cDNA microarray. Human Pathol. 2004 Oct;35(10):1196–1209.

Patent Status: U.S. Patent Application No. 10/533,459 filed 02 May 2005 (HHS Reference No. E–248–2002/0–US–04).

Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov*.

Immunotoxin Useful for Treatment of AIDS

Description of Invention: Human Immunodeficiency Virus (HIV) attacks and destroys T cells, leading to the development of Acquired Immunodeficiency Syndrome (AIDS) in patients. Although significant progress has been made treating patients with AIDS, an effective cure has yet to be identified. For example, highly active antiretroviral therapy (HAART) has shown dramatic reduction of viral replication while allowing recovery of the immune system in HIV patients. However, HAART does not directly kill HIV-infected T cells, allowing the virus to persist in the body and resume replication and infection of T cells after HAART is stopped. This ultimately results in a return to pre-treatment levels of viral replication and the persistence of the disease in patients.

The current technology concerns an invention that can be used to address this limitation of HAART. An immunotoxin has been created that targets a toxin (PE38) to the HIV-specific Envelope glycoprotein (gp120) that is displayed on the surface of T cells that have been infected with the HIV virus. The immunotoxin kills the HIV-infected T cells and other infected cell types that serve as a viral reservoirs during HAART, thereby reducing the ability of the virus to replicate and infect other cells after HAART is stopped. Recent data shows that the immunotoxin blocks the spread of HIV–1 *in vitro* and does not induce hepatotoxicity in rhesus monkeys, suggesting the procedure could be effective in human patients. By combining the immunotoxin with a treatment regimen such as HAART, it may be possible to significantly improve treatment of HIV infection.

Applications:

- Reduction of HIV–1 infected cell populations in patients to reduce viral reservoirs.
- Treatment of HIV infection in combination with therapeutic regimens such as HAART.

Advantages:

- Overcomes a limitation of current HIV therapies by specifically depleting infected cell reservoirs.
- Specific targeting of HIV-infected cells allows depletion of infected cells without affecting uninfected cells.
- Combination therapy combines inhibition of HIV replication and selective killing of infected cells that still persist.

Development Status: Preclinical stage of development.

Patent Status:

- US Patent Application 09/673,707 (HHS Reference No. E–201–1998/0–US–06), pending.
- European Patent 1085908 (HHS Reference No. E–201–1998/0–EP–05).

For more information, see:

- PE Kennedy et al. Anti-HIV–1 immunotoxin 3B3(Fv)-PE38: enhanced potency against clinical isolates in human PBMCs and macrophages, and negligible hepatotoxicity in macaques. J Leukoc Biol. 2006 Nov;80(5):1175–1182.
- TK Bera et al. Specific killing of HIV-infected lymphocytes by a recombinant immunotoxin directed against the HIV–1 envelope glycoprotein. Mol Med. 1998 Jun;4(6):384–391.

Inventors: Ira Pastan *et al.* (NCI)

Licensing Status: Available for licensing.

Licensing Contact: David A. Lambertson, Ph.D.; 301–435–4632; *lambertsond@mail.nih.gov*.

Collaborative Research Opportunity: The Center for Cancer Research, Laboratory of Molecular Biology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: November 4, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–27196 Filed 11–10–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0508]

Guidance for Industry on Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.'' The guidance document is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments'' to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

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

FOR FURTHER INFORMATION CONTACT: Michele Mital, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 301–796–4800, *Michele.Mital@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 21, 2009 (74 FR 54052), FDA announced the availability of a draft guidance document entitled ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.'' The agency considered received comments as it finalized this guidance. This guidance document is designed to assist domestic owners and operators with submitting tobacco product establishment registration and tobacco product listing information. Under section 905(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 387e(b)), added by the

Tobacco Control Act, every person who owns or operates any domestic establishments engaged in the manufacture, preparation, compounding, or processing of a regulated tobacco product must register with FDA by December 31 of each year. Moreover, all registrants must at the time of registration file with FDA a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution, along with certain accompanying information, including all labeling (see section 905(i)(1) of the act, as added by the Tobacco Control Act).

FDA does not intend to enforce the requirement to submit registration and product listing information under section 905 of the act by December 31, 2009, provided that the submission is received by FDA on or before February 28, 2010. We recognize that the forms developed by FDA are new to industry, and so may require additional time to complete accurately. While electronic submission of registration and listing information is not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data management and submission. FDA does recognize, however, that electronic submission requires several additional steps, such as obtaining an Electronic Submissions Gateway account and becoming familiar with the eSubmitter electronic application. FDA therefore believes that this additional time for the first submission of this registration and listing information should result in submission of higher quality information.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.'' 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. 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 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 brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0650.

V. Electronic Access

An electronic version of the guidance document is available on the Internet at *http://www.regulations.gov* and *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm*.

Dated: November 6, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–27182 Filed 11–6–09; 4:15 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for the treatment of cancer. The outcome of the evaluation will provide information to internal NCI committees that will decide whether NCI should support requests and make available contract resources for development of the potential therapeutic to improve the treatment of various forms of cancer. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Experimental Therapeutics Program (NExT).

Date: December 9, 2009.

Time: 8:30 a.m.–4:30 p.m.

Agenda: To evaluate the NCI Experimental Therapeutics Program Portfolio.

Place: Bethesda Marriott—Pooks Hill, 5115 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Barbara Mroczkowski, Executive Secretary, NCI Experimental Therapeutics Program, National Cancer Institute, NIH, 31 Center Drive, Room 3A44, Bethesda, MD 20892, (301) 496–4291, *mroczkowskib@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 3, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–27217 Filed 11–10–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, November 18, 2009, 3 p.m. to November 18, 2009, 10 p.m., Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue, NW., Washington, DC, 20036 which was published in the **Federal Register** on November 3, 2009, 74 FR 56855.

The starting time of the meeting on November 18, 2009 has been changed to 6 p.m. until adjournment at 10 p.m. The meeting date and location remain the same. The meeting is closed to the public.

Dated: November 5, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–27216 Filed 11–10–09; 8:45 am]

BILLING CODE 4140–01–P