DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0467]

''Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection'' dated October 2002. The guidance document provides recommendations for assessing donor suitability and product safety for donors diagnosed with West Nile Virus (WNV) infections or with illnesses potentially caused by WNV. The guidance applies to Whole Blood and blood components intended for use in transfusion and blood components including recovered plasma, Source Leukocytes, and Source Plasma intended for use in further manufacturing into injectable or non-injectable products. These recommendations are intended to reduce the risk of transfusion transmitted WNV, particularly in areas where human cases are occurring.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection'' dated October 2002. To address the possible risk of transmission of WNV by blood transfusion, we are providing recommendations for donor deferral, and for product quarantine and retrieval related to reports of post-donation illnesses in the donor, or WNV infection in recipients of blood. We are continuing to consult with experts on WNV at the Centers for Disease Control and Prevention (CDC) and elsewhere to ensure the greatest possible safety of the blood supply. In addition, epidemiologic and laboratory investigations are rapidly evolving. We will evaluate promptly any new data or experiences related to this issue and provide further updates as appropriate. FDA developed the recommendations in the guidance with other Public Health Service agencies of the Department of Health and Human Services.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

The agency is soliciting public comment, but is implementing this guidance immediately because of public health concerns related to the possible risk of transfusion transmitted WNV. Interested persons may, at any time, submit written or electronic comments to the Dockets Management Branch (*see* **ADDRESSES**) regarding this guidance document. Two copies of any mailed comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: November 15, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02–30156 Filed 11–27–02; 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 agencies 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.

Backbone-Substituted Bifunctional DOTA Ligands, Complexes and Compositions Thereof, and Methods of Using the Same

Martin Brechbiel, Hyun-soon Chung (NCI), DHHS Reference No. E–035–2002 filed 06 Sep 2002, Licensing Contact: Matthew Kiser; 301/435–5236; *kiserm@od.nih.gov*.

The subject technology is directed to three backbone-substituted 1,4,7,10-tetraazacyclododecane (DOTA) compounds. These compounds can be

chelated with radionuclides and used as imaging or therapeutic agents. In particular, the compounds can be complexed with a paramagnetic element (*e.g.* Gd (III)) and used as contrast agents in magnetic resonance imaging (MRI) applications.

The DOTA derivatives of the invention are such that the macrocyclic backbone was pre-arranged or pre-organized in order to lower the energy barrier to complex formation, thereby potentially increasing the rate of complex formation. The pre-organization and macrocyclic effect of the DOTA sub-structure accelerates complexation with metal ions and isotopes (*e.g.* Y (III), Gd (III); etc.), while maintaining a high level of stability of the complexes.

Alleviating Symptoms of Th2-Like Cytokine Mediated Disorders by Reducing IL–13 Receptor-Expressing Cells in the Respiratory Tract

Raj K. Puri *et al.* (FDA), PCT application PCT/US02/00616, which claims priority to U.S. Provisional Patent Application 60/337,179 (E–296–01/0) filed December 4, 2001, Licensing Contact: Brenda Hefti; 301/435–4632; *heftib@od.nih.gov.*

This invention relates to the alleviation of symptoms of Th2-like cytokine mediated disorders, such as allergy, asthma, and to hyperinflammatory responses in the respiratory tract to infectious diseases and parasitic infections, including tuberculosis, schistosomiasis, leishmania, and filiarsis.

This invention claims a variety of methods and uses of a chimeric molecule comprising a toxic moiety and a targeting moiety that specifically binds to a cell surface receptor for IL–13, to alleviate symptoms of a variety of respiratory disorders. This method has been proven successful in various mouse models in vivo.

Use of Mx GTPases in the Prognosis and Treatment of Cancer

J. Frederic Mushinski, Jane B. Trepel, Michel Andre Horisberger, PhuongMai Nguyen, Chand Khanna (NCI), DHHS Reference No. E–292–01/0 filed 18 Oct 2001, Licensing Contact: Matthew Kiser; 301/435–5236; *kiserm@od.nih.gov.*

The present invention describes novel approaches in the diagnosis, reduction of progression and treatment of cancer using Mx GTPases (Mxs) and Mx-encoding nucleic acids. The diagnostic benefits of this invention include methods of assessing the metastatic potential of cancer cells by determining the level of an Mx or Mx-encoding nucleic acid present in the cells. This invention also provides a method for administration of an Mx or expression of a nucleic acid encoding an Mx at, in, or near cancer cells, as well as a method for systemic induction of an Mx protein to reduce cancer progression in both solid tumors and hematologic malignancies.

Use of a Promoter of T-Cell Expansion and an Inducer of CD40 Stimulation in the Treatment or Prevention of a Pathologic State

William J. Murphy, Robert Wiltrout, Bruce Blazar, Susan E. Wilson (NCI), DHHS Reference Nos. E–150–01/0 filed 23 Aug 2001 and E–150–01/1 filed 23 Aug 2002, Licensing Contact: Matthew Kiser; 301/435–5236; *kiserm@od.nih.gov.*

The present invention provides a method for the prevention and treatment of pathologic states in mammals by administering a promoter of T-cell expansion with an inducer of CD40 stimulation in synergistically effective amounts. The disclosed invention could provide treatments for cancers, viral infections, HIV, bacterial infections, fungal infections, and allergic conditions. A method for assessing the treatment administered is also described.

Dated: November 19, 2002.

Jack Spiegel,

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

[FR Doc. 02–30227 Filed 11–27–02; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, Child Development Review SEP.

Date: December 5–6, 2002.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Marita R. Hopmann, PhD, Scientific Review Administrator, Division of Scientific ReviewNational Institute of child Health, and Human Development, 6100 building, Room 5E01, Bethesda, MD 20892, (301) 435–6911, *hopmannm@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.209, Contraception and Infertility Loan Repayment Program; 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research, National Institutes of Health, HHS)

Dated: November 21, 2002.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 02–30231 Filed 11–27–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health National

National Institute of Child Health And Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Board on Medical Rehabilitation Research.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Advisory Board on Medical Rehabilitation Research.

Date: December 5–6, 2002.

Time: December 5, 2002, 8:45 a.m. to 5 p.m.

Agenda: The agenda will include reports by the Director, NICHD and Director, NCMRR, update on NCMRR training activities, discussion of the future of medical rehabilitation, and other business of the Board.