

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

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Cardiovascular and Renal 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: Cardiovascular and Renal 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 and 18, 2002, from 8:30 a.m. to 4:30 p.m.

Location: Holiday Inn, Kennedy Ball-room, 8777 Georgia Ave., Silver Spring, MD.

Contact: Jaime Henriquez, 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, f-800-741-8138 (301-443-0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

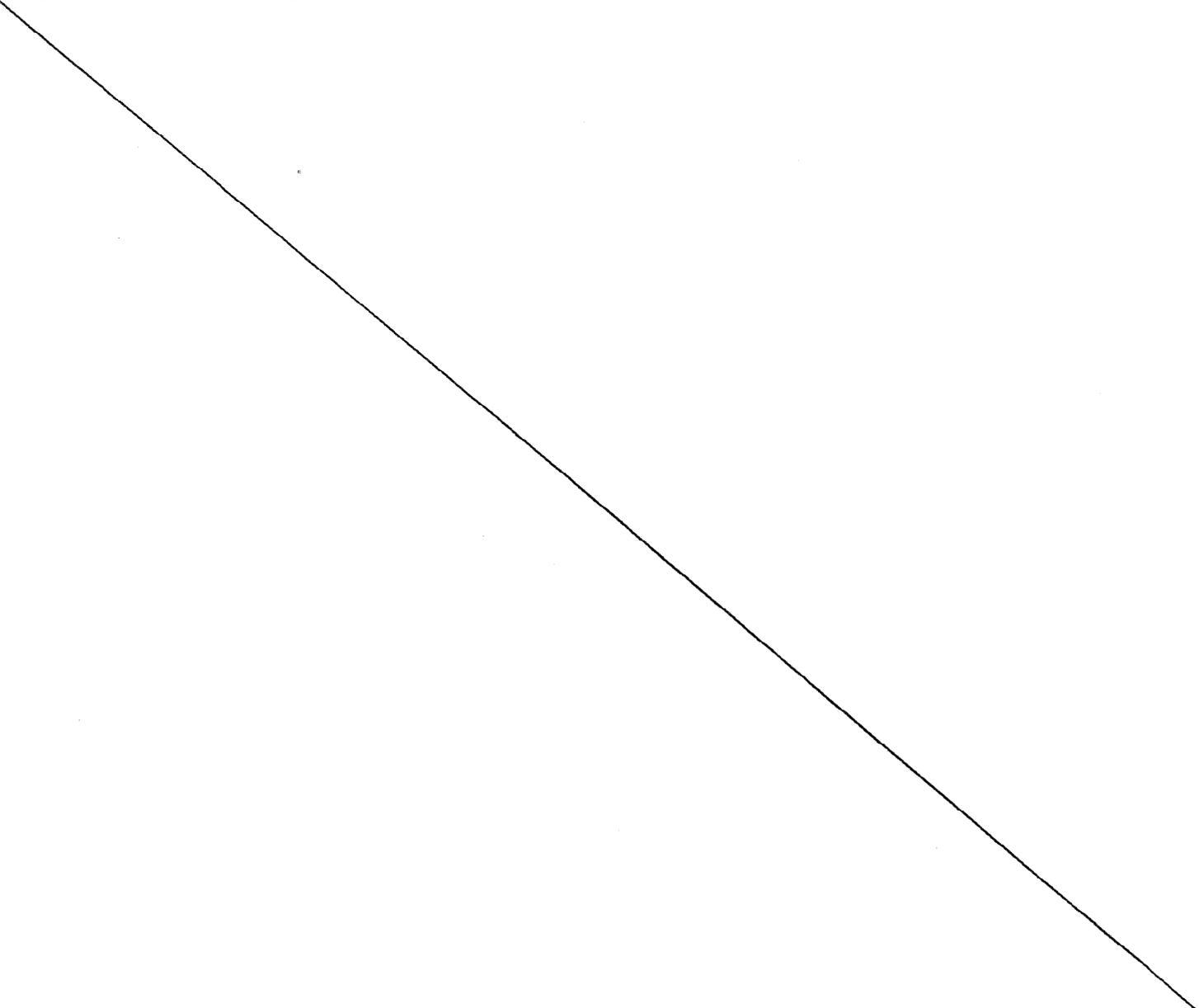
Agenda: On January 17, 2002, the committee will discuss new drug application (NDA) 20-757/S-021, AVAPRO (irbesartan), Sanofi-Synthelabo (c/o Bristol-Myers Squibb), for the treatment of hypertensive patients with type 2 diabetic renal. disease. On January 18, 2002, the committee will discuss NDA 21-387, pravastatin/aspirin, Bristol-Myers Squibb, co-package, for long-term management to reduce the risk of death, nonfatal myocardial infarction, myocardial

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revascularization procedures, and ischemic stroke in patients with clinically evident coronary heart disease.

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 January 7, 2002, Oral presentations from the public will be scheduled each day 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 January 7, 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.

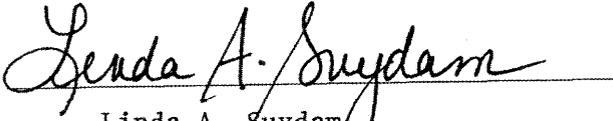


Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app,

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Dated: 12-14-01

December 14, 2001.


Linda A. Suydam,
Senior Associate Commissioner.

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

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Dawn P. Hawkins