CPG entitled ''Distributor Medical Device Reporting.'' Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The agency will review all comments, but in issuing a final CPG, need not specifically address every comment. The agency will make changes to the CPG in response to comments, as appropriate. A copy of the draft CPG and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of the draft CPG may also be downloaded to a personal computer with access to the World Wide Web (www). The Office of Regulatory Affairs (ORA) and CDRH Home Pages include the draft CPG and may be accessed at ''http://www.fda.gov/ora'' or ''http://www.fda.gov/cdrh'' respectively. The draft CPG will be available on the Compliance References or Compliance Information pages for ORA and CDRH respectively.

Dated: August 15, 1997.

Gary Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 97–22702 Filed 8–27–97; 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: Food 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 September 25 and 26, 1997, 8:30 a.m. to 5 p.m.

Location: Holiday Inn—Eisenhower Metro Center, Eisenhower Station Ballroom, 2460 Eisenhower Ave., Alexandria, VA.

Contact Person: Lynn A. Larsen, Center for Food Safety and Applied Nutrition (HFS–5), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4727, or Catherine M. DeRoever, Advisory Committee Staff (HFS–22), 202–205–4251, FAX 202–205–4970, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will be conducting an informational meeting during which it will be receiving updates on past issues that were referred to the committee and on other activities related to food safety. There will also be briefings by the current working groups formed to discuss the Final Report from the Keystone National Policy Dialogue on Food, Nutrition, and Health, as well as simultaneous working group sessions. Two working groups are expected to have work products for committee discussion.

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 17, 1997. Oral presentations from the public will be scheduled between approximately 4 p.m. and 5 p.m. on September 25, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 17, 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: August 21, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–22854 Filed 8–27–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Mammography Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop: Mammography Workshop. The topics to be discussed are: Update on the Mammography Quality Standards Act (MQSA), State regulations on mammography, the medical physicist's responsibilities, FDA's MQSA compliance, the radiographic processor, and preparation for the MQSA inspection.

Date and Time: The public workshop will be held on Tuesday, September 23, 1997, 8:30 a.m. to 5 p.m.; registration, 8 a.m. to 8:30 a.m. Registration will close on September 16, 1997.

Location: The public workshop will be held at the Medical Forum Bldg., 950 22d St. North, Birmingham, AL 35203, 205–458–8800.

Contact: Ralph T. Trout, Food and Drug Administration (HFR–SE19), 60 Eighth St. NE., Atlanta, GA 30309, 404–347–4001, ext. 5248, FAX 404–347–4349.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by Tuesday, September 16, 1997. Space is limited, therefore interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact Ralph T. Trout at least 7 days in advance.

SUPPLEMENTARY INFORMATION: This workshop is being sponsored by FDA's Southeast Region and the radiological health programs of the States of the Southeast Region. These States are Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, and Tennessee, and the Commonwealth of Puerto Rico and the Virgin Islands. The purpose of this workshop is to provide mammography facilities with an update on MQSA and technical training in the area of mammography.

Dated: August 22, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–22980 Filed 8–25–97; 4:44 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medicated Feed Good Manufacturing Practices (GMP's) Training Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Pacific Region is announcing a training workshop to

provide industry and regulators with current information concerning changes in the regulation of medicated feeds including the Animal Medicinal Drug Use Clarification Act, veterinary feed directives, feed mill licensing and current good manufacturing practices for medicated feeds. The training workshop is being conducted in cooperation with the California Department of Food and Agriculture (CDFA) and the Association of American Feed Control Officials (AAFCO).

DATES: The 2-day training workshop will be held on September 23, 1997, from 8 a.m. to 5 p.m., and September 24, 1997, from 8:30 a.m. to 3 p.m.

ADDRESSES: The workshop will be held at the Delta King Hotel, 1000 Front St., Old Sacramento, CA 95814.

