

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

Dated: February 17, 2005.

Sheila Dearybury Walcoff,
Associate Commissioner for External Relations.

[FR Doc. 05-3741 Filed 2-25-05; 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 March 17, 2005, from 8 a.m. to 4 p.m.

Location: Hilton Washington DC North/Gaithersburg, Crystals Ballroom, 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 a premarket notification submission for use in the induction, maintenance, and reversal of mild hypothermia in the treatment of unconscious adult patients with spontaneous circulation after out-of-hospital cardiac arrest when the initial rhythm was ventricular fibrillation.

Background information for the topic, including the agenda and questions for the committee, will be available to the public one 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 March 5, 2005. 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 March 5, 2005, 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 Shirley Meeks at 240-276-0450, ext. 105, 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 17, 2005.

Sheila Dearybury Walcoff,
Associate Commissioner for External Relations.

[FR Doc. 05-3742 Filed 2-25-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of

proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443-1891.

Comments are invited on: (a) Whether the proposed collection of information is 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 respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Evaluation of the Implementation and Outcomes of the Maternal and Child Health Bureau's National Healthy Start Program—Phase II (NEW)

The Health Resources and Service Administration's Maternal and Child Health Bureau (MCHB) initiated the Healthy Start Program in 1991 in response to concerns about high infant mortality rates. The Phase II evaluation includes a survey of Healthy Start Program participants designed to collect information that is important to understanding the implementation of Healthy Start and the program effects from a client perspective. Specifically, the goals of the survey are to: describe the participant population, assess the services they received during the prenatal and early postpartum periods, describe their experiences and satisfaction with the health system and services, and examine their health behaviors.

The survey will be administered to participants at eight grantee sites. The survey will use a mixed-mode approach: it will be conducted primarily by telephone using computer-assisted telephone interviewing (CATI) with in-person field follow up if the telephone attempts are unsuccessful.

Data gathered from the survey will be used to provide HRSA the information necessary to assess the grantees' achievement of MCHB's goal to improve perinatal outcomes among racial and ethnic minorities.

The estimated burden on respondents is as follows:

Respondents	Number of respondents	Responses per respondent	Total responses	Minutes per response	Total burden (hours)
Participants	1000	1	1000	30	500

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 11A-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of notice.

Dated: February 17, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05-3712 Filed 2-25-05; 8:45 am]

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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.

Compositions and Methods for the Treatment of Immune-Related Disease

F. Xavier Valencia and Peter E. Lipsky (NIAMS), U.S. Provisional Application filed 07 Jan 2005 (DHHS Reference No. E-355-2004/0-US-01).

Licensing Contact: Fatima Sayyid; 301/435-4521; sayyidf@mail.nih.gov.

The ability of the immune system to discriminate between self and non-self is controlled by central and peripheral

tolerance mechanisms. One of the most important ways the immune system controls the outcome of such a response is through naturally occurring CD4+CD25+ regulatory T cells.

The present invention relates to compositions and methods for treating immune related disease, a method for determining the presence of or predisposition to an immune related disease, and a pharmaceutical composition for treating an immune related disease in a mammal.

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

Expression Tags for High Yield Soluble Expression of Recombinant Proteins

Deb K. Chatterjee and Dominic Esposito (NCI), U.S. Provisional Application No. 60/564,982 filed 26 Apr 2004 (DHHS Reference No. E-103-2004/0-US-01).

Licensing Contact: Susan Carson, 301-435-5020; carsonsu@mail.nih.gov.

Production of large quantities of soluble and correctly folded proteins is essential for a variety of applications ranging from functional analysis and structure determination to clinical trials. *E. coli* is a widely used expression system that offers the advantages of ease of handling, cost-effectiveness and the ability to produce proteins in high yield. However, the enhanced production obtainable with *E. coli* expression systems is frequently accompanied by problems of protein insolubility, production host non-viability and aberrant protein folding. Many strategies have been proposed to address these problems, in particular the use of fusion vectors that mediate the expression of a target gene linked to a peptide signal sequence or to a "chaperone" or "carrier" protein that is capable of "escorting" the fusion protein out of the cytoplasm and into the periplasmic space. However, there remains a need for methods that provide soluble proteins that are correctly folded and in functional form without unacceptably diminishing the yield of recovered protein or requiring complex host strains.

NIH researchers have developed a fusion polynucleotide in which a polynucleotide encoding a desired target protein is linked to one or more

chaperone protein domains (Sbp and DsbC) with or without the signal sequence. This permits the expressed proteins to be transported to the periplasm or to be retained in the cytoplasm respectively and these vectors were used to successfully express significant amounts of such difficult to express proteins as Hif1a, Folliculin (fol), a Folliculin domain (FD), Wnt5a, Endostatin, YopD, IL13 and IFN-Hybrid3. These fusion vectors are available for licensing and are useful tools for the expression of commercially viable amounts of functional proteins of therapeutic and scientific interest.

In addition to licensing, the technology is available for further development through collaborative research with the inventors via a Cooperative Research and Development Agreement (CRADA).

Novel Potent Monoamine Oxidase Inhibitors

Kenneth L. Kirk *et al.* (NIDDK), U.S. Provisional Application No. 60/484,710 filed 03 Jul 2003 (DHHS Reference No. E-226-2003/0-US-01); PCT Application No. PCT/US04/21505 filed 01 Jul 2004 (DHHS Reference No. E-226-2003/0-PCT-02).

Licensing Contact: Norbert Pontzer; 301/435-5502; pontzern@mail.nih.gov.

Copper- (EC, 1.4.3.6) and flavin-containing amine oxidases (EC, 1.4.3.4) make up two general classes of the widely distributed monoamine oxidases. Reversible and irreversible inhibitors of the flavin monoamine oxidases have been developed and investigated for treatment of diseases of the CNS such as depression, Parkinson's disease and Alzheimer's disease. These researchers have developed several new arylethyl and benzyl amine derivatives that incorporate both the key cyclopropane ring and fluorine substitution at strategic positions. The combined effects of this substitution pattern have led to new inhibitors of greatly increased potency and selectivity for all classes of monoamine oxidases. Their potent copper amine oxidase inhibitors are the best reversible inhibitors known and could provide vascular protection in advanced diabetics. Further information on these compounds can be found in Yoshida *et al.*, J. Med. Chem. (25 Mar 2004) 47 (7): 1796-1806, 2004, and Yoshida *et al.*,