

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier	SN Reese

Food and Drug Administration

Pregnancy Labeling Subcommittee Advisory Committee for Reproductive Health
Drugs; 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: Pregnancy Labeling Subcommittee of the Advisory Committee for Reproductive Health Drugs.

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 September 12, 2000, 10 a.m. to 12 noon.

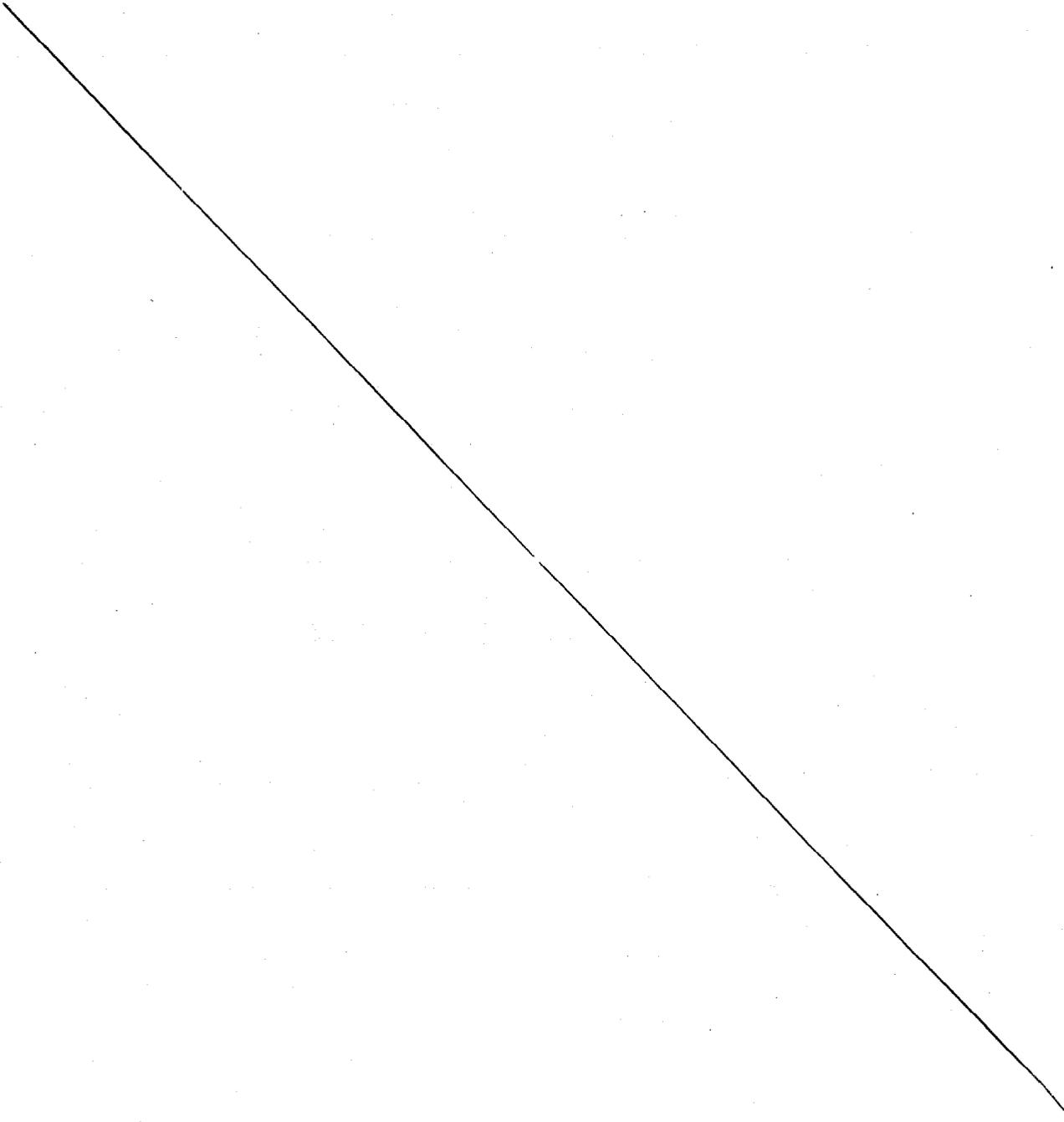
Location: Hyatt Regency, One Bethesda Metro Center, Bethesda, MD.

Contact Person: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or by e-mail: at PETERSONJ@CDER.FDA.GOV, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12537. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will meet to identify and discuss those drug and biologic products for which improved pregnancy labeling is critical for: (1) Effective prescribing during pregnancy, or (2) proper counseling of pregnant women who have been inadvertently exposed.

Procedure: Interested persons may present data, information, or views, orally or in writing on issues pending before the subcommittee. Written submissions may be made to the contact person

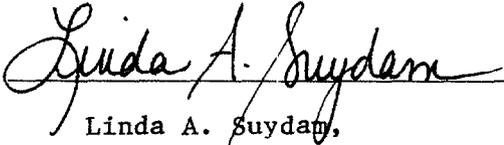
by September 6, 2000. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 6, 2000, and submit a brief statement 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: 8/10/00
August 10, 2000


Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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Suzette N. Reese