

that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: February 16, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-3592 Filed 2-23-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0528]

Draft Guidance for Industry: Manufacturing Biological Drug Substances, Intermediates, or Products Using Spore-Forming Microorganisms; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Manufacturing Biological Drug Substances, Intermediates, or Products Using Spore-Forming Microorganisms" dated February 2005. The draft document is intended to provide guidance to manufacturers using spore-forming microorganisms in the production of certain biological products. The draft guidance document provides recommendations to industry in response to changes made to the requirements for spore-forming microorganisms to allow greater flexibility in manufacturing.

DATES: Submit written or electronic comments on the draft guidance by May 25, 2005, to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40),

Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Manufacturing Biological Drug Substances, Intermediates, or Products Using Spore-Forming Microorganisms" dated February 2005. The draft document is intended to provide guidance to manufacturers using spore-forming microorganisms in the production of certain biological products. The draft guidance document provides recommendations to industry in response to changes made to the requirements for spore-forming microorganisms to allow greater flexibility in manufacturing.

In the **Federal Register** of December 30, 2003, FDA published the direct final rule entitled "Revision of the Requirements for Spore-Forming Microorganisms" (68 FR 75116) and the accompanying proposed rule entitled "Revision of the Requirements for Spore-Forming Microorganisms; Companion to Direct Final Rule" (68 FR 75179) to modify the regulatory requirements for the manufacturing of biological products with spore-formers to allow greater manufacturing flexibility. The modifications were intended to provide alternatives to the then-existing requirements for separate, dedicated facilities and equipment for work with spore-forming microorganisms. In the **Federal Register** of May 14, 2004 (69 FR 26768), FDA published the "Revision of the Requirements for Spore-Forming Microorganisms; Confirmation of

Effective Date" confirming the effective date of June 1, 2004, for the direct final rule.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this 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 requirement of the applicable statutes and regulations.

II. Comments

The 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 the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final 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. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: February 16, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer 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 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 contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, SBIR Topic 197: EDRN—Bioinformatics Research Program.

Date: March 15, 2005.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6130 Executive Blvd., EPN Room C, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Kirt Vener, PhD, Branch Chief, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8061, Bethesda, MD 20892, (301) 496-7174, venerk@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(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: February 17, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

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BILLING CODE 4140-01-M

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 Cancer Institute Special Emphasis Panel, Small Grants Program for Cancer Epidemiology and Cancer Research Small Grant Program.

Date: March 29-31, 2005.

Time: 7 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Thomas M. Vollberg, PhD, Scientific Review Administrator, Special Review And Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 7142, Bethesda, MD 20892, 301/594-9582, vollbert@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(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: February 17, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

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applications, 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, Review of Training Applications.

Date: March 21-22, 2005.

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

Agenda: To review and evaluate grant applications.

Place: Hotel Rouge, 1315, 16th Street, NW., Washington, DC 20036.

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

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Review of Academic/Teacher Awards (K07s).

Date: March 30, 2005.

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: Zoe Huan, MD, Health Scientist Administrator, Review Branch, Room 7190, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, MSC 7924, Bethesda, MD 20892-7924. 301-435-0314.

(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: February 16, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-3561 Filed 2-23-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer 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 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

DEPARTMENT OF HEALTH OF 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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research 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 section 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