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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 Pearlina 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 Pearlina 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.

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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: