

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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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). At least one portion of the meeting will be closed 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 January 17, 2002, from 8 a.m. to 5 p.m., and January 18, 2002, from 8 a.m. to 3 p.m.

Location: Holiday Inn, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Kimberly L. 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, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12545. Please call the Information Line for up-to-date information on this meeting.

Agenda: On January 17, 2002, the committee will discuss the use of two new drug applications (NDAs): NDA 20-833, Flovent Diskus, and NDA 21-077, Advair Diskus, GlaxoSmithKline, as maintenance therapy in patients with chronic obstructive pulmonary disease (COPD). On January 18, 2002, the meeting will be open to the public from 8 a.m. to 9 a.m., unless public participation does not last that long; from 9 a.m. to 3 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information.

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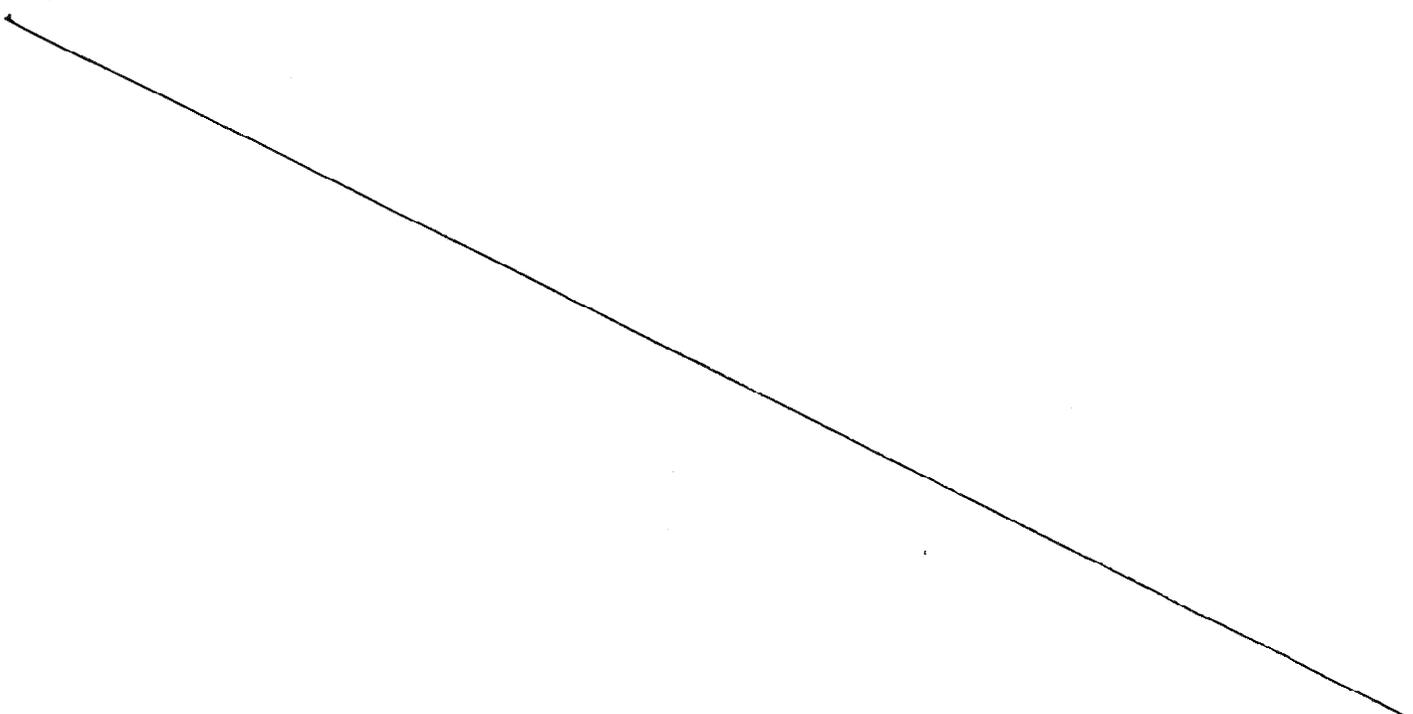
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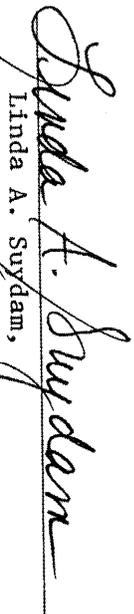
Procedure: On January 17, 2002, from 8 a.m. to 5 p.m. and on January 18, 2002, from 8 a.m. to 9 a.m., the meeting will be open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 11, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on January 17, 2002, and between approximately 8 a.m. and 9 a.m. on January 18, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 11, 2002, 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 January 18, 2002, from 9 a.m. to 3 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)).

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



Dated: December 19, 2001.


Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 01-???) Filed ??-?-01; 8:45 am]

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