of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

Filing Objections and Requests for a Hearing on a Regulation or Order—21 CFR Part 12 (OMB Control Number 0910–0184)—Extension

The regulations in 21 CFR 12.22, issued under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(2)), set forth the instructions for filing objections and requests for a hearing on a regulation or order under § 12.20(d) (21CFR 12.20(d)). Objections and requests must be submitted within the time specified in § 12.20(e). Each objection, for which a hearing has been requested, must be separately numbered and specify the provision of the regulation or the proposed order. In addition, each objection must include a detailed description and analysis of the factual information and any other document, with some exceptions, supporting the objection. Failure to include this information constitutes a waiver of the right to a hearing on that objection. FDA uses the description and analysis to determine whether a hearing request is justified. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under 21 CFR 12.24 and do not limit the evidence that may be presented if a hearing is granted.

Respondents to this information collection are those parties that may be adversely affected by an order or regulation.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.22	5	1	5	20	100

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

The burden estimate for this collection of information is based on past filings. Agency personnel, responsible for processing the filing of objections and requests for a public hearing on a specific regulation or order, estimate approximately five requests are received by the agency annually, with each requiring approximately 20 hours of preparation time.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: January 7, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–574 Filed 1–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Pulmonary-Allergy 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: Pulmonary-Allergy 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 February 4, 2009, from 8:30 a.m. to 5 p.m.

Location: Hilton Washington DC North/ Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD. The hotel telephone number is 301–977–8900.

Contact Person: Kristine T. Khuc, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5630 Fishers Lane (for express delivery, 5630 Fishers Lane,rm. 1093), Rockville, MD 20857, 301–827–7001, Fax: 301–827–6776, e-mail: *Kristine.Khuc@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512545. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss biologics license application (BLA) No. 125277, KALBITOR, for ecallantide injection by Dyax Corp., for the proposed indication of treatment of acute attacks of hereditary angioedema.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the

year 2009 and scroll down to the appropriate advisory committee link.

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 on or before January 23, 2009. Oral presentations from the public will be scheduled approximately between 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person 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 on or before January 21, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 22, 2009.

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 Kristine T. Khuc at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

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

Dated: January 8, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–686 Filed 1–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, January 26, 2009, 2 p.m. to January 26, 2009, 4 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on December 31, 2008, 73 FR 80417–80418.

The meeting has been changed to an AED meeting starting January 26, 2009, 8 a.m. to January 27, 2009, 5 p.m. The meeting title has been changed to ''Coagulation and Thrombosis''. The meeting is closed to the public.

Dated: January 6, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–403 Filed 1–13–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the NIH Advisory Board for Clinical Research.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended to discuss personnel matters, the disclosure of which would constitute a clearly unwarranted invasion of privacy.

Name of Committee: NIH Advisory Board for Clinical Research.

Date: January 26, 2009.

Open: 10 a.m. to 1:15 p.m.

Agenda: To review the strategic and operational issues of the NIH Intramural Research Program, including the Clinical Center.

Place: National Institutes of Health, Building 10, 10 Center Drive, CRC Medical Board Room 4–2551, Bethesda, MD 20892,

Closed: 1:15 p.m. to 2 p.m.

Agenda: To discuss personnel matters.

Place: National Institutes of Health, Building 10, 10 Center Drive, CRC Medical Board Room 4–2551, Bethesda, MD 20892.

Contact Person: Maureen E. Gormley, Executive Secretary, Mark O. Hatfield Clinical Research Center, National Institutes of Health, Building 10, Room 6–2551, Bethesda, MD 20892, 301/496–2897.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Dated: January 7, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–515 Filed 1–13–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Cancer Institute Board of Scientific Advisors.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Board of Scientific Advisors.

Date: March 2–3, 2009.

Time: March 2, 2009, 8 a.m. to 6 p.m.

Agenda: Director's Report: Ongoing and New Business; Reports of Program Review Group(s); and Budget Presentations; Reports of Special Initiatives; RFA and RFP Concept Reviews; and Scientific Presentations.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, Conference Room 10, Bethesda, MD 20892.