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Display Date	12-29-98
Publication Date	12-30
Certifier	J. J. [Signature]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-1020]

Draft Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse To Be Used by the Consumer; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse to Be Used By The Consumer." This draft guidance addresses screening devices sold over-the-counter for testing drugs of abuse. This type of device is intended for use in the home setting as a screening test for any, or any combination, of the following five substances in urine:

Amphetamine/methamphetamine, cocaine, cannabinoids, opiates, and phencyclidine.

DATES: Written comments concerning this draft guidance must be received by *(insert date 90 days after date of publication in the Federal Register)*.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse to Be Used By The Consumer" to the Division of Small Manufacturers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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Joseph L. Hackett, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-3084.

SUPPLEMENTARY INFORMATION:

I. Background

Over the last several years, FDA has worked to clarify the regulation of products for use in the home setting intended to screen for drugs of abuse. On September 17, 1997, FDA released for comment a draft guidance document entitled “Points to Consider for Approval of Home Drugs of Abuse Screening Kits.” On September 25, 1997, FDA held an open public meeting of the Clinical Chemistry and Clinical Toxicology Panel (the Panel), an FDA advisory committee, in order to discuss and receive comments on the September 1997 guidance. Based upon comments and recommendations received at this meeting from the Panel, the public, and manufacturers, FDA has revised the September 1997 guidance.

II. Significance of Guidance

This draft guidance represents the agency’s current thinking on drugs of abuse home screening kits. 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. This guidance is not final nor is it in effect at this time. This draft guidance replaces the September 17, 1997, guidance.

The agency has adopted good guidance practices (GGP’s), which set forth the agency’s policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP’s.

III. Electronic Access

In order to receive “Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse to Be Used By the Consumer” via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 2209 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes “Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse to Be Used By the Consumer,” 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>”.

IV. Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. 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: 12-15-98
December 15, 1998



D.B. Burlington
Director
Center for Devices and Radiological Health

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

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