Inspections and reinspections involve the same procedure, require the same amount of time, and are therefore charged at the same rate.

[FR Doc. E6–10174 Filed 6–27–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Blood Products 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 July 13, 2006, from 8 a.m. to 4:30 p.m. and on July 14, 2006, from 8 a.m. to 3:30 p.m.

Location: Hilton Hotel, Washington DC North/Gaithersburg, 620 Perry Pkwy, Gaithersburg, MD 20877.

Contact Person: Donald W. Jehn, or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 13, 2006, the Committee will hear updates on the following topics: (1) Summary of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability meeting held on May 9 and 10, 2006; (2) summary of workshop on testing for malarial infections in blood donors to be held on July 12, 2006; (3) Committee report on the office of blood research and review site visit, review of intramural research; (4) west nile virus update and (5) FDA acceptance criteria for *in vivo* red blood cell survival studies. The Committee will discuss the FDA review of Nabi Biopharmaceuticals' Hepatitis B Immunoglobulin Intravenous (IGIV) for prevention of recurrent Hepatitis B Virus (HBV) disease after orthotopic liver transplantation. In the afternoon the Committee will hear an overview of the research program of the Laboratory of Bacterial, Parasitic and Unconventional Agents, Division of Emerging and Transfusion Transmitted Diseases, OBRR, CBER. On July 14, 2006, from 8 a.m. to 3:30 p.m. the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

Procedure: On July 13, 2006, from 8 a.m. to 3:30 p.m., the meeting is open to the public. 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 on or before July 5, 2006. Oral presentations from the public will be scheduled between approximately 11 a.m. to 11:30 a.m. and 3 p.m. to 3:30 p.m. on July 13, 2006. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person 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 on or before July 5, 2006.

Closed Committee Deliberations: On July 13, 2006, between 3:30 p.m. and 4:30 p.m. the meeting will be closed to permit discussion of information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c) (6)). The Committee will discuss a review of the individual research programs. On July 14, 2006, the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c) (4)). This portion of the meeting will be closed to permit discussion of this material.

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 Donald W. Jehn or Pearline K. Muckelvene 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: June 20, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. 06–5870 Filed 6–27–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0254]

Draft Guidance for Industry: Analytical Methods Description for Type C Medicated Feeds; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft guidance for industry (#137) entitled ''Analytical Methods Description for Type C Medicated Feeds.'' This draft guidance provides our recommendations for describing methods for analyzing new animal drugs in Type C medicated feeds.

DATES: Submit written or electronic comments on this draft guidance by September 11, 2006 to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

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. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Rebecca L. Owen, Center for Veterinary Medicine (HFV–141), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9842, e-mail: *rebecca.owen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 512 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360b) establishes the requirements for new animal drug approval. FDA regulations in part 514 (21 CFR part 514) specify the information you must submit as part of your new animal drug application (NADA) and the proper format for the NADA submission. As part of your NADA submission, you must include a ''detailed description of the collection of samples and the analytical procedures to which they are subjected'' (§ 514.1(b)(5)(vii). This should include a description of practicable methods of analysis which have adequate sensitivity to determine the amount of the new animal drug in the final dosage form (§ 514.1(b)(5)(vii)(*a*). This draft guidance provides recommendations for describing methods for analyzing new animal drugs in Type C medicated feeds. This draft guidance applies to instrumental methods only (e.g., High Pressure Liquid Chromatography, Gas Chromatography. For guidance on other methods (e.g., microbiological methods) you should contact the center.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in § 514.1 have been approved under OMB control numbers 0910–0032 and 0910–0154.

III. Significance of Guidance

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on the 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 alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

This 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 this draft 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 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.

V. Electronic Access

Copies of the draft guidance document entitled ''Analytical Methods Description for Type C Medicated Feeds'' may be obtained from the CVM Home Page (*http://www.fda.gov/cvm*) and from the Division of Dockets Management Web site (*http://www.fda.gov/ohrms/dockets/default.htm*).

Dated: June 21, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–5860 Filed 6–27–06; 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.

Agonist Epitopes for Renal Cell Carcinoma

Description of Technology: Approximately 30,000 patients are diagnosed with renal cell carcinoma (RCC) each year in the United States, and an estimated 12,000 patients die of this disease. Most patients are diagnosed with advanced local disease or metastatic disease. Metastatic RCC carries a poor prognosis with median survivals in the range of 10–12 months. Drugs that inhibit VEGF receptor tyrosine kinases such as Sorafenib and Sunitinib have recently been approved by the FDA to treat metastatic RCC. Although a significant percentage of patients will achieve a partial response or disease stabilization with these agents, complete responses are rare and disease progression eventually ensues. RCC is unusual among solid tumors as it appears to be susceptible to immunotherapy. Cytokines such as IL–2 and IFN-alpha nonspecifically stimulate the immune system resulting in disease regression. Unfortunately, these drugs achieve success in only a minority (15–20%) of the metastatic RCC patient population. Therefore, new methods are needed to improve on immune-based therapies and expand the curative potential of therapies for patients with RCC.

The present invention discloses peptides and antigen epitopes specific for RCC for use in the diagnosis, vaccination, or adoptive infusion of antigen specific T cells to treat patients with metastatic RCC. The immunogenic peptide, which binds to the HLA–A11 epitope, was identified in a patient with metastatic RCC that under went an investigational allogeneic hematopoietic stem cell transplant. Cancer regression occurred post-transplant consistent with a graft-vs-tumor effect. A T-cell line, expanded from the patient's blood cells at the time of tumor regression, was isolated and subsequently shown to kill the patients RCC cells in vitro. Expression and sequencing studies revealed that the patient's T-cells recognize an antigen epitope derived from a human endogenous retrovirus (HERV). Further, pre-clinical studies using quantitative real-time PCR found that this HERV was expressed in eight of 14 RCC tumor cell lines with no HERV expression in patient fibroblasts, hematopoietic cells or in c-DNAs analyzed from 48 different normal tissues. Plans are underway to investigate the immunogenic potential of this peptide to induce expansion of T-cells that are cytotoxic to RCC cells in vitro and in pre-clinical animal models.

Inventors: Richard W. Childs, *et al.* (NHLBI).

Publications: Details of the invention are published in:

1. I. Delgado-Espinoza, *et al.*, ''Nonmyeloablative transplantation for solid tumors: A new frontier for allogeneic immunotherapy,'' *Expert Rev Anticancer Ther.* 2004 Oct;4(5):865–75.