FOR FURTHER INFORMATION CONTACT:

For information regarding this notice: Mark Roh, Food and Drug Administration, Oakland Federal Bldg., 1301 Clay St., Oakland, CA 94612, 510–637–3980; or Karen Robles, Food and Drug Administration, 801 ''I'' St., rm. 443, Sacramento, CA 95814, 916–498–6400, ext. 14; or

For information regarding registration and the workshop: Steven Wong, GMP Training Workshop Coordinator, California Dept. of Food & Agriculture, Feed Inspection Program, 1220 ''N'' St., rm. A–472, Sacramento, CA 95814, 916–654–0574, FAX 916–653–2407.

SUPPLEMENTARY INFORMATION: This training workshop is to further assist the medicated feed industry and Federal and State regulators with interpretation and understanding of the current regulations concerning medical feed mills. Attention will also be given to recent and proposed changes in the regulatory procedures and policy.

Registration is being handled by AAFCO. AAFCO is collecting a minimal registration fee of $50.00 to cover the cost of the facility and preparation of course materials. Space is limited and early registration is recommended.

Dated: August 22, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–22979 Filed 8–25–97; 4:44 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

System Suitability (Validation) of Chromatographic Analysis/Out-of-Specification Results; Notice of Public Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing that it will hold a series of two public meetings that will be offered in two locations. The topics to be discussed are validating chromatographic systems and evaluating out-of-specification test results.

Date and Time: The public meetings will be held on September 12, 1997, 8 a.m. to 12 m. and 1 p.m. to 4 p.m.; and September 24, 1997, 2 p.m. to 5:30 p.m. (both meetings).

Location: On September 12, 1997, the meetings will be held at the Independence Seaport Museum Penn's Landing, 211 South Columbus Blvd., and Walnut St., Philadelphia, PA, 215–413–8622, FAX 215–925–6713. On September 24, 1997, the meetings will be held at the Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD, 301–657–1234, FAX 301–657–6453.

Contact: Richard A. Baldwin, Division of Field Science (HFC–141), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6388, FAX 301–443–5153.

Registration: Registration for the September 24, 1997, meetings is required through the Parenteral Drug Association. For more information on how to register, contact the Parenteral Drug Association at 301–986–0293, or e-mail info@pda.org.

SUPPLEMENTARY INFORMATION: On September 12, 1997, FDA's Office of Regulatory Affairs and the Office of External Affairs are cosponsoring two meetings entitled ''System Suitability (Validation) for Chromatographic Analysis'' and ''Out-of Specification Results.'' On September 24, 1997, FDA, in cooperation with the Parenteral Drug Association, will offer the same meetings in Bethesda MD. The goal of these meetings is to provide consistent practices and procedures between FDA and the pharmaceutical industry.

Requests for handouts are available from the Division of Field Science. Submit requests to Denise Jones, Division of Field Science (HFC–141), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

If you need special accommodations due to a disability, please notify the contact person at least 7 days in advance.

Dated: August 22, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–22978 Filed 8–25–97; 4:44 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Potency and Dosage of Von Willebrand Factor Concentrates; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''FDA Sponsored Workshop on Potency and Dosage of von Willebrand Factor Concentrates (vWF).'' The topics to be discussed include potency assays and standards for vWF concentrates; pharmacokinetic studies and clinical trials of vWF concentrates; the correlation of dosage regimens with clinical outcome; and labeling of vWF concentrates.

Date and Time: The workshop will be held on September 26, 1997, 8 a.m. to 5 p.m.

Location: The workshop will be held at Jack Masur Auditorium, National Institute of Health, 8800 Rockville Pike, Bldg. 10, Bethesda, MD 20892.

Contact: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514, FAX 301–827–2843.

SUPPLEMENTARY INFORMATION:

FDA has the responsibility of ensuring that product labeling provides information about product potency and dosage. In the case of replacement therapy for deficiencies in coagulation factor activity, this has been done by assessing the potency of a product relative to a defined standard, and by measuring the pharmacokinetics of the product. This information has been used to establish a dosage that will raise the concentration of circulating coagulation activity to a targeted level for a known period of time. Clinical trials establish the clinical benefit of a given dosage regimen. This model has been difficult to apply to products submitted to FDA for licensure for the treatment of vWF because there is no standardized in vitro test for vWF potency; there is no vWF