 13, 2007. Oral presentations from the public will be scheduled between approximately 10:45 and 11:15 a.m. and 2:45 and 3:15 p.m. on February 27, 2007, and between approximately 10:40 and 11:10 a.m. and 2:50 and 3:20 p.m. on February 28, 2007. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time

requested to make their presentation on or before February 5, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 6, 2007.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Christine Walsh or Denise Royster at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 1, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7-1899 Filed 2-6-07; 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.

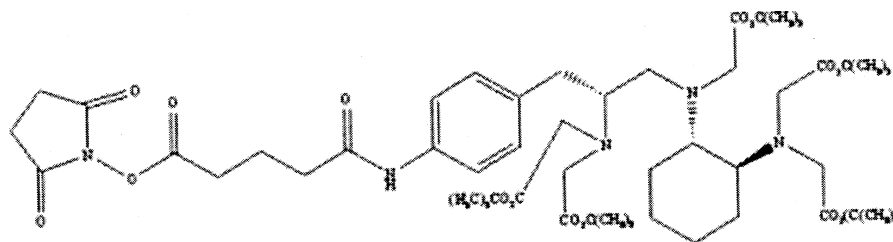
ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is 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.

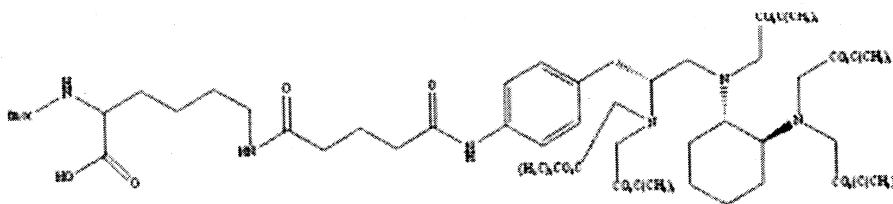
ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Metal Chelators and Target-Moiety Complexes for Imaging

Available for licensing and commercial development are bifunctional metal chelators, metal chelator-targeting moiety complexes, metal chelator-targeting moiety-metal conjugates, kits, and methods of preparing them in a non-aqueous, automated peptide synthesizer system. These bifunctional chelators are useful for radiolabeling targeting moieties with SPECT and PET radioisotopes for molecular imaging for diagnosis and/or treatment of cancer. The metal chelators may be used in conventional synthetic methods to form targeting moieties [e.g., peptides, proteins, and Starburst polyamidoamine dendrimers (PAMAM)], capable of conjugating diagnostic and/or therapeutic metals. The formulae for two such chelators are shown below:



I



II

Inventors: Martin Wade Brechbiel and Thomas Clifford (NCI).

Publications:

1. T Clifford et al. Validation of a novel CHX-A'' derivative suitable for peptide conjugation: small animal PET/CT imaging using yttrium-86-CHX-A''-octreotide. *J Med Chem.* 2006 Jul 13;49(14):4297-4304.

2. HS Chong et al. Synthesis and evaluation of novel macrocyclic and acyclic ligands as contrast enhancement agents for magnetic resonance imaging. *J Med Chem.* 2006 Mar 23;49(6):2055-2062.

Licensing Status: Available for exclusive or non-exclusive licensing or collaborative research opportunity.

Patent Status: U.S. Provisional Application No. 60/603,781 filed 23 Aug 2004 (HHS Reference No. E-317-2004/1-US-01); International Patent Application PCT/US2005/028125 filed 09 Aug 2005 (HHS Reference No. E-317-2004/1-PCT-02).

Licensing Contact: Michael A. Shmilovich, Esq.; 301/435-5019; shmilovm@mail.nih.gov.

Dated: January 30, 2007.

Steven M. Ferguson,

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

[FR Doc. 07-526 Filed 2-6-07; 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, 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.

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Extended Transgene Expression for a Non-Integrating Adenoviral Vector Containing Retroviral Elements

Description of Technology: Anthrax lethal toxin (LeTx) consists of two

components: The protective antigen (PrAg) and the lethal factor (LF). PrAg binds to the cell surface where it is activated by furin protease, followed by the formation of a PrAg heptamer. LF is then translocated into the cytosol of a cell via this heptamer, where it acts as a metalloprotease on all but one mitogen-activated protein kinase kinase (MAPKK). Approximately 70% of human melanomas contain a mutation (B-RAF V600E) that constitutively activates a MAPKK pathway, and LeTx has been shown to have significant toxicity towards cells which have this mutation. This suggested a potential use for LeTx in cancer therapy. Unfortunately, native LeTx is toxic to normal cells, detracting from its *in vivo* applicability.

PrAg has been engineered to be activated by a matrix metalloprotease (MMP), instead of by furin protease. Because MMPs are highly expressed in tumor cells, this modification increases selectivity towards cancer cells. Surprisingly, mouse data shows that the modified LeTx (denoted PrAg-L1/LF) is less cytotoxic to "normal" cells *in vivo*, when compared to wild-type LeTx. Significantly, PrAg-L1/LF maintained its high toxicity toward human tumors in mouse xenograft models of human tumors, including melanomas. However, this toxicity applied not only to tumors having mutations that constitutively activate MAPKKs, but also to other tumor types such as lung and colon carcinomas. The absence of toxicity to "normal" cells coupled to its effectiveness on a wide range of cancer