safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse event reports associated with this drug and has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined previously, DECADRON–LA (dexamethasone acetate injection), 8 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DECADRON–LA (dexamethasone acetate injection), 8 mg/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to DECADRON–LA (dexamethasone acetate injection), 8 mg/mL, may be approved by the agency.

Dated: August 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–19287 Filed 8–23–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 21, 2004, from 9 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Geretta Wood, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8320, ext. 143, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512625. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations regarding clinical trial design in the evaluation of cardiopulmonary resuscitation enhancing devices/therapies for cardiac arrest patients. Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*.

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 by September 7, 2004. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 7, 2004, 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.

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 AnnMarie Williams, Conference Management Staff, at 301–594–1283, ext. 113, 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: August 17, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–19288 Filed 8–23–04; 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 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.

Pichia pastoris Cloning Systems for Expressing and Secreting Proteins of Interest

James Hartley (NCI/SAIC-Frederick).DHHS Reference No. E–305–2004/0—Research Tool.

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

Biological materials of a *Pichia pastoris* cloning and expression system are available for licensing for internal use. The system provides a vector for transgenically expressing proteins that are secreted through signal peptide mediation (*e.g.*, the α mating factor signal peptide). This expression system utilizes the Gateway® cloning platform from Invitrogen without interference from the Gateway® *attB1* sequence. The α mating factor signal peptide encoding sequence includes an *attB1* insertion at an XhoI site upstream from some gene of interest (*e.g.*, human interferon Hyb3). The *attB1* site does not alter the secretion or processing of the signal peptide.

Computer-Based Model for Identification and Characterization of Non-Competitive Inhibitors of Nicotinic Acetylcholine Receptors and Related Ligand-Gated Ion Channel Receptors

I. W. Wainer *et al.* (NIA). U.S. Patent Application No. 10/411,206 filed 11 Apr 2003 (DHHS Reference No. E–158–2003/0-US–01); PCT Application No. PCT/US04/10978 filed 09 Apr 2004 (DHHS Reference No. E–158–2003/1-PCT–01); U.S. Patent Application No. 10/820,809 filed 09 Apr 2004 (DHHS Reference No. E–158–2003/1-US–02).

Licensing Contact: Cristina Thalhammer-Reyero; (301) 435–4507; *thalhamc@mail.nih.gov.*

This invention relates to a computer system for generating molecular models of ligand-gated ion channels and in particular, molecular models of the inner lumen of a ligand-gated ion channel and associated binding pockets. It further relates to a computer system simulating interaction of the computer-based model of the ligand-gated channel and non-competitive inhibitor compounds for identification and characterization of non-competitive inhibitors and to inhibitor compounds so discovered. It also includes methods for treating various disorders related to ligand-gated ion channel receptor function, and provides a way to examine compounds for ''off-target'' activity that may cause undesirable side effects to a desired target activity or that may represent a new therapeutic activity for a known compound.

Ligand gated ion channels (LGICs) are currently very important targets for drug discovery in the pharmaceutical industry. The superfamily is separated into the nicotinic receptor superfamily (muscular and neuronal nicotinic, GABA-A and-C, glycine and 5-HT3 receptors), the excitatory amino acid superfamily (glutamate, aspartate and kainate receptors) and the ATP purinergic ligand gated ion channels. These families only differ in the number of transmembrane domains found in each subunit (nicotinic–4 transmembrane domains, excitatory amino acid receptors–3 transmembrane domains, ATP purinergic LGICs–2 transmembrane domains). In particular, the nicotinic acetylcholine receptors control the fast permeation of cations through the postsynaptic cell membrane, and are key targets in drug discovery for a number of diseases, including Alzheimer's and Parkinson's disease.

Modulators of Nuclear Hormone Receptor Activity: Novel Compounds, Diverse Applications for Infectious Diseases, Including Anthrax (*B. anthracis*)

E. M. Sternberg (NIMH), J. I. Webster (NIMH), L. H. Tonelli (NIMH), S. H. Leppla (NIAID), and M. Maoyeri (NIAID). U.S. Provisional Application No. 60/416,222 filed 04 Oct 2002 (DHHS Reference No. E–247–2002/0-US–01); U.S. Provisional Application No. 60/419,454 filed 18 Oct 2002 (DHHS Reference No. E–348–2003/0-US–01); PCT Application No. PCT/US03/31406 filed 03 Oct 2003 (DHHS Reference No. E–247–2002/1-PCT–01).

Licensing Contact: Peter Soukas; (301) 435–4646; *soukasp@mail.nih.gov.*

Technology summary and benefits: Nuclear hormones such as glucocorticoids dampen inflammatory responses, and thus provide protection to mammals against inflammatory disease and septic shock. The Anthrax lethal factor represses nuclear hormone receptor activity, and thus may contribute to the infectious agent causing even more damage to the host. This observation can be exploited to find new means of studying and interfering with the normal function of nuclear hormone receptors. Scientists at NIH have shown that under the appropriate conditions, these molecules can be used to modulate the activity of various nuclear hormone receptors. Identifying useful agents that modify these important receptors can provide relief in several human disorders such as inflammation, autoimmune disorders, arthritis, malignancies, shock and hypertension.

Long-term potential applications: This invention provides novel agents that can interfere with the action of nuclear hormone receptors. It is well known that malfunction or overdrive of these receptors can lead to a number of diseases such as enhanced inflammation; worse sequelae of infection including shock; diabetes; hypertension and steroid resistance. Hence a means of controlling or fine-tuning the activity of these receptors can be of great benefit. Current means of affecting steroid receptor activity are accompanied by undesirable side-effects. Since the conditions for which these treatments are sought tend to be chronic, there is a critical need for safer drugs that will have manageable side-effects.

Uniqueness or innovativeness of technology: The observation that the lethal factor from Anthrax has a striking effect on the activity of nuclear hormone receptors opens up new routes to controlling their activity. The means of action of this repressor is sufficiently different from known modulators of hormone receptors (*i.e.* the classical antagonists). For instance, the repression of receptor activity is non-competitive, and does not affect hormone binding or DNA binding. Also, the efficacy of nuclear hormone receptor repression by Anthrax lethal factor is sufficiently high that the pharmacological effect of this molecule is seen at vanishingly small concentrations. Taken together, these attributes may satisfy some of the golden rules of drug development such as the uniqueness or novelty of the agent's structure, a low threshold for activity, high level of sophistication and knowledge in the field of enquiry, and the leeway to further refine the molecule by rational means.

Stage of Development: In vitro studies have been completed, and a limited number of animal studies have been carried out.

Dated: August 16, 2004.

Steven M. Ferguson,

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

[FR Doc. 04–19300 Filed 8–23–04; 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.

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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