

for discussion at the public meeting. During the October 16, 2003, public meeting, NIOSH indicated that subsequent future standards efforts following the completion of the PAPR CBRN standard would be in this sequence: Integrated self-contained breathing apparatus (SCBA)/PAPR, integrated SCBA/air-purifying respirators (APR), closed-circuit SCBA, and supplied air respirators. NIOSH wishes to obtain comments from individuals regarding this tentative priority order sequence to determine if it reflects the priorities of the stakeholder community's needs for respiratory protection. Recent acts of terrorism have created an urgent awareness of domestic security and preparedness issues. Municipal, State, and Federal responder groups, particularly these in locations considered potential targets, have been developing and modifying response and consequence management plans. Since the World Trade Center and anthrax incidents, most emergency response agencies have operated with a heightened appreciation of the potential scope and sustained resources requirements for coping with such events. The Federal Interagency Board for Equipment Standardization and Interoperability (IAB) has worked to identify personal protective equipment that is already available on the market for responders' use. The IAB has identified the development of standards or guidelines for respiratory protection equipment as a top priority. NIOSH, NIST, the National Fire Protection Association (NFPA), and the Occupational Safety and Health Administration have entered into a Memorandum of Understanding defining each agency or organization's role in developing, establishing, and enforcing standards or guidelines for responders' respiratory protective devices. NIST has initiated Interagency Agreements with NIOSH and RDECOM to aid in the development of appropriate protection standards or guidelines. NIOSH has the lead in developing standards or guidelines to test, evaluate, and approve respirators.

NIOSH, RDECOM, and NIST have hosted public meetings on April 17 and 18, 2001; June 18 and 19, 2002; October 16 and 17, 2002; April 29, 2003; June 25, 2003, and October 16, 2003, presenting their progress in assessing respiratory protection needs of responders to CBRN incidents. The methods or models for developing hazard and exposure estimates and the status in evaluating test methods and performance standards that may be applicable as future CBRN respirator standards or guidelines were discussed at these meetings.

Three NIOSH CBRN respirator standards and several NFPA standards for ensembles, SCBA and protective clothing were the first adopted by the U.S. Department of Homeland Security (DHS). On February 26, 2004, DHS adopted, as DHS standards, three NIOSH criteria for testing and certifying respirators for protection against CBRN exposures. NIOSH uses the criteria to test (1) SCBA for use by emergency responders against CBRN, (2) APR for use by emergency responders against CBRN exposures, and (3) escape respirators for protection against CBRN.

For Further Information Contact: NPPTL Event Management, 3610 Collins Ferry Road,

P.O. Box 880, Morgantown, West Virginia 26507-0880, Telephone (304) 285-4750, Fax (304) 285-4459, e-mail npptlevents@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 18, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04-6529 Filed 3-23-04; 8:45 am]

BILLING CODE 4163-19-P

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 April 21, 2004, from 9 a.m. to 5 p.m.

Location: Gaithersburg Marriott Washingtonian Center, Ballroom Salons E, F, and G, 9751 Washingtonian Blvd., 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, make recommendations, and vote on a premarket approval application for a carotid stent indicated for use in the treatment of carotid artery disease in high-risk 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>. Material for the April 21, 2004, session will be posted on April 20, 2004.

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 April 12, 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 April 12, 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: March 17, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04-6485 Filed 3-23-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science; 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: Advisory Committee for Pharmaceutical Science.

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 April 13 and 14, 2004, from 8:30 a.m. to 5 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Hilda Scharen or Kimberly Topper, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: SCHARENH@cder.fda.gov or TOPPERK@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On April 13, 2004, the committee will receive an update from the Clinical Pharmacology Subcommittee. The committee will also discuss and provide comments on the following topics: (1) A proposal for resolving the issues related to the parametric tolerance interval test for dose content uniformity for inhalation products, (2) the Process Analytical Technologies progress and next steps, and (3) process analytical technology for products in the Office of Biotechnology Products, Center for Drug Evaluation and Research and in the Center for Biologics Evaluation and Research. On April 14, 2004, the committee will discuss and provide comments on the following topics: (1) Bioequivalence testing/methods strategy for products exhibiting high variability and (2) bioequivalence concepts and definition.

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 April 6, 2004. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on April 13, 2004, and 1 p.m. and 2 p.m. on April 14, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 6, 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 Hilda Scharen or Kimberly Topper 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: March 17, 2004.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04-6484 Filed 3-23-04; 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, 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.

Cell-Based Assay of I-kappaB Kinase Activity

Richard Eric Davis *et al.* (NCI).

DHHS Reference No. E-109-2004/0—Research Tool.

Licensing Contact: Mojdeh Bahar; (301) 435-2950; baharm@mail.nih.gov.

The present invention is directed to a cell-based assay of I-kappaB Kinase (IKK) Activity, providing a facile probe for cellular assays of activity/activation and drug screening. IKK activation is essential to diseases including certain types of cancer and undesired immune responsiveness such as autoimmunity and transplant rejection. In the assay, cells of interest are engineered to express an easily-measured exogenous form of I-kB, driven by a promoter that is relatively independent of Nuclear factor of Kappa-B (NFkB) activity. Since the rate of synthesis of the "reporter" from the I-kB is stable, its level is then principally determined by its rate of degradation, and therefore correlates inversely with IKK activity.

The assay has been used to screen molecules for their IKK inhibitor activity, determine whether the toxicity of agents towards NFkB-dependent lines occurs via the inhibition of IKK, and to determine whether genetic manipulations such as overexpression, exogenous mutants, or RNA interference affect constitutive or inducible IKK activity or activation.

Available materials include retroviral plasmids encoding the reporter or controls, and cell lines stably infected with these plasmids and validated in the assay. These reporter cell lines have IKK activity that is either constitutively high or easily inducible through various pathways (TNF-alpha, CD40L, IL-1beta, etc.).

Specific Antibodies to the Lymphatic Endothelial Cell Specific Hyaluronic Acid Receptor, LYVE-1

Sam T. Hwang, Adela R. Cardones (NCI).

DHHS Reference No. E-107-2004/0—Research Tool.

Licensing Contact: Mojdeh Bahar; 301/435-2950; baharm@mail.nih.gov.

This invention is drawn to specific anti-sera to human LYVE-1. LYVE-1 is a lymphatic endothelial cell-specific transmembrane form of CD44 that may have a role in recruitment of immune cells and cancer cells to lymphatics. Following skin-immunization of 10 mice with cDNA encoding human LYVE-1, the inventors have developed specific anti-sera to human LYVE-1. The anti-sera work well for flow cytometry and fluorescence microscopy and recognize native LYVE-1 epitopes. The antibody would be useful to scientists studying the role of lymphatic vessels in immune diseases and cancer. It may also be useful for clinical