

U.S./EC MRA, the agency anticipates that European manufacturers will request third-party review for approximately 55 to 100 medical device products annually. The agency expects that interest and participation in the program will increase with time. The agency further estimates based on dialogue with EC officials, that 11 firms will be designated to act as EC CABs.

C. Quality System Reports

EU CABs are required to submit to FDA reports of their third-party evaluations. Based upon information gathered during the negotiation of the U.S./EC MRA, the agency anticipates that European manufacturers will request third-party audits for approximately 165 medical device products annually. The agency estimates that 11 EU CABs will perform these evaluations.

II. Recordkeeping

FDA requires the reviewers to keep in their records a copy of the report that they submit to FDA for each review. The agency anticipates that 55 premarket reports and 165 quality system reports will be generated and required to be maintained by EU CABs annually. The agency further estimates that each reviewer will require no more than 10 hours (2 hours per recordkeeping per report) for each to maintain such records annually.

Dated: September 27, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-24998 Filed 10-4-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective 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). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 16, 2001, from 8:30 a.m. to 5 p.m.

Location: Hilton Washington DC North, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact: Thomas H. Perez, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6758, e-mail: PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will consider the safety and efficacy of Activated Protein C (human, recombinant, human kidney cells, new biologic license application (BLA) 125029), Eli Lilly & Co., for the treatment of severe sepsis.

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 October 9, 2001. Oral presentations from the public will be scheduled on October 16, 2001, 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 October 9, 2001, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the October 16, 2001, Anti-Infective Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Anti-Infective Drugs Advisory Committee were available at this time, the Commissioner of Food and Drugs 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: October 1, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01-25107 Filed 10-2-01; 5:03 pm]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nonclinical Studies Subcommittee of the Advisory Committee for Pharmaceutical Science; 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: Nonclinical Studies Subcommittee of the Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 13, 2001, from 8 a.m. to 12:15 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee conference room 1066, 5630 Fishers Lane, Rockville, MD.

Contact: Kimberly Topper, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: TopperK@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will discuss the activities of the two expert working groups requested by this subcommittee: The working group on biomarkers of cardiac tissue injury and the working group on biomarkers of vasculitis (vascular damage). Representatives from each working group will report their progress and plans, and the subcommittee will discuss these activities and provide feedback to the working groups. Administrative oversight of the subcommittee will be discussed, including the possibility of integration with the Scientific Advisory Board of the FDA National Center for Toxicological Research.

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 November 6, 2001. Oral