II. Scope of the Public Meeting

The public meeting is intended to review FDA's regulatory and scientific approach to levothyroxine sodium products, including manufacturing standards, in vitro dissolution studies, and bioavailability/bioequivalence methods.

The public meeting will also review clinical, scientific, and methodological issues relevant to the possible use of serum thyrotropin concentration as a pharmacodynamic measure of levothyroxine sodium bioequivalence.

The public meeting will include representatives from FDA and from the three medical societies. A series of brief presentations will frame the issues under consideration, followed by panel discussions involving speakers and moderators, with questions and comments from the audience. Other interested constituencies (e.g., patient advocacy and education groups, pharmaceutical sponsors, general public) will have an opportunity to provide input during the question and comment periods.

III. Registration, Agenda, and Presentations

No registration is required to attend the meeting. Seating will be on a first-come, first-served basis. If you need special accommodations due to a disability, please contact (see **FOR FURTHER INFORMATION CONTACT**).

The agenda for public meeting will be available on FDA's Center for Drug Evaluation and Research Web site at *http://www.fda.gov/cder/meeting/levothyroxine.htm* and at the meeting. After the meeting, the agenda, presentations, and transcript will be placed on file in the Division of Dockets Management under the docket number found in the heading of this document and on CDER's Web site identified previously.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the topics discussed in this document. Submit two copies of mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcripts

Copies of the transcript may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 20 working days after the meeting at a cost of 10 cents per page or on compact disc at a cost of $14.25 each. You may also examine the transcript at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 14, 2005.

Jeffery Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7883 Filed 4–19–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0133]

Draft ''Guidance for Industry: Assessing 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 draft document entitled ''Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection,'' dated April 2005. The draft guidance document provides revisions to the previously published recommendations for assessing donor suitability and product safety when donors are diagnosed with or suspected of West Nile Virus (WNV) infections based on symptoms and laboratory tests. This draft guidance proposes revised deferral periods for such donors, and updates information on product retrieval and quarantine. When finalized, this guidance will supersede ''Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection,'' dated May 2003.

DATES: Submit written or electronic comments on the draft guidance by May 20, 2005, to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft 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 draft guidance 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 draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (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: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Assessing Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection,'' dated April 2005. FDA developed the information in this draft guidance after consulting with other Public Health Service agencies of the Department of Health and Human Services.

This draft guidance:

- Applies to donors of blood and blood components intended for transfusion;
- Applies to donors of blood components intended for use in further manufacturing into injectable products or noninjectable products, including recovered plasma, Source Leukocytes, and Source Plasma;
- Provides updated scientific data;
- Removes the current recommendation for donor deferral based upon a reported history of headache with fever in the week before donation;
- Proposes new deferral periods for donors who are diagnosed with or suspected of WNV infections;
- Describes the use of the investigational nucleic acid test (NAT) for WNV in deferring reactive donors; and
- Provides information about the use of individual donor NAT testing to re-enter reactive donors if a blood establishment, at its discretion, chooses to reenter such donors.

This draft guidance, when finalized, will supersede ''Guidance for Industry: Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection,'' dated May 2003.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The information collection provisions in this guidance for 21 CFR 601.12 were approved under OMB control number 0910–0338; 21 CFR 606.170(b) was approved under OMB control number 0910–0116; and 21 CFR 606.171 was approved under OMB control number 0910–0458.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

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

Dated: April 13, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7821 Filed 4–19–05; 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.

Methods for Tumor Treatment Using Dendrimer Conjugates

Hisataka Kobayashi and Peter Choyke (NCI)

U.S. Provisional Application filed 11 Mar 2005 (DHHS Reference No. E–107–2005/0–US–01)

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

Available for licensing and commercial development are dendrimer based methods for treating cancer. The dendrimer conjugate comprises an effective amount of an anti-tumor agent. A generation 5 DAB, generation 2 polylysine, or generation 6–8 PAMAM dendrimer (*e.g.,* PAMAM–G6) conjugate is administered to a cancer patient. The anti-tumor agent is selectively concentrated in the lymphatic system to treat metastatic disease. The anti-tumor agent can be one that is activated after selective aggregation in the lymphatic system. When an activatable anti-tumor agent is used, it may be activated by applying physical energy to the subject's body, for example by external application of that energy to the body. In particular examples, the external energy is heat, ultrasound, or electromagnetic energy. In particular, the physical energy can be a particle beam, such as a neutron beam.

The dendrimer conjugates may include an imaging agent, which permits the lymphatic system to be imaged when selective intra-lymphatic concentration of the dendrimer occurs. Further, when the dendrimer conjugate includes an activatable anti-tumor agent, the method may include selectively applying physical energy to the subject's body to selectively activate the anti-tumor agent in the lymphatic system. The dendrimer conjugate can include gadolinium, wherein the gadolinium acts as a contrast agent to image the lymphatic system.

In a particular example, the dendrimer conjugate includes a gadolinium-imaging agent that is activatable by a neutron beam. Once the gadolinium containing dendrimer conjugate is concentrated in the lymphatic system, detecting selective concentration of the dendrimer conjugate in the lymphatic system images the lymphatic system. The presence of tumor in lymph nodes can also be detected using this imaging technique. A neutron beam is then selectively applied to the imaged lymphatic system to selectively activate the anti-tumor agent at target areas in the lymphatic system for the treatment of metastatic tumor. In this example, the target area may be a lymph node, such as a sentinel lymph node, or a lymphatic vessel. The target area, when imaged, may show evidence of primary or metastatic tumor.

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

A Universal Antigen Delivery Platform for Enhanced Immune Response

John T. Patton and Zenobia F. Taraporewala (NIAID)

U.S. Provisional Application No. 60/633,036 filed 03 Dec 2004 (DHHS Reference No. E–322–2004/0–US–01)

Licensing Contact: Chekesha Clingman; 301/435–5018; *clingmac@mail.nih.gov.*

The present invention relates to a universal antigen delivery platform based on rotavirus NSP2 fusion proteins and methods for the use of such fusion proteins to enhance an immune response to an antigen. This technology