(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

Market a New Drug, Biologic, or an Antibiotic for Human Use.'' The new harmonized form is intended to be used by applicants for all drug and biological products. The new harmonized form, when fully implemented, will allow biological product manufacturers to submit a single application, the BLA, instead of two separate license application submissions, a product license application (PLA), and an establishment license application (ELA).

This draft guidance document represents the agency's current thinking on content and format of the CMC information and establishment description information for biological in vitro diagnostic products. 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 requirements 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

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written comments to the Dockets Management Branch (address above) regarding the draft guidance document. Written comments may be submitted at any time, however, comments should be submitted January 11, 1998, to ensure their adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests for copies should be identified with the docket number found in the 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 draft guidance document by using the World Wide Web (WWW). For WWW access connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: November 2, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–30094 Filed 11–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1048–N]

RIN 0938–AJ27

Medicare Program; Request for Nominations for the Practicing Physicians Advisory Council

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice requests nominations from medical organizations representing physicians for individuals to serve on the Practicing Physicians Advisory Council (the Council).

Section 4112 of the Omnibus Budget Reconciliation Act of 1990 established the Council to advise the Secretary of the Department of Health and Human Services on proposed regulations and manual issuances related to physicians' services. Four council members' terms of service are scheduled to expire on February 28, 1999.

EFFECTIVE DATE: Nominations will be considered if we receive them at the appropriate address, provided below, no later than 5 p.m. on November 30, 1998.

ADDRESSES: Mail or deliver nominations to the following address: Health Care Financing Administration, Center for Health Plans and Providers, Office of Professional Relations, Attention: Aron Primack, M.D., Executive Director, Practicing Physicians Advisory Council, Room 435H, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Aron Primack, M.D., Executive Director, Practicing Physicians Advisory Council, (202) 690–7418.

SUPPLEMENTARY INFORMATION: Section 4112 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101–508), added a new section 1868 to the Social Security Act (the Act), which established the Practicing Physicians Advisory Council (the Council). The Council advises the Secretary of the Department of Health and Human Services (the Secretary) on proposed regulations and manual issuances related to physicians' services. An advisory committee created by the Congress, such as this one, is subject to the provisions of the Federal Advisory Committee Act (5 U.S.C. App. 2).

Section 1868(a) of the Act requires that the Council consist of 15 physicians, each of whom must have submitted at least 250 claims for physicians' services under Medicare in the previous year. At least 11 Council members must be physicians as defined in section 1861(r)(1) of the Act; that is, State-licensed physicians of medicine or osteopathy. The other four Council members may include dentists, podiatrists, optometrists, and chiropractors.

The Council must include both participating and nonparticipating physicians, as well as physicians practicing in rural and underserved urban areas. In addition, section 1868(a) of the Act provides that nominations to the Secretary for Council membership must be made by medical organizations representing physicians.

This notice is an invitation to all organizations representing physicians to submit nominees for membership on the Council. Current members whose terms expire in 1999 will be considered for reappointment, if renominated, subject to the Federal Advisory Committee Management Handbook. The Secretary will appoint new members to the Council from among those candidates determined to have the expertise required to meet specific agency needs and in a manner to ensure appropriate balance of membership.

Each nomination must state that the nominee has expressed a willingness to serve as a Council member and must be accompanied by a short resume or description of the nominee's experience. To permit an evaluation of possible sources of conflict of interest, potential candidates will be asked to provide detailed information concerning financial holdings, consultant positions, research grants, and contracts.

Section 1868(b) of the Act provides that the Council meet once each calendar quarter, as requested by the Secretary, to discuss proposed changes in regulations and manual issuances that relate to physicians' services. Council members are expected to participate in all meetings.

Section 1868(c) of the Act provides for payment of expenses and a per diem allowance for Council members at a rate equal to payment provided members of other advisory committees. In addition to making these payments, the Department of Health and Human Services provides management and support services to the Council.