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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Allergenic 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: Allergenic 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 February 22, 1999, 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

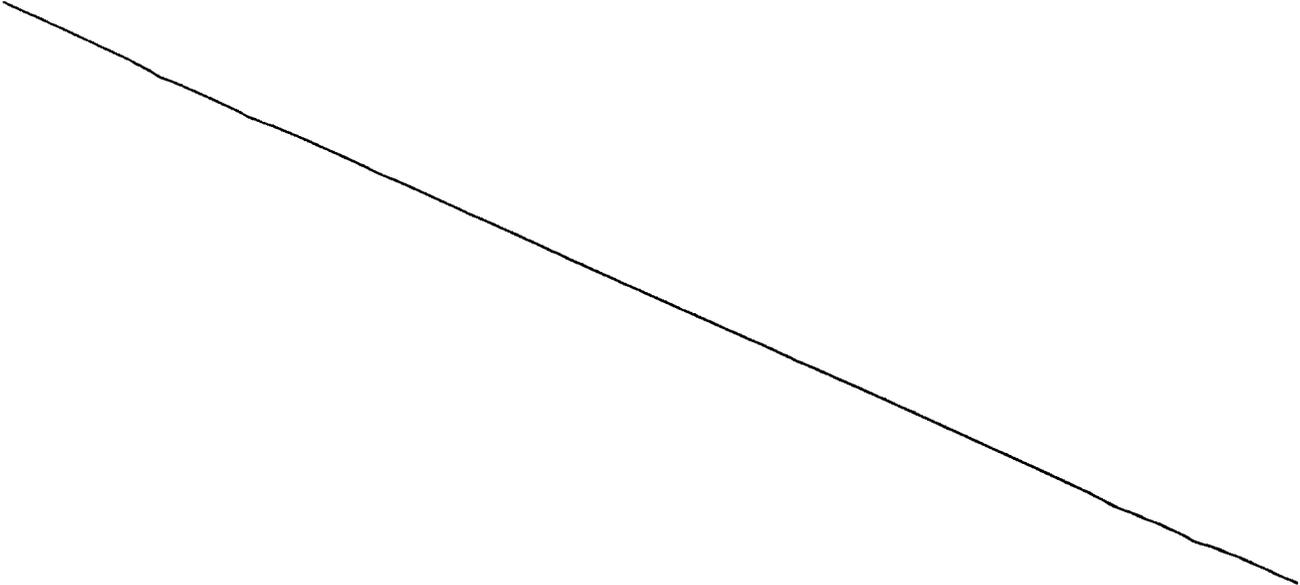
Contact Person: William Freas or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (HFM-21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss: (1) The current organization and the research programs of the Laboratory of Immunobiochemistry, Division of Allergenic Products and Parasitology, Office of Vaccines Research and Review; (2) regulatory proposals concerning the potency limits for standardized allergen vaccines and the requirements for protein content of these vaccines; (3) modifications of the competitive ELISA assay; (4) proposed package insert for allergen extracts; (5) issues regarding use of pure allergens versus U.S. standards; and (6) an update on the status of class IIIA allergen extracts.

Procedure: On February 22, 1999, from 8 a.m. to 3 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 16, 1999. Oral presentations from the public will be scheduled 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 February 16, 1999, 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 February 22, 1999, from 3 p.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)) regarding applications under FDA review.

FDA regrets that it was unable to publish this notice 15 days prior to the February 22, 1999, Allergenic Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Allergenic Products Advisory Committee were available at this time, the Commissioner 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: February 3, 1999

MA Friedman

Michael A. Friedman
Deputy Commissioner for Operations

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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