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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

**Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices
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: Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues as provided in the Federal Food, Drug, and Cosmetic Act.

Date and Time: The meeting will be held on December 6, 1999, 9 a.m. to 6:30 p.m., and December 7, 1999, 8:30 a.m. to 3 p.m.

Location: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Veronica J. Calvin, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1243, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12514. Please call the Information Line for up-to-date information on this meeting.

Agenda: On December 6, 1999, the committee will discuss, make recommendations, and vote on a premarket approval application for a device indicated for frequent, automatic, and noninvasive monitoring of glucose levels in adults with diabetes. On December 7, 1999, the committee will discuss and make recommendations on general issues regarding over-the-counter devices for

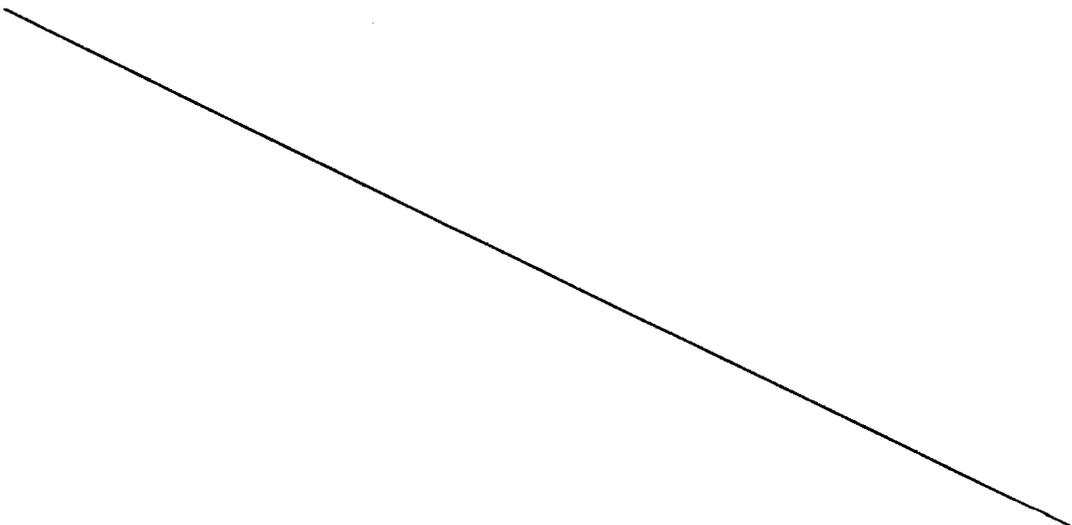
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measurement of vaginal pH. The discussion will include appropriate claims, study designs to support claims, performance expectations, and labeling.

Procedure: On December 6, 1999, from 9 a.m. to 6:30 p.m., and on December 7, 1999, from 9 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 November 24, 1999. On December 6, 1999, oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m. and between approximately 5:15 p.m. and 5:45 p.m. On December 7, 1999, oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m. and between approximately 2 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 24, 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.

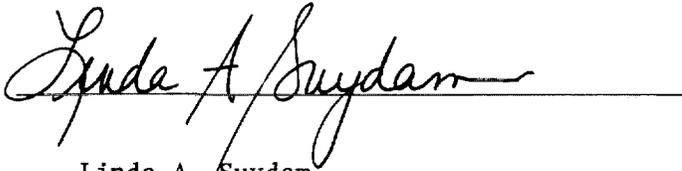
Closed Committee Deliberations: On December 7, 1999, from 8:30 a.m. to 9 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) relating to these products.



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

2).

Dated: 11/2/99
November 2, 1999



Linda A. Suydam
Senior Associate Commissioner

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

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