

Ombudsman the name and IND number of any investigational biological product trial that was placed on clinical hold during the past 12 months that they want the committee to review. Submissions should be made by January 12, 1998, for the February meeting; by March 31, 1998, for the May meeting; by June 30, 1998, for the August meeting; and by September 29, 1998, for the November meeting to Amanda Bryce Norton, FDA Chief Mediator and Ombudsman (address above).

Dated: December 9, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Product, Establishment, and Biologics License Applications, Refusal to File; Meeting of Oversight Committee

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the 1998 meetings of its standing oversight committee in the Center for Biologics Evaluation and Research (CBER) that conducts a periodic review of CBER's use of its refusal to file (RTF) practices on product license applications (PLA's), establishment license applications (ELA's), and biologics license applications (BLA's). CBER's RTF oversight committee examines all RTF decisions that occurred during the previous quarter to assess consistency across CBER offices and divisions in RTF decisions.

**DATES:** The next meetings will be held on January 13, 1998; April 14, 1998; July 14, 1998; and October 13, 1998.

**FOR FURTHER INFORMATION CONTACT:** Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM-4), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0379.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 15, 1995 (60 FR 25920), FDA announced the establishment and first meeting of CBER's standing oversight committee. As explained in the notice, the importance to the public health of getting new biological products on the market as efficiently as possible has

made improving the biological product evaluation process an FDA priority. CBER's managed review process focuses on specific milestones or intermediate goals to ensure that a quality review is conducted within a specified time period. CBER's RTF oversight committee continues CBER's effort to promote the timely, efficient, and consistent review of PLA's, ELA's, and BLA's.

FDA regulations on filing PLA's, ELA's, and BLA's are found in 21 CFR 601.2 and 601.3. A sponsor who receives an RTF notification may request an informal conference with CBER, and thereafter may ask that the application be filed over protest, similar to the procedure for drugs described under 21 CFR 314.101(a)(3).

CBER's standing RTF oversight committee consists of senior CBER officials, a senior official from the FDA's Center for Drug Evaluation and Research, and the FDA Chief Mediator and Ombudsman. Meetings will ordinarily be held once a quarter to review all of the RTF decisions. The purpose of such a review is to assess the consistency within CBER in rendering RTF decisions. If there are no RTF decisions to review, however, the meeting may be cancelled. FDA intends to post any meeting cancellation on the CBER home page at "<http://www.fda.gov/cber/confmeet.htm>". Publication of any meeting cancellation will be made only as time permits.

Because the committee's deliberations will deal with confidential commercial information, all meetings will be closed to the public. The committee's deliberations will be reported in the minutes of the meeting. Although those minutes will not be publicly available because they will contain confidential commercial information, summaries of the committee's deliberations, with all such confidential commercial information omitted, may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. If, following the committee's review, an RTF decision changes, the appropriate division within CBER will notify the sponsor.

Dated: December 9, 1997.

**William K. Hubbard,**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Orthopaedic and Rehabilitation Devices Panel of the Medical Devices 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:** Orthopaedic and Rehabilitation Devices Panel of the Medical Devices 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 January 12, 1998, 11 a.m. to 6 p.m., and January 13, 1998, 7:30 a.m. to 5:30 p.m.

**Location:** Parklawn Bldg., conference rooms G and H, 5600 Fishers Lane, Rockville, MD.

**Contact Person:** Jodi H. Nashman, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12521. Please call the Information Line for up-to-date information on this meeting.

**Agenda:** On January 12, 1998, the committee will discuss and make recommendations for reclassification petitions for non- and semi-constrained shoulders and uni- and total patellofemoral knees. On January 13, 1998, the committee will discuss and make recommendations for the reclassification petitions for patellofemoral knees and constrained elbows, and for the classification of calcium sulfate pre-formed pellets (plaster of paris pellets).

**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 January 5, 1998. Oral presentations from the public regarding the reclassification petitions for non- and semi-constrained shoulders and uni- and total patellofemoral knees will be scheduled between approximately 11 a.m. and 12 m. on January 12, 1998. Oral presentations