

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-1020]

Medical Devices Draft Guidance on Over the Counter (OTC) Screening Tests for
Drugs of Abuse: Guidance for Premarket Notifications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

19MB

Display Date	11-8-00 @ 4:21pm
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Certifier	S. Reek

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications." FDA is issuing this draft guidance to provide information about studies and labeling considerations applicable to OTC screening tests that use urine as the clinical specimen for any combination of one or more of these drugs: Amphetamine (and, or methamphetamine), cocaine, cannabinoids, opiates, and phencyclidine. This draft guidance defines OTC use for the purposes of this document as use in home, workplace, insurance, and sports settings, and includes requests for comments on confirmatory testing and OTC alcohol testing. This draft guidance is neither final nor in effect at this time.

DATES: Submit written comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications," to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850.

Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments on the draft guidance to the Dockets

Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Jean M. Cooper, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1243.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 30, 1998 (63 FR 71932), FDA announced the availability for comment of a draft guidance entitled "Guidance for Premarket Submissions for Tests for Screening Drugs of Abuse to Be Used By The Consumer." FDA invited interested persons to comment on the draft guidance by March 30, 1999. FDA is replacing that draft guidance document with a new draft guidance entitled "Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications." This second draft guidance provides more detailed recommendations on what to include in a premarket notification for this device, and includes new information addressing the relevant least burdensome provisions of the Food and Drug Administration Modernization Act of 1997.

The draft guidance recommends including in the premarket notification:

- OTC studies showing correct results at concentrations 50 percent above and 50 percent below the cutoff;
- Description of the patient reporting format;
- Studies on the stability of the device; and
- The confirmatory laboratory's credentials.

The draft guidance also seeks public comment on premarket review of OTC alcohol tests.

The draft guidance also addresses labeling for these devices.

As part of its efforts to ensure that FDA considers the least burdensome path to market, the agency has drafted the guidance to:

- Clarify that OTC screening tests for drugs of abuse ordinarily will be reviewed as a premarket notification;
- Suggest the use of spiked urine samples instead of urine obtained from individuals using drugs; and
- Suggest combining drugs in these spiked urine samples in order to reduce the number of samples tested.

II. Significance of Guidance

This draft guidance represents the agency's current thinking on submissions for OTC screening tests for drugs of abuse. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), and published the final rule, which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (65 FR 56468, September 19, 2000). This guidance document is issued as a Level 1 guidance consistent with the GGP's.

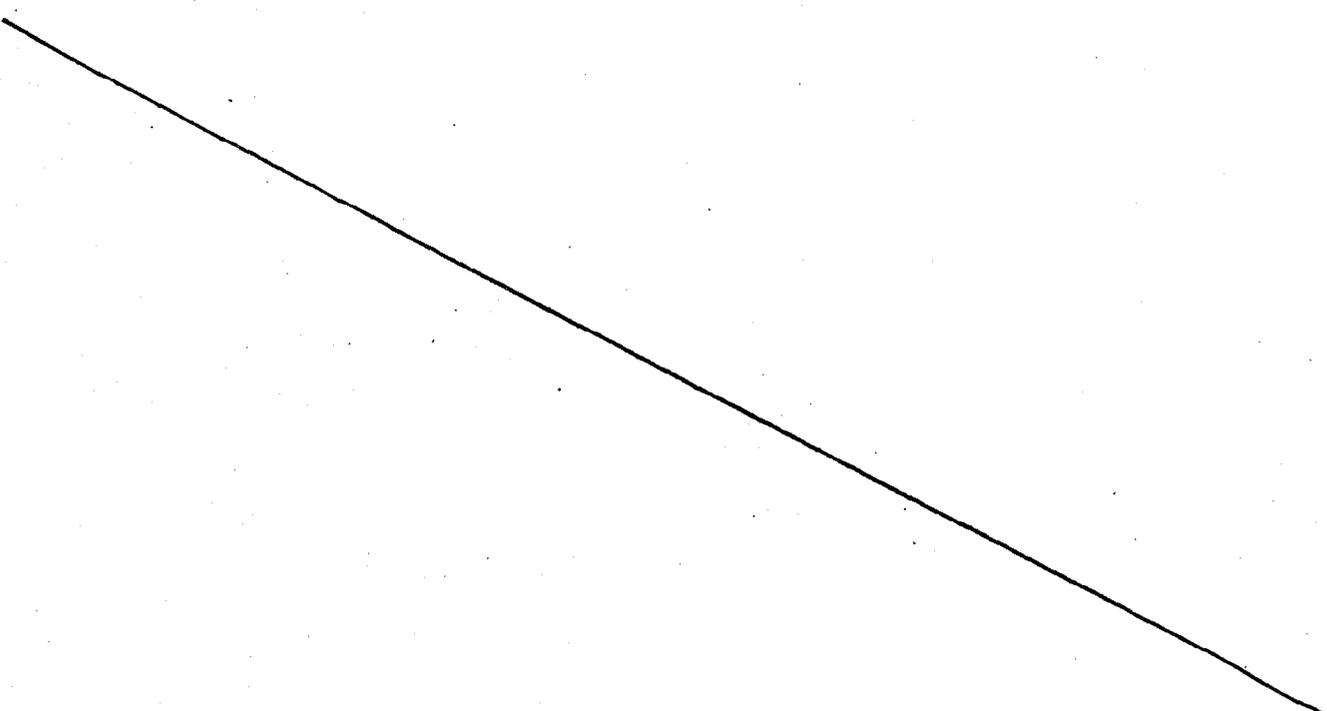
III. Electronic Access

In order to receive the draft guidance entitled "Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (2209) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. "Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications" is available at <http://www.fda.gov/cdrh/ode/guidance/2209.pdf>.

IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written comments regarding this draft guidance by *[insert date 90 days after date of publication in the Federal Register]*. Two copies of any comments are to be submitted, except that individuals may



submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11/2/00
November 2, 2000

Linda S. Kahan

Linda S. Kahan,
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Center for Devices and Radiological Health.

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