determines that a firm's response is satisfactory, a warning letter should not be issued. If CDRH is essentially satisfied with the firm's response but needs further clarification, it may seek additional information via telephone or untitled correspondence.

If a firm fails to respond to CDRH's untitled letter, a warning letter should be sent to the establishment by CDRH when the 15 working day timeframe has expired. If CDRH receives a response to the untitled letter within 15 working days, CDRH has 30 working days from the receipt date to determine whether the response is satisfactory. If the written response is determined to be unsatisfactory, CDRH should send a warning letter to the establishment.

When no warning letter is issued by CDRH due to a firm's satisfactory written response, a postinspectional notification letter should be sent by CDRH to the establishment, with a copy to the home district, which includes the following language:

''While this inspection found deficiencies concerning [insert 'premarket notification (510(k)),' 'labeling,' or both as appropriate] that would warrant a warning letter if uncorrected, your written response has satisfied us that you either have taken or are taking appropriate corrective actions. At this time, FDA does not intend to take further action based on these inspectional findings. The agency is relying on your commitment regarding corrective actions and, should we later observe that these deficiencies have not been remedied, future regulatory action (e.g. seizure, injunction and civil penalties) may be taken without further notice.''

When a CDRH decision is made not to send a warning letter due to a satisfactory written response from the firm, the district should classify the inspection as VAI for the labeling or 510(k) issues.

When no warning letter is issued, as described previously, and the next inspection of the firm discloses significant 510(k) and/or labeling deficiencies, then FDA personnel should proceed as if a warning letter had been issued for the previous inspection and consider appropriate enforcement action.

C. Administrative

Copies of all warning letters will be forwarded to the Division of Compliance Management and Operations (DCMO), Office of Enforcement (OE) (HFC–210). When warning letters are not issued for 510(k) or labeling deficiencies under this pilot, copies of the postinspectional notification letters issued for inspections that are initiated between March 29, 1999, and September 8, 2000, should be sent to Jeffrey B. Governale, Division of Compliance Policy (DCP)/OE, HFC–230.

CDRH's OC will monitor the warning and postinspectional notification letters and evaluate the pilot 18 months after it begins. Any questions about this pilot should be directed to Chester T. Reynolds, OC/CDRH, HFZ–300.

II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding this pilot program. Two copies of any comment are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments will be considered in determining whether to revise, revoke, or adopt this pilot program on a permanent basis. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

A copy of the pilot may also be downloaded to a personal computer with access to the World Wide Web (WWW). The Office of Regulatory Affairs (ORA) and the CDRH home pages include the pilot and may be accessed at ''http://www.fda.gov/ora'' or ''http://www.fda.gov/cdrh'', respectively. The pilot will be available on the compliance references or program areas/compliance information pages for ORA and CDRH, respectively.

Dated: March 1, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–5523 Filed 3–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0964]

''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product.'' The guidance document is intended to provide guidance to applicants on the content and format of the chemistry, manufacturing and controls (CMC) and establishment description sections of the ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use'' (revised Form FDA 356h) for a biological in vitro diagnostic product. This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives and the FDA Modernization Act of 1997, and is intended to reduce unnecessary burdens for industry without diminishing public health protection.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product'' 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 guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Biological In Vitro Diagnostic Product.'' The guidance document is intended to provide guidance to applicants in completing the CMC section and the establishment description information of revised Form FDA 356h. The guidance document announced in this notice supersedes the draft guidance entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment

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 should 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]

BILLING CODE 4140–01–M

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