

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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**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.

Date and Time: The meeting will be held on November 13, 2000, 10 a.m. to 4:30 p.m., and November 14, 2000, 8:30 a.m. to 4 p.m.

Location: Hilton, Salons C, D, and E, 620 Perry Pkwy., 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 November 13, 2000, the committee will discuss two draft guidances: "Guidance for Prescription Use Drugs of Abuse Assays Premarket Notifications" and "Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications." The prescription use guidance will be available to the public on the Internet at <http://www.fda.gov/cdrh/ode/odecl052.html> and supersedes the document entitled "Review Criteria for Assessment of

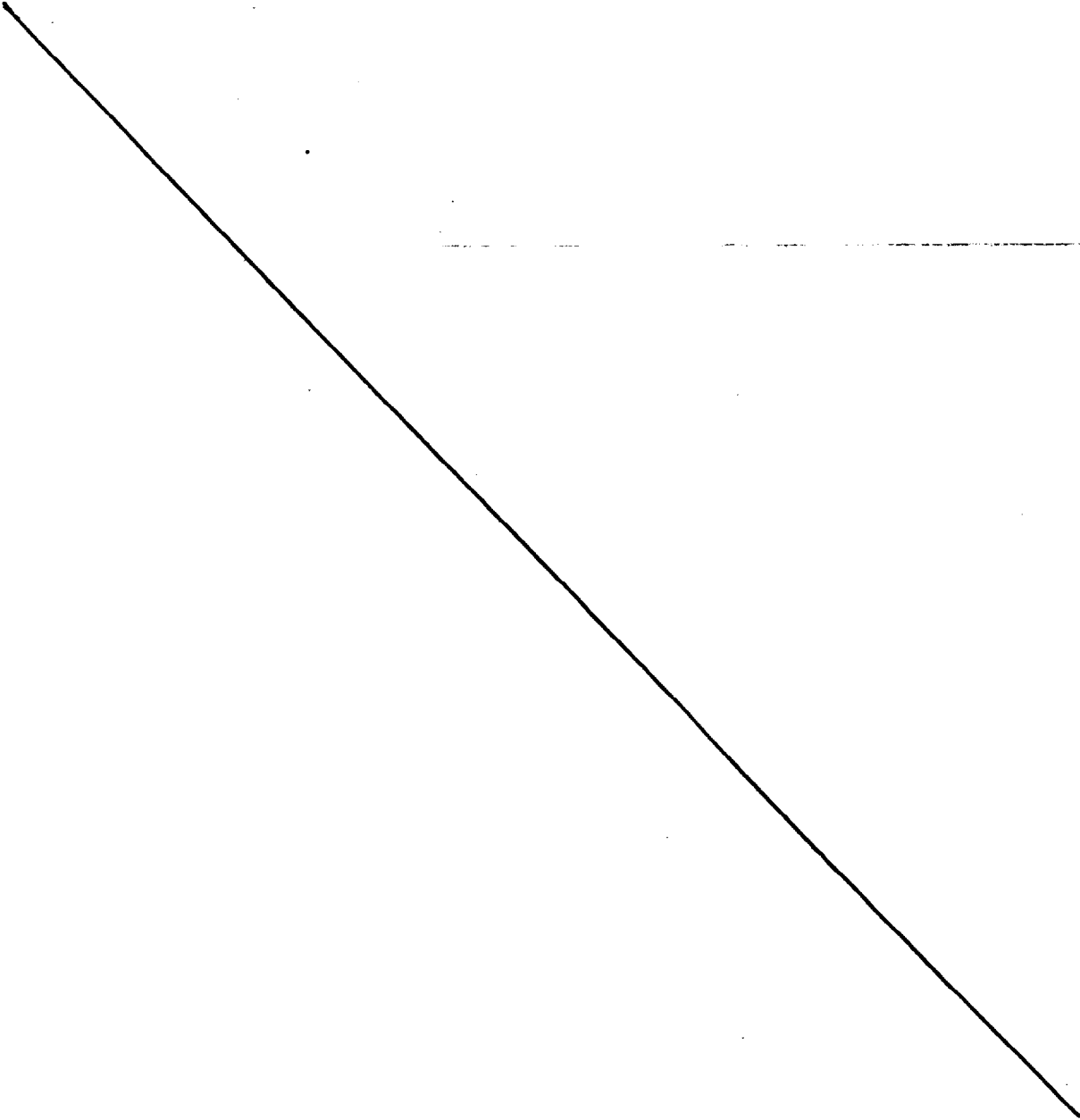
In Vitro Diagnostic Devices for Drugs of Abuse Assays Using Various Methodologies.” The OTC use guidance will be available to the public on the Internet at <http://www.fda.gov/cdrh/ode/91.html> and supersedes the document entitled “Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse To Be Used by the Consumer.” Draft questions for the committee regarding these guidances will be available to the public on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>. On November 14, 2000, the committee will discuss and make recommendations on a premarket notification (510(k)) for a first-of-a-kind prescription use screening device for heroin in human hair.

Procedure: On November 13, 2000, from 10 a.m. to 4:30 p.m., and on November 14, 2000, from 9 a.m. to 4 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 6, 2000. On November 13, 2000, oral presentations from the public regarding the prescription use guidance will be scheduled between approximately 10:45 a.m. and 11:15 a.m., and oral presentations from the public regarding the OTC use guidance will be scheduled between approximately 1:15 p.m. and 2 p.m. On November 14, 2000, oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m. and between approximately 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 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.

Closed Committee Deliberations: On November 14, 2000, 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 present and future agency issues.

FDA regrets that it was unable to publish this notice 15 days prior to the November 13 and 14, 2000, 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.



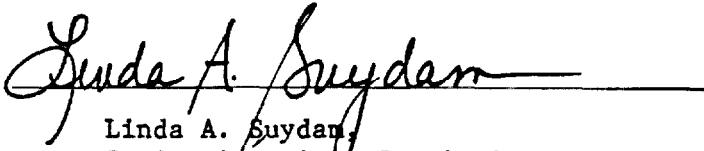
Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

OCT 27 2000

Dated: _____

October 27, 2000



Linda A. Suydam,
Senior Associate Commissioner.

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

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