CENTER FOR DRUG EVALUATION AND RESEARCH

ADVISORY COMMITTEE: ANESTHETIC and LIFE SUPPORT DRUGS ADVISORY COMMITTEE

DATE OF MEETING: 02/05/98

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AGENDA

Food and Drug Administration
Center for Drug Evaluation and Research

Anesthetic and Life Support Drugs Advisory Committee

Holiday Inn
8120 Wisconsin Avenue
Bethesda, Maryland

Proposed Agenda

February 5, 1998

8:00	Call to Order and Opening Remarks	Terese T. Horlocker, MD Acting Chair, ALSAC
	Introduction of Committee Conflict of Interest Statement	Karen M. Templeton-Somers, PhD Executive Secretary, ALSAC
8:10	Introduction	Lilia Talarico, MD Director Division of Gastrointestinal and Coagulation Drug Products
8:20	**Industry presentations**	
	Organon Inc. Orgaran (danaparioid sodium) Injection	Albert P. Mayo Director of Regulatory Affairs Organon Inc.
	Pharmacia & Upjohn Prevention of Perioperative Thromboembolic Complications with Low Molecular Weight Heparins in Patients Receiving Epidural/Spinal Anesthesia: Risk/Benefit Considerations	Graham F. Pineo, MD, FRCPC Director, Thrombosis Research Unit Dept. of Medicine University of Calgary Calgary, AB
	Experience with Fragmin®	Mårten Rosenqvist, MD, PhD Medical Director Cardiovascular/Thrombosis Pharmacia & Upjohn

Industry presentations , continued

	Rhone-Polenc Rorer Lovenox (enoxaparin sodium) Injection	Janet Rush, MD Vice-President Cardiovascular Clinical Research Rhone-Polenc Rorer
	Wyeth Laboratories Normiflo (ardeparin sodium) Injection	Philip J. DeVane, MD Vice President, Clinical Affairs North American Medical Director
10:00	Break	
10:15	**FDA Presentations**	
	Spinal and Epidural Hematomas/Bleeds in U.S. Lovenox Users	Diane Wysowski, PhD Division of Pharmacovigilance and Epidemiology Office of Epidemiology and Biostatistics
	The Biology and Clinical Use of the Low Molecular Weight Heparins	Kenneth Bauer, MD Harvard Medical School Chief, Hematology-Oncology Brockton/West Roxbury, VA Medical Center
	Is Regional Anesthesia Contraindicated in the Anticoagulated Patient?	Terese T. Horlocker, MD Department of Anesthesiology Mayo Clinic
12:00	LUNCH	
1:00	**Open Public Hearing**	
	Coumadin® (warfarin sodium, USP)	David Grandison, MD VP, Medical Affairs The DuPont Merck Pharmaceutical Company
2:00	Committee Discussion of the Issues	
	Vote on the Questions to the Committee	
3:30	Adjourn	

ANESTHETIC AND LIFE SUPPORT DRUGS ADVISORY COMMITTEE
CENTER FOR DRUG EVALUATION AND RESEARCH

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anesthetic and Life Support 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: Anesthetic and Life Support 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 5, 1998, 8 a.m. to 5:30 p.m.

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

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug 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

Guest Experts
(non-voting)

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Jack Hirsh, M.D.
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QUESTIONS

Anesthetic and Life Support Drugs Advisory Committee

February 5, 1998

The class labeling revisions to the package inserts for the low molecular weight heparins (LMWHs) and heparinoids describing the potential for spinal/epidural hematomas associated with the use of these drugs and spinal/epidural anesthesia or spinal puncture include the following:

(1) a "Boxed Warning",

(2) additional information in the WARNINGS section, "Hemorrhage" subsection, and

(3) additional information in the PRECAUTIONS section, the "Laboratory Tests" subsection.

Questions for the Committee

1. Are the revisions sufficient to convey the risks associated with these products when spinal/epidural anesthesia or spinal puncture is used?

2. If insufficient, what additional actions should be initiated? Consider the following:

   (a) Further revisions to the package insert including the addition of information on how to use anticoagulants for thromboprophylaxis in the setting of neuraxial anesthesia or spinal puncture;

   (b) Restricted use of LMWHs and heparinoids to "special circumstances" in patients administered spinal/epidural anesthesia;

   (c) Contraindication of the use of LMWHs and heparinoids in patients with spinal/epidural catheters.

3. If further labeling revisions are proposed, what pharmacological or clinical data would be necessary to support the proposed changes?

4. Should the class labeling be extended to all approved anticoagulants (e.g., heparin and warfarin products)?