

*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]  
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## 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-