

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® (danaparoid 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.

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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. DeRoeve, 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.

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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.