Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4090, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12529. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear presentations and discuss the occurrence of spinal/epidural hematomas with the concurrent use of approved low molecular weight heparins or heparinoids and spinal/epidural anesthesia or spinal puncture. The committee will also consider labeling for low molecular weight heparins and heparinoids concerning these adverse events. The approved drug products under discussion and their sponsors are: (1) Lovenox® (enoxeparin sodium) Injection, Rhone-Poulenc Rorer Pharmaceuticals, Inc.; (2) Fragmin® (dalteparin sodium) Injection, Pharmacia & Upjohn; (3) Orgaran® (danaparioid sodium) Injection, Organon, Inc.; and (4) Normiflo™ (ardeparin sodium) Injection, Wyeth Laboratories, Inc.

Procedure: On February 5, 1998, from 8 a.m. to 3:45 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 January 29, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 29, 1998, 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 February 5, 1998, from 3:45 p.m. to 5:30 p.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)). The investigational new drug and Phase I and II drug products in process will be presented and recent action on selected new drug applications will be discussed.

FDA regrets that it was unable to publish this notice 15 days prior to the February 5, 1998, Anesthetic and Life Support Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Anesthetic and Life Support Drugs Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: January 22, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–2024 Filed 1–23–98; 11:47 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food 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 February 11, 12, and 13, 1998, 8:30 a.m. to 5 p.m.

Location: DoubleTree Hotel, Pentagon City, 300 Army Navy Dr., Arlington, VA.

Contact Person: Catherine M. DeRoever, Center for Food Safety and Applied Nutrition (HFS–22), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4251, FAX 202–205–4970, E-mail CDEROEVE@BANGATE.FDA.GOV, 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: On February 11, 12, and 13, 1998, the committee will undertake discussions on dietary supplements. Issues raised in the report of the White House Commission on Dietary Supplement Labeling relating to postmarket surveillance and consumer research will be discussed. Also, two aspects relating to good manufacturing practices (GMP's) for dietary supplements will be addressed. The agency is interested in recommendations for ensuring the identity for different types of dietary ingredients and on recordkeeping requirements. On February 13, 1998, two committee working groups will continue discussing assignments stemming from the Keystone report on health claims.

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 February 9, 1998. Oral presentations from the public will be scheduled between approximately 4 p.m. and 5 p.m. on February 11 and 12, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 9, 1998, 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: January 22, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–2023 Filed 1–23–98; 11:47 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Open Meeting For Representatives of Health Professional Organizations

AGENCY: Food and Drug Administration

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting with representatives of health professional organizations. The meeting will be chaired by Sharon Smith Holston, Deputy Commissioner for External Affairs. The agenda will include presentations and discussions on the topics of the FDA Modernization Act of 1997, and the role of FDA in the regulation of products used in complementary and alternative medicine. There will also be a brief update on tobacco.

DATES: The meeting will be held on Monday, February 9, 1998, from 1:30 p.m. to 3 p.m.

ADDRESSES: The meeting will be held at the Bethesda Hyatt, One Metro Center, Bethesda, MD.

REGISTRATION: There is no registration fee, however, space is limited. Persons will be registered in the order in which calls are received. Please call Betty B. Palsgrove at 301–827–6618 to register. Registrations also may be transmitted by fax to 1–800–344–3332 or 301–443–2446. Please include the name and title of the person attending and the name of the organization.

FOR FURTHER INFORMATION CONTACT: Peter H. Rheinstein, M.D., J.D., Office of Health Affairs (HFY–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6630.

SUPPLEMENTARY INFORMATION:

The purpose of the meeting is to provide an opportunity for representatives of health professional organizations and other interested persons to be briefed by senior FDA staff. It will also provide an opportunity for informal discussion on these topics of particular interest to health professional organizations.

This public meeting is free of charge; however, space is limited. Registration for the meeting will be accepted in the order received and should be sent to the contact person. Registration should include the name and title of the person attending and the name of the organization being represented, if any.

Dated: January 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–1850 Filed 1–26–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Imaging Drugs 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Medical Imaging Drugs 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 February 9, 1998, 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Leander B. Madoo, Center for Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–80–741–8138 (301–443–0572 in the Washington, DC area), code 12540. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the safety and efficacy of new drug application (NDA) 20–887 AcuTect™, Diatide, Inc., a radiopharmaceutical agent for the detection and localization of acute venous thrombosis.

Procedure: On February 9, 1998, from 8 a.m. to 1 p.m. and from 2 p.m. to 5 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 February 2, 1998. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 2, 1998, 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 February 9, 1998, from 1 p.m. to 2 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information relating to NDA 20–887 AcuTect™ (5 U.S.C. 552b(c)(4)).

FDA regrets that it was unable to publish this notice 15 days prior to the February 9, 1998, Medical Imaging Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Medical Imaging Drugs Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: January 22, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–2022 Filed 1–23–98; 11:47 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0017]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance on Validation of Analytical Procedures: Definition and Terminology (#63), and Validation of Analytical Procedures: Methodolgy (#64); Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of two draft guidance for industry (GFI) documents entitled ''Validation of Analytical Procedures: Definition and Terminology'' (number 63) and ''Validation of Analytical Procedures: Methodology'' (number 64). These related draft GFI documents have been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from two guidelines, Q2A and Q2B, that were adopted by the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use. The draft guidance is intended to provide guidance on characteristics that should be considered during the validation of analytical procedures included as part of registration applications for approval of veterinary medicinal products submitted to the European Union, Japan, and the United States.

DATES: Submit written comments on these draft GFI documents by March 30, 1998.

ADDRESSES: Submit written comments on the two draft GFI documents to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD 20857. Comments should be identified with the full title of the draft GFI document and the docket number found in the heading of this document.