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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic 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 is open to the public.

Name of Committee: Endocrinologic and Metabolic 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 April 22 and 23, 1999, 8 a.m. to 5 p.m.

Location: Pook's Hill Marriott, Ballroom, 5151 Pook's Hill Rd., Bethesda, MD.

Contact Person: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD-2 1), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8 138 (301-443-0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

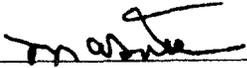
Agenda: On April 22, 1999, the committee will discuss the safety and efficacy of new drug application (NDA) 21-071, Avandia™ (rosiglitazone, SmithKline Beecham) for the treatment of hyperglycemia in type 2 diabetes mellitus, as monotherapy and in combination with metformin. On April 23, 1999, the committee will discuss the safety and efficacy of NDA 21-073, Actos™ (pioglitazone, Takeda Pharmaceuticals) to improve glycemic control in patients with type 2 diabetes mellitus.

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 April 14, 1999. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 14, 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.

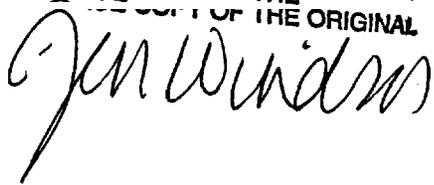
Notice of this meeting is given under the Federal Advisory Committee Act (5 U. S. C., app.

2).

Dated: March 3, 1999



Michael A. Friedman
Deputy Commissioner for
Operations

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

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