

Description Information for a Biological In Vitro Diagnostic Product" published in the **Federal Register** of November 10, 1998 (63 FR 63067).

In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of Form FDA 356h that will be used as a single harmonized application form for all drug and licensed biological products. Manufacturers may voluntarily begin using this form for a biological in vitro diagnostic product. FDA will announce in the future when manufacturers are required to use this form for all products. Use of the new harmonized Form FDA 356h will allow a biologic product manufacturer to submit one biologics license application instead of two separate applications (product license application and establishment license application).

This guidance document represents the agency's current thinking with regard to the content and format of the CMC and establishment description sections of a license application for a biological in vitro diagnostic product. 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 statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document by using the World Wide Web (WWW). For WWW access, connect to CBER at "http://www.fda.gov/cber/guidelines.htm".

Dated: March 1, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99-5521 Filed 3-5-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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 would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel, Comparative Medicine.

Date: March 25, 1999.

Time: 1:00 pm to 2:00 pm.

Agenda: To review and evaluate grant applications.

Place: Office of Review, National Center for Research Resources, 6705 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Bela J. Gulyas, Director, Office of Review, National Center for Research Resources, National Institutes of Health, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892, 301-435-0811.

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

Dated: March 2, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99-5660 Filed 3-5-99; 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 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 would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel HIV in the Lungs, Heart and Blood: Role of Chemokines and Their Receptors.

Date: March 30, 1999.

Time: 8:00 am to 3:00 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Anne P. Clark, Scientific Review Administrator, NIH, NHLBI, DEA, Review Branch, Rockledge II, 6701 Rockledge Drive, Room 7186, Bethesda, MD 20892-7924, (301) 435-0280. (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; 93.9839, Blood Diseases and Resources Research, National Institutes of Health, HHS).

Dated: March 2, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99-5657 Filed 3-5-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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