(except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 2, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–30005 Filed 11–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Donor Suitability; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop: Blood Donor Suitability. The workshop is intended to gather current scientific data on certain high risk criteria used in donor deferral.

Date and Time: The workshop will be held on Monday, November 23, 1998, 8:30 a.m. to 5 p.m.

Location: The workshop will be held at the Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD 20857.

Contact: Robbin Gordon, Project Manager, Conference Management Associates, Inc., Three Corporate Sq., suite 180, Atlanta, GA 30329–2013, 404–633–9117, FAX 404–636–6311.

Registration: Send or fax registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by Friday, November 13, 1998.

Registration at the site will be done on a space available basis on the day of the workshop beginning at 7:30 a.m. There is no registration fee for the workshop.

If you need special accommodations due to disability, please contact Carol White Hales at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The purpose of the workshop is to gather current scientific data on certain blood donor suitability issues. At the workshop, FDA will review the use of certain donor deferral criteria based on high risk behavior (i.e., intravenous drug abuse, male to male sex, and sex for drugs or money).

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 workshop at a cost of 10 cents per page. The workshop transcript will also be available on the Center for Biologics Evaluation and Research website at ''http://www.fda.gov/cber/minutes/workshop-min.htm''.

Dated: November 2, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–30006 Filed 11–9–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0964]

Draft ''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 the draft 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 draft guidance document, when finalized, is intended to assist applicants in the preparation of the chemistry, manufacturing, and controls (CMC) section and the establishment description section of a biologics license application (BLA), revised Form FDA 356h, for biological in vitro diagnostic products. This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives and FDA Modernization Act of 1997, and it is intended to reduce unnecessary burdens for industry without diminishing public health protection.

DATES: Written comments may be submitted at any time, however, comments should be submitted by January 11, 1998, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of ''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, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The 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 **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

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

FOR FURTHER INFORMATION CONTACT: Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft 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.'' This draft document, when finalized, is intended to provide general information for the content and format of the CMC section and establishment description section of the BLA for biological in vitro diagnostic products. This draft document is intended for use by those firms which manufacture any licensed in vitro diagnostic product used to screen donor blood, determine donor suitability, test for retroviral infection, or determine transfusion compatibility (e.g., blood grouping and typing reagents). This draft document is not intended to cover those in vitro diagnostic products used to test for endotoxins, such as limulus amebocyte lysate (LAL), or those products for which a premarket application (PMA) or a 510(k) must be submitted.

In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of a new harmonized Form FDA 356h entitled ''Application to