Security Blvd., Room C4–07–07, Baltimore, Maryland, 21244 telephone 410–786–1542 (procedures).

Notice: In the interest of security, (CMS) has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Notice: This is a public meeting. However, because of fire code requirements, should the number of attendants meet the capacity of the room the meeting will be closed.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: October 1, 2001.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01–25050 Filed 10–4–01; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Mine Safety and Health Research Advisory Committee: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Mine Safety and Health Research Advisory Committee (MSHRAC).

Time and Date: 9 a.m.–4 p.m., November 1, 2001.

Place: National Institute for Occupational Safety and Health (NIOSH), 626 Cochrans Mill Road, Building 140, Pittsburgh, Pennsylvania 15236, telephone 412/386–6602.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: This committee is charged with providing advice to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NIOSH, on priorities in mine safety and health research, including grants and contracts for such research, 30 U.S.C. 812(b)(2), section 102(b)(2).

Matters To Be Discussed: Agenda for this meeting will focus on NIOSH updates and overviews from various regional offices, international and stakeholder collaboration, and alternate fuels for mining systems.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Lewis V. Wade, Ph.D., Executive Secretary, MSHRAC, NIOSH, CDC, 200 Independence Avenue, SW., Room 715–H, Hubert Humphrey Building, P12 Washington, DC 20201–0004, telephone 202/401–2192, fax 202/260–4464.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: October 1, 2001.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–25049 Filed 10–4–01; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0402]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Third-Party Premarket Submission Review and Quality System Inspections Under United States/ European Community Mutual Recognition Agreement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for medical devices; third-party premarket submission review and quality system inspections under United States/ European Community (U.S./EC) Mutual Recognition Agreement (MRA).

DATES: Submit written or electronic comments on the collection of information by December 4, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Third-Party Premarket Submission Review and Quality System Inspections Under U.S./EC Mutual Recognition Agreement (OMB Control No. 0910–0378)—Extension

The third-party program under the U.S./EC MRA is intended to implement that part of the U.S./EC MRA that covers the exchange of quality system evaluation reports for all medical

devices and premarket evaluation reports for selected low-to-moderate risk devices. Under the MRA, firms may apply to become designated as a U.S. Conformity Assessment Body (CAB). Firms who are designated will be qualified to conduct quality system evaluations for all classes of devices and product type examinations and verifications for selected devices based on EC requirements under the voluntary third-party program authorized by MRA. Firms designated as European Union (EU) CABs could conduct quality system evaluations for all classes of devices and premarket 510(k) evaluations for selected devices based on FDA requirements. Under the voluntary third-party program, reports of these evaluations would be submitted by the EU CABs to FDA. The EU CABs would also be required to maintain copies of their evaluation reports.

FDA requests approval of the following collection of information:

Requests for Designation as U.S. CABs—Under this program, U.S. companies were allowed to apply for designation as a U.S. CAB. Such designation enabled the company to perform third-party reviews of U.S. products for export to the EU and third-party audits of quality systems established by manufacturers of medical devices manufactured for export to the EU. Third-party review of U.S. products for export and third-party audit of quality systems was elective and at the discretion of the manufacturer of the product. At the present time, only eight U.S. CABs are active. The agency is not accepting applications for U.S. CAB designation at this time and in the foreseeable future.

Premarket Reports by EU CABs—Under this program, EU CABs will be able to perform third-party evaluations for certain products manufactured in Europe for export to the United States. Third-party evaluation is elective and at the discretion of the manufacturer of the product.

Quality System Reports by EU CABs—Under this program, EU CABs will be able to perform third-party audits of the quality systems established by EU manufacturers of products manufactured for export to the United States. Third-party audit of quality systems is elective and at the discretion of the manufacturer of the product.

EU CABs must maintain records of their third-party evaluations of quality systems and premarket submissions for certain products manufactured for export to the United States for a period of no less than 3 years.

The program implements that part of the U.S./EC MRA that covers the exchange of quality system evaluation reports for all medical devices and premarket evaluation reports for selected low-to-moderate risk devices.

Respondents to this information collection are businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

ITEM	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Premarket Reports by EC CABs	11	5	55	40	2,200
Quality System Reports by EC CABs	11	15	165	32	5,280
Totals					7,480

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

ITEM	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Premarket Reports by EC CABs	11	5	55	10	550
Quality System Reports by EC CABs	11	15	165	10	1,650
Totals					2,200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The following is an explanation of the burden estimate.

I. Reporting Burden

A. Requests for Designation as U.S. CAB

U.S. firms who have applied and have been accepted for designation as a U.S. CAB will be able to perform third-party evaluations of U.S. products for export to the EU. Likewise, European firms who have applied and been designated as EC CABs, will be able to perform third-party reviews of products to be exported to the United States. The application for nomination as an EU CAB does not represent a paperwork burden subject to the PRA because the designation procedure is an internal process that is required by, and administered by, European authorities. Only the application for designation as a U.S. CAB represents a paperwork burden under the PRA. However, the agency has received 10 applications for designation as U.S. CABs, 8 of whom are still active. The agency is not accepting any applications at this time, and does .not anticipate accepting any applications in the near future. Thus burden for U.S. CAB designation is nonexistent at this time.

B. Premarket 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 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