skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled by inhaled corticosteroids. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for XOLAIR (U.S. Patent No. 6,267,958) from Genentech, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 8, 2005, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of XOLAIR represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for XOLAIR is 3,440 days. Of this time, 2,329 days occurred during the testing phase of the regulatory review period, while 1,111 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: January 20, 1994. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 20, 1994.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act*: June 5, 2000. The applicant claims June 2, 2000, as the date the product license application (BLA) for XOLAIR (BLA 103976/0) was initially submitted. However, FDA records indicate that BLA 103976/0 was submitted on June 5, 2000.

3. *The date the application was approved*: June 20, 2003. FDA has verified the applicant's claim that BLA 103976/0 was approved on June 20, 2003.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 463 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by March 31, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 31, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information 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. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 6, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–1078 Filed 1–27–06; 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 March 6, 2006, from 8:30 a.m. to 5 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research, Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Cathy A. Groupe, 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, FAX: 301–827–6776, e-mail: *GroupeC@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512530. Please call the information line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 21–572/S–008, CUBICIN (daptomycin for injection 500 mg/vial), Sponsor Cubist Pharmaceuticals, for the proposed indication of the treatment of *Staphylococcus aureus* bacteremia, including those with known or suspected endocarditis caused by methicillin-susceptible and methicillin-resistant strains.

The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* under heading ''Anti-Infective Drugs Advisory Committee (AIDAC).'' (Click on the year 2006 and scroll down to AIDAC meetings.)

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 February 27, 2006. Oral presentations from the public will be scheduled between 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 February 27, 2006, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Cathy A. Groupe at least 7 days in advance of the meeting.

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

Dated: January 20, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–1069 Filed 1–27–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products 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: Blood Products 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 March 9, 2006, from 8 a.m. to 5 p.m. and March 10, 2006, from 8:30 a.m. to 4:30 p.m.

Location: Hilton Hotel Washington DC North/ Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Donald W. Jehn, or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 9, 2006, in the morning the committee will hear updates on the following topics: (1) Summary of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability January 2006 meeting; (2) current considerations for blood donor screening for West Nile Virus; (3) classification of transfusion recipient identification (ID) systems; and (4) summary of the workshop on behavior-based donor deferrals in the Nucleic Acid Test (NAT) era. The committee will then discuss rapid tests for detection of bacterial contamination of platelets. In the afternoon, the committee will discuss public comments on the ''Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods (DRAFT).'' On March 10, 2006, in the morning the committee will discuss proposed studies to support the approval of over-the-counter (OTC) home-use human immunodeficiency virus (HIV) test kits. In the afternoon, the committee will hear an overview of the research programs of the Office of Blood Research and Review, Center for Biologics Evaluation and Research (CBER), as presented to a subcommittee of the Blood Products Advisory Committee during their site visit on July 22, 2005, and discuss a subcommittee report in closed session. Additionally, the committee will hear an overview of the research programs in the Laboratory of Biochemistry and Vascular Biology and the Laboratory of Cellular Hematology, Division of Hematology, Office of Blood Research and Review, CBER and in closed session discuss the report from the laboratory site visit of October 6, 2005.

Procedure: On March 9, 2006, the meeting is open to the public. On March 10, 2006, from 8:30 a.m. to 3:15 p.m. and again from 4:15 p.m. to 4:30 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 February 28, 2006. Oral presentations from the public will be scheduled on March 9, 2006, between approximately 9:45 a.m. to 11:30 a.m. and 2:30 p.m. to 3:30 p.m. On March 10, 2006, oral presentations from the public will be scheduled between approximately 9:30 a.m. to 10:30 a.m. and 2:45 p.m. to 2:55 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 28, 2006, 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 March 10, 2006, from 3:15 p.m. to 4:15 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)) and to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The committee will discuss a subcommittee's report of the internal research programs in the Office of Blood Research and Review, CBER. In addition, the committee will discuss the site visit report for the Laboratory of Biochemistry and Vascular Biology and Laboratory of Cellular Hematology, Division of Hematology, Office of Blood Research and Review, CBER.

Following this closed session, the committee will provide summarized comments regarding the Office Site Visit Report in an open public session.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Donald W. Jehn or Pearline K. Muckelvene at least 7 days in advance of the meeting. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 20, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–1075 Filed 1–27–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request Evaluation of the Impact of the New Conflicts of Interest Regulations on the National Institutes of Health's Ability To Recruit and Retain Staff

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of Human Resources (OHR) of the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Evaluation of the Impact of the Conflicts of Interest Regulations on the National Institutes of Health's Ability to Recruit and Retain Staff. *Type of Information Collection Request:* New Collection. *Need and Use of Information Collection:* To assess the impact of new Department of Health and Human Services (HHS) ethics regulations on the NIH's ability to continue to attract and recruit highly qualified scientific personnel. This information collection