

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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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). The meeting will be open 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.

Date and Time: The meeting will be held on October 29, 2001, from 8 a.m. to 5 p.m.

Location: Hilton DC North-Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD.

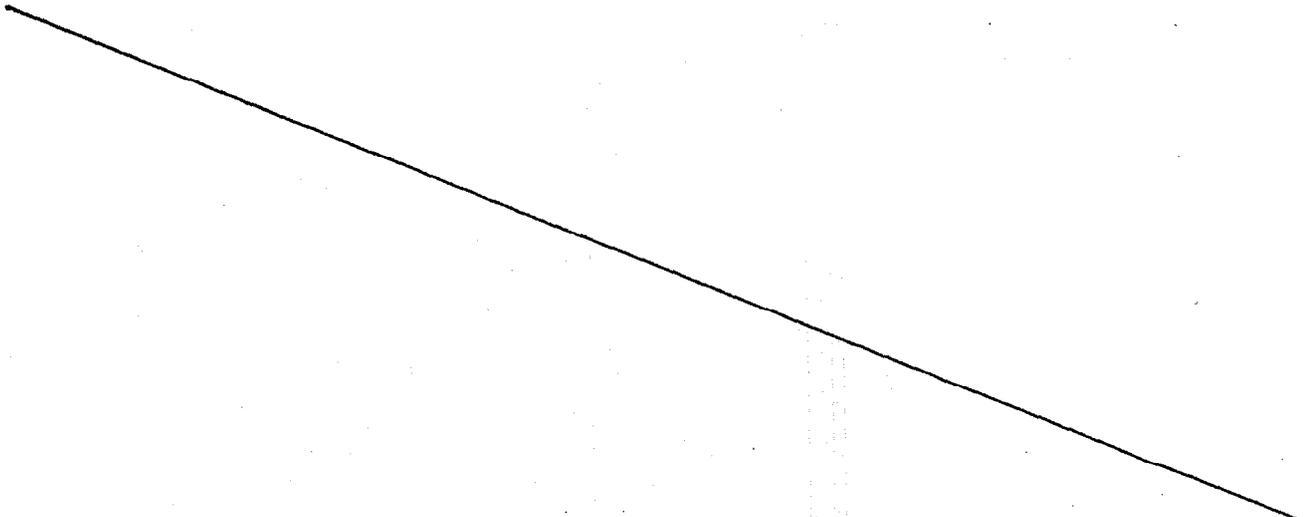
Contact: Veronica J. Calvin, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1243, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12514. Please call the Information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

Agenda: The committee will provide advice and recommendations on the types of data and/or labeling needed in premarket notification (510(k)) submissions for glucose test systems to address problems associated with using blood samples from alternate sites, such as the forearm, upper arm, thigh, calf, or base of the thumb. Background information, including the agenda and

questions for the committee, will be available to the public on October 26, 2001, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

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 October 19, 2001. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon and between approximately 3 p.m. and 3:30 p.m. on October 29, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 19, 2001, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the October 29, 2001, Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

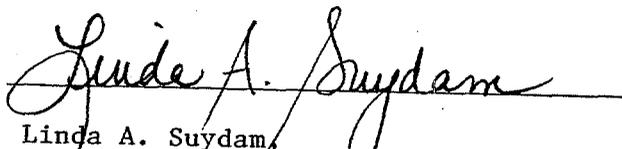


Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 10/11 101

October 11, 2001.


Linda A. Suydam,
Senior Associate Commissioner.

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

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