

Contact Person: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6129, FAX: 301-827-2843, e-mail: wilczek@cber.fda.gov.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by April 23, 2004. Early registration is recommended because seating is limited to 176 participants. Registration will be done on a space available basis on the day of the workshop, beginning at 7:15 a.m. There is no registration fee.

If you need special accommodations due to a disability, please contact Joseph Wilczek (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA, in co-sponsorship with the Hitchcock Foundation, is sponsoring a public workshop on the development of a new standard for assessing the in vivo quality of platelet products through radiolabeling studies. The workshop objectives are to review current methods in radiolabeling studies, to propose a new approach that will set the performance of fresh platelets as a gold standard, to present data on application of a new standard, and to discuss the development of a novel experimental protocol. The public workshop agenda is posted on FDA's Internet at <http://www.fda.gov/cber/meetings/radiopl0504.htm>.

Transcripts: Transcripts of the workshop 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 15 working days after the meeting at a cost of 10 cents per page. In addition, the transcript will be placed on FDA's Internet at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: April 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-8023 Filed 4-7-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0160]

Guidance for Industry: Use of Unapproved Hormone Implants in Veal Calves; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#172) entitled "Use of Unapproved Hormone Implants in Veal Calves." This guidance outlines special measures to ensure the safety of veal in response to the identified illegal use of unapproved hormone implants in veal calves.

DATES: Submit written or electronic comments on agency guidances at any time.

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

Submit written requests for single copies of the 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.

FOR FURTHER INFORMATION CONTACT:

Gloria J. Dunnavan, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1168, e-mail: gloria.dunnavan@fda.gov.

SUPPLEMENTARY INFORMATION:

I. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation in § 10.115 (21 CFR 10.115). It is being implemented immediately without prior public comment, under § 10.115(g)(2), because of the agency's urgent need to provide guidance concerning veal that has been implanted with unapproved hormones. However, under GGPs, FDA requests comments on the guidance and will revise the document, if appropriate.

Comments will be considered by the agency in the development of future policy.

This guidance represents 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 alternative approach may be used if such approach satisfies the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the 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.

III. Electronic Access

Copies of this guidance document 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: April 5, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-8075 Filed 4-6-04; 2:25 pm]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Meetings

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 meetings.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings 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 grant applications and

the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Initial Review Group; Comparative Medicine Review Committee.

Date: June 2–3, 2004.

Open: June 2, 2004, 8 a.m. to 8:30 a.m.

Agenda: To discuss program planning and other issues.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Closed: June 2, 2004, 8:30 a.m. to adjournment.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Guo Zhang, MD, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, One Democracy Plaza, 6701 Democracy Blvd., Room WS-1064, 10th Floor, Bethesda, MD 20814-9692, (301) 435-0812, zhanggu@mail.nih.gov.

Name of Committee: Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities.

Date: June 8–11, 2004.

Open: June 8, 2004, 8 a.m. to 9 p.m.

Agenda: To discuss planning and other issues.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Closed: June 8, 2004, 9 a.m. to adjournment.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Sheryl K. Brining, PhD, Director of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd., Rm. 1074, MSC 4874, Bethesda, MD 20892-4874, (301) 435-0809, sb44k@nih.gov.

Name of Committee: National Center for Research Resources Initial Review Group; Clinical Research Review Committee.

Date: June 9–10, 2004.

Open: June 9, 2004, 8 a.m. to 8:30 a.m.

Agenda: To discuss program planning and other issues.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Closed: June 9, 2004, 8:30 a.m. to adjournment.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Mohan Viswanathan, PhD, Deputy Director, Office of Review, NCRR, National Institutes of Health, 6701 Democracy Blvd., Room 1084, MSC 4874, 1 Democracy Plaza, Bethesda, MD 20892-4874, 301-435-0829, mv10f@nih.gov.

Name of Committee: National Center for Research Resources Initial Review Group; Research Centers In Minority Institutions Review Committee.

Date: June 23–24, 2004.

Open: June 23, 2004, 8 a.m. to 9 a.m.

Agenda: To discuss program planning and other issues.

Place: Doubletree Rockville Hotel, 1750 Rockville Pike, Rockville, MD 20892.

Closed: June 23, 2004, 9 a.m. to adjournment.

Agenda: To review and evaluate grant applications.

Place: Doubletree Rockville Hotel, 1750 Rockville Pike, Rockville, MD 20892.

Contact Person: Eric H. Brown, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Boulevard, Room 1068, Bethesda, MD 20892-4874, 301-435-0815, browne@ncrr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure; 93.306, 93.333, National Institutes of Health, HHS)

Dated: April 1, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04-7986 Filed 4-7-04; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

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 meetings.

The meetings 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 grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Topical Thalidomide for Aphthous Stomatitis—HIV/AIDS.

Date: April 21, 2004.

Time: 9 a.m. to 3 p.m.

Agenda: To review and evaluate contract proposals.

Place: Sheraton Columbia Hotel, 10207 Wincopin Circle, Columbia, MD 21044.

Contact Person: David A Wilson, PhD, Scientific Review Administrator, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7204, MSC 7924, Bethesda, MD 20892, 301/435-0929.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Clinical Trial Nitric Oxide Synthase Inhibition in Cardiogenic Shock.

Date: May 3, 2004.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Silver Spring, 8727 Colesville Road, Silver Spring, MD 20910.

Contact Person: Judy S Hannah, PhD, Scientific Review Administrator, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7190, Bethesda, MD 20892, 301/435-0287.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 31, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04-7924 Filed 4-7-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which