General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on September 25, 1997, 8 a.m. to 4 p.m.

Location: Holiday Inn, Versailles Ballrooms III and IV, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Sharon K. Lappalainen, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12514. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will provide advice and recommendations to the agency regarding over-the-counter drugs of abuse testing systems and comment on a draft points-to-consider document for these products. Single copies of the draft points-to-consider document entitled ''Points to Consider for Approval of Home Drugs of Abuse Test Kits'' are available to the public by contacting the Division of Small Manufacturers Assistance, 1350 Piccard Dr., Rockville, MD 20851, 1–800–638–2041, or on the Internet using the World Wide Web (WWW) (http://www.fda.gov/cdrh/draftgui.html).

Procedure: On September 25, 1997, from 9 a.m. to 4 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 18, 1997. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 18, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed committee deliberations: On September 25, 1997, from 8 a.m. to 9 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)) relating to present and future agency issues.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 28, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–23729 Filed 9–5–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: National Mammography Quality Assurance Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on October 28, 1997, 9 a.m. to 5 p.m., and October 29, 1997, 8 a.m. to 5 p.m.

Location: Sheraton Premiere Hotel at Tysons Corner, conference room 6, 8661 Leesburg Pike, Vienna, VA.

Contact Person: Charles A. Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12397. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 28 and 29, 1997, the committee will discuss regulation of interventional mammography under the Mammography Quality Standards Act of 1992.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 26, 1997. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. on October 28, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 26, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 3, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–23728 Filed 9–5–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 90N–0349]

Draft ''Guidance for Industry: Efficacy Evaluation of Hemoglobin- and Perfluorocarbon-Based Oxygen Carriers;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Efficacy Evaluation of Hemoglobin- and Perfluorocarbon-Based Oxygen Carriers.'' The document is intended as general guidance for manufacturers, investigators, sponsors, and other parties interested in the design, endpoints, and efficacy criteria for clinical trials of hemoglobin- and perfluorocarbon-based oxygen carrier products.

DATE: Written comments may be submitted at any time, however, comments should be submitted by December 8, 1997, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of ''Efficacy Evaluation of Hemoglobin- and Perfluorocarbon-Based Oxygen Carriers'' to (1) 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, or (2) the Drug Information Branch, Division of Communications Management (HFD–210), Center for Drug Evaluation and Research, FDA, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing 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. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Background

The draft document is intended to serve as an adjunct to FDA's ''Points to Consider (PTC) in Safety Evaluation of Hemoglobin-Based Oxygen Carriers,'' which is dated August 27, 1990. That PTC was announced as available in the **Federal Register** of January 8, 1991 (56 FR 698), and was published in the April 1991 issue of *Transfusion* (31: 369–371, 1991). This draft document was developed, in part, from presentations and discussions at the ''Workshop on Criteria for Efficacy of Red Cell Substitutes,'' held in Bethesda, MD, on January 11, 1994, and sponsored by the National Heart, Lung, and Blood Institute, the Department of the Army, and FDA. The draft document is intended as general guidance for manufacturers, investigators, sponsors, and other parties interested in the design, endpoints, and efficacy criteria for clinical trials of hemoglobin- and perfluorocarbon-based oxygen carrier products.

This guidance document represents the agency's current thinking on hemoglobin- and perfluorocarbon-based oxygen carriers. 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. This document is intended to provide information and does not set forth requirements. FDA encourages manufacturers, sponsors, investigators, and other interested parties to prospectively discuss with FDA the design of clinical trials, selection of clinical trial endpoints, and development of efficacy criteria to prevent expenditure of time, personnel, money, and other resources on clinical trials that FDA may later determine are unacceptable.

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 to the Dockets Management Branch (address above) written comments on the draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by December 8, 1997,, to ensure 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 brackets in the heading of this document. A copy of this 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 using the World Wide Web (WWW). For WWW access connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: August 29, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–23655 Filed 9–5–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies, and Laboratories That Have Withdrawn From the Program

AGENCY: Substance Abuse and Mental Health Services Administration, HHS (Formerly: National Institute on Drug Abuse, ADAMHA, HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be identified as such at the end of the current list of certified laboratories, and will be omitted from the monthly listing thereafter.

This Notice is now available on the internet at the following website: http://www.health.org

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, Room 13A–54, 5600 Fishers Lane, Rockville, Maryland 20857; Tel.: (301) 443–6014.

SUPPLEMENTARY INFORMATION:

Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

ACL Laboratory, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840 (formerly: Bayshore Clinical Laboratory)

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400

Alabama Reference Laboratories, Inc., 543 South Hull St., Montgomery, AL 36103, 800–541–4931/334–263–5745