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

presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 6, 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.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 28, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–24997 Filed 10–4–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1562]

Guidance for Industry on Cancer Drug and Biological Products—Clinical Data in Marketing Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Cancer Drug and Biological Products—Clinical Data in Marketing Applications.'' This guidance provides recommendations for sponsors designing clinical trials to demonstrate the safety and efficacy of cancer treatments on the collection of data that can be submitted to support marketing claims in new drug applications (NDAs), biologics license applications (BLAs), or applications for supplemental indications.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communications, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. A faxed copy of this guidance can also be obtained by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT:

Grant A. Williams, Center for Drug Evaluation and Research (HFD–150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5740, or

Patricia Keegan, Center for Biologics Evaluation and Research (HFM–573), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5093.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Cancer Drug and Biological Products—Clinical Data in Marketing Applications.'' This guidance provides general principles for data collection and submission for sponsors of investigational new drug applications, NDAs, BLAs, or supplemental applications for new indications. The guidance is intended to enable sponsors to more effectively create plans to record and report the data from controlled trials that form the clinical basis for approval of anticancer drug and biological products

In the **Federal Register** of November 9, 2000 (65 FR 67389), FDA announced the availability of a draft version of this guidance. After FDA considered public comments on the draft guidance, the agency determined that revision of the draft guidance was necessary. The final guidance notes that tumor images usually are not submitted as part of the marketing application, but this should be clarified at presubmission meetings with FDA. The final guidance also states that information on drug dosing should be collected from all patients rather than from a sample of patients, as suggested in the draft guidance. Collecting dosing information in all patients allows a full assessment of the adequacy of dosing in both the investigational arm and the control arm of the submitted studies.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on clinical data in marketing applications for cancer drug or biologic products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (address above). Two copies of written mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/cber/guidelines.htm, or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: September 28, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–24946 Filed 10–4–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1169]

Guidance for Industry on Content and Format for Geriatric Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Content and Format for Geriatric Labeling.'' FDA established the ''Geriatric use'' subsection in the labeling for human prescription drug and biological products to provide pertinent information about the appropriate use of drugs in the elderly (persons aged 65 and over). This guidance is intended to provide industry with information on submitting