*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 June 10, 2004, from 8 a.m. to 5:30 p.m.

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

*Contact Person*: Shalini Jain, 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, or e-mail: jains@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512545. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: The committee will discuss the possible removal of the essential use designation of albuterol under 21 CFR 2.125.

*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 May 24, 2004. Oral presentations from the public will be scheduled between approximately 11 a.m. and 1 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 24, 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 Kimberly Littleton 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: May 3, 2004.

**Peter J. Pitts,**

*Associate Commissioner for External Relations.*

[FR Doc. 04–10590 Filed 5–10–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004D–0163]**

### Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System.'' This guidance document describes a means by which the immunomagnetic circulating cancer cell selection and enumeration system may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify the immunomagnetic circulating cancer cell selection and enumeration system into class II (special controls). This guidance document is immediately in effect as the special control for the immunomagnetic circulating cancer cell selection and enumeration system but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

**DATES:** Submit written or electronic comments on this guidance at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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*. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Nina Chace, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293, ext. 138.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying the immunomagnetic circulating cancer cell selection and enumeration system into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for the device. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

#### II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs (§ 10.115). The guidance represents the agency's current thinking on the

immunomagnetic circulating cancer cell selection and enumeration system. 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 requirements of the applicable statute and regulations.

**III. Electronic Access**

To receive ''Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System'' by fax machine, call FDA's Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1531) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of cleared submissions, approved applications, and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

**IV. Paperwork Reduction Act of 1995**

This 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 (the PRA) (44 U.S.C. 3501–3520) . The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

**V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit two paper copies of any mailed comments, except that individuals may submit paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 26, 2004.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 04–10594 Filed 5–10–04; 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.

**Eosinophil-Derived Neurotoxin, an Antimicrobial Protein With Ribonuclease Activity, is an Immunostimulant**

De Yang *et al.* (NCI).

U.S. Provisional Patent Application Nos. 60/466,797 and 60/466,796, filed 29 Apr 2003 (DHHS Reference Nos. E–175–2003/0–US–01 and E–191–2003/0–US–01).

*Licensing Contact:* Brenda Hefti; 301/435–4632; *heftib@mail.nih.gov.*

Eosinophil-derived neurotoxin (EDN) has *in vitro* anti-viral activity that is dependent on its ribonuclease activity. This invention discloses that EDN is a selective chemoattractant and activator of dendritic cells, resulting in dendritic cell migration, maturation, and a production of a wide variety of cytokines. Based on these potent chemotactic and activating effects on dendritic cells, EDN might be useful as a clinical immunoadjuvant for the promotion of immune responses to specific antigens of tumors or pathogenic organisms.

**Detection of Antigen-Specific T Cells and Novel T Cell Epitopes by Acquisition of Peptide/HLA–GFP Complexes**

Steven Jacobson, Utano Tomaru, and Yoshihisa Yamano (NINDS).

U.S. Provisional Application No. 60/457,006 filed 24 Mar 2003 (DHHS Reference No. E–084–2003/0–US–01); U.S. Provisional Application No. 60/480,083 filed 20 Jun 2003 (DHHS Reference No. E–084–2003/1–US–01); PCT Application filed 24 Mar 2004 (DHHS Reference No. E–084–2003/2–PCT–01).

*Licensing Contact:* Brenda Hefti; 301/435–4632; *heftib@mail.nih.gov.*

This invention relates to a method for identifying specific T cell epitopes and antigen-specific T cells through labeling with an HLA–GFP complex expressed on an antigen-presenting cell. The T cells acquired the peptide-HLA–GFP complex through T cell mediated endocytosis upon specific antigen stimulation. This basic method can be used for several purposes. First, it can be used to generate a T-cell immune response through the attachment of a reporter peptide to the antigen-presenting cell. It can also be used as a way to assay a population of cells to determine whether any T cells specific for a particular antigen are present. This might be useful in applications related to autoimmunity, infectious disease, or cancer. Third, it can be used as a therapeutic to eliminate antigen-specific T cells associated with disease, if coupled to a toxic moiety.

**Protein Kinase C Inhibitor, Related Composition, and Method of Use**

Shaomeng Wang, Peter Blumberg (NCI), Nancy Lewin (NCI).