Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, 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 The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr. 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: Validation of Growth-Based Rapid Microbiological Methods for Sterility Testing of Cellular and Gene Therapy Products,'' dated February 2008. This draft guidance applies to somatic cellular therapy and gene therapy products. This draft guidance does not apply directly to human cells, tissues, and cellular and tissue products (HCT/Ps) which are regulated solely under section 361 of the Public Health Service Act as described under 21 CFR 1271.10, or HCT/Ps which are regulated as medical devices under 21 CFR part 820. Such products are not subject to the sterility testing provision in § 610.12 (21 CFR 610.12), or to the requirement in 21 CFR 610.9 to demonstrate that an alternative RMM is equivalent to the sterility method specified in the regulations. However, HCT/P and device establishments seeking to validate an RMM may find these recommendations useful.

The principles of RMM validation described in this draft guidance apply only to growth-based RMMs. Growth-based RMMs, like traditional methods of detecting viable microorganisms as described in § 610.12, rely on the ability to recover and detect organisms from the product and demonstrate their viability by multiplication in liquid media. The specific recommendations in this document may not be applicable for non-growth-based RMMs which detect microbiological surrogates. This draft guidance focuses on RMMs with qualitative results (i.e., detection of microorganisms). If the RMM does not have the capability to speciate microorganisms, an additional method for speciation will be needed for investigation of detected contaminants. Early discussions with product review staff at CBER are encouraged for individuals intending to use or develop an RMM at any time in the product lifecycle using growth-based, viability-based, surrogate-based, or RMMs that provide quantitative results.

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 FDA'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. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA Regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information to which this draft guidance refers are covered by 21 CFR parts 601 (on BLAs) and 312 (on INDs), and were approved under OMB Control No. 0910–0338 and 0910–0014, respectively.

III. 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 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 the 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.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

IV. 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: January 29, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–2398 Filed 2–8–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Hemoglobin Based Oxygen Carriers: Current Status and Future Directions; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: Hemoglobin Based Oxygen Carriers: Current Status and Future Directions. The purpose of the public workshop is to discuss the safety of hemoglobin-based oxygen carriers (HBOCs) as related to a variety of potential uses of these investigational products. We are having this discussion because clinical and nonclinical studies of HBOCs, as either blood substitutes or as resuscitation fluids, have raised questions about the safety of these products as a group. The public workshop will feature presentations and roundtable discussions led by experts from academic institutions, government, and industry.

Date and Time: The public workshop will be held on April 29, 2008, from 8:30 a.m. to 5 p.m. and April 30, 2008, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at the Lister Hill Center Auditorium, Building 38A, National Institutes of Health, 8800 Rockville Pike, Bethesda, MD 20894.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6129, FAX: 301–827–2843, e-mail: *rhonda.dawson@fda.hhs.gov*.

Registration: Mail or fax your registration information (including name, title, firm name, address, and telephone and fax numbers) to the contact person by April 11, 2008. There

is no registration fee for the public workshop. Early registration is recommended because seating is limited to 175 attendees. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: FDA; the National Heart, Lung, and Blood Institute, National Institutes of Health; and the Department of Health and Human Services' Office of the Secretary and Office of Public Health and Science are co-sponsoring this public workshop. The primary goal of the workshop is to discuss what is known about the safety of HBOCs, and possible paths forward for development of these products. Topics to be discussed on April 29, 2008, will include: (1) Introduction to the issues and unmet needs surrounding HBOC development, (2) overview of the physiology and chemistry of hemoglobin in HBOCs, (3) nitric oxide physiology and pathophysiology related to HBOCs, (4) review of nonclinical studies of HBOCs, (5) risk-benefit considerations in clinical trials of HBOCs, (6) proposed clinical indications for HBOCs, and (7) industry's experience with HBOC clinical trials. Panel deliberations on the safety and efficacy of HBOCs in various clinical settings and potential mechanisms of effects on organs will be the main topics of discussion on April 30, 2008. We also will discuss future development pathways with a focus on the use and development of animal models, biochemical redesign approaches, and alternative clinical designs where benefit exceeds risk.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Dated: February 4, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–2397 Filed 2–8–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Request for Nominations

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill five (5) upcoming vacancies on the Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL).

Authority: 42 U.S.C. 294f, section 756 of the PHS Act, as amended. The Advisory Committee is governed by provisions of Public Law (Pub. L.) 92–463, as amended (5 U.S.C. Appendix 2) which sets forth standards for the formation and use of advisory committees.

DATES: The Agency must receive nominations on or before March 12, 2008.

ADDRESSES: All nominations are to be submitted by mail to Louis D. Coccodrilli, Designated Federal Official, ACICBL, Bureau of Health Professions (BHPr), HRSA, Parklawn Building, Room 9–05, 5600 Fishers Lane; Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Adriana Guerra, Public Health Fellow, Division of Medicine and Dentistry, by e-mail *aguerra@hrsa.gov* or telephone, (301) 443–6194.

SUPPLEMENTARY INFORMATION: Under the authorities that established the ACICBL, the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463), and section 2119 of the Act, 42 U.S.C. 00aa–19, as added by Pub. L. 99–660 and amended, HRSA is requesting nominations for five (5) voting members.

The ACICBL provides advice and recommendations to the Secretary and to the Congress concerning policy, program development and other matters of significance related to interdisciplinary, community-based training grant programs authorized under sections 751–756, Title VII, Part D of the Public Health Service Act. The ACICBL prepares an annual report describing the activities conducted during the fiscal year, identifying findings and developing recommendations to enhance Title VII Interdisciplinary, Community-Based Training Grant Programs. The Annual Report is submitted to the Secretary of the U.S. Department of Health and Human Services, and ranking members of the Committee on Health, Education, Labor and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives.

The Department of Health and Human Services is requesting a total of five (5) nominations for voting members of the ACICBL from schools that have administered or are currently administering awards from the following programs: Allied Health—one (1) nominee, Geriatric Education and Training Programs—one (1) nominee, and Health Education and Training Centers (HETCs)—one (1) nominee. Nominations are also requested for two (2) students, residents, and/or fellow representatives.

The legislation governing this Committee requires a fair balance of health professionals who represent the general population with regard to a broad geographic distribution and an evenness of urban and rural areas, along with professionals who are women and minorities. As such, the pool of appropriately qualified nominations should reflect these requirements to the degree possible.

Interested individuals may nominate multiple qualified professionals for membership to the ACICBL to allow the Secretary a diverse listing of highly qualified potential candidates. Nominees willing to serve as members of the ACICBL should not have an appearance of a conflict of interest that would preclude their participation. Potential candidates will be asked to provide detailed information concerning consultancies, research grants, or contracts to permit an evaluation of possible sources of conflicts of interest. In addition, a curriculum vitae and a statement of interest will be required of the nominee to support experience working with Title VII Interdisciplinary, Community-Based Training Grant Programs, expertise in the field, and personal desire in participating on a National Advisory Committee. Qualified candidates will be invited to serve a two or three-year term. All nominations must be received no later than March 12, 2008.