

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1587]

Medical Devices Draft Guidance on Guidance for Prescription Use Drugs of Abuse Assays Premarket Notifications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

JMB

Display Date	11-8-00
Publication Date	11-14-00
Certifier	SNR/0020

21 pm

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Guidance for Prescription Use Drugs of Abuse Assays Premarket Notifications." FDA is issuing this guidance to express the general principles FDA applies in evaluating premarket notifications (510(k)s) for prescription use drugs of abuse assays. The principles described in this draft guidance document apply only to in vitro diagnostic (IVD) submissions for 510(k) clearance for these devices. This draft guidance is neither final nor in effect at this time.

DATES: Submit written comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Guidance for Prescription Use Drugs of Abuse Assays Premarket Notifications" to the Division of Small Manufacturers Assistance (HFZ-220), Center for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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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
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document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.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

This draft guidance recommends data and labeling that manufacturers should submit in support of substantial equivalence for prescription use drugs of abuse assays. The recommendations and general principles in this draft guidance are provided to assist manufacturers in the preparation of premarket notifications (510(k)s) for these devices. This document will supersede the document, "Review Criteria for Assessment of In Vitro Diagnostic Devices for Drugs of Abuse Assays Using Various Methodologies," August 31, 1995. This draft guidance explains the types of studies to conduct and how to present the study data in greater detail than the document it is replacing.

II. Significance of Guidance

This draft guidance represents the agency's current thinking regarding data and labeling for prescription use drugs of abuse device submissions for 510(k) clearance. 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 regulations for the development, issuance, and use of guidance documents (65 FR 56468, September 19, 2000). This guidance document is issued as a Level 1 draft guidance consistent with the GGP's.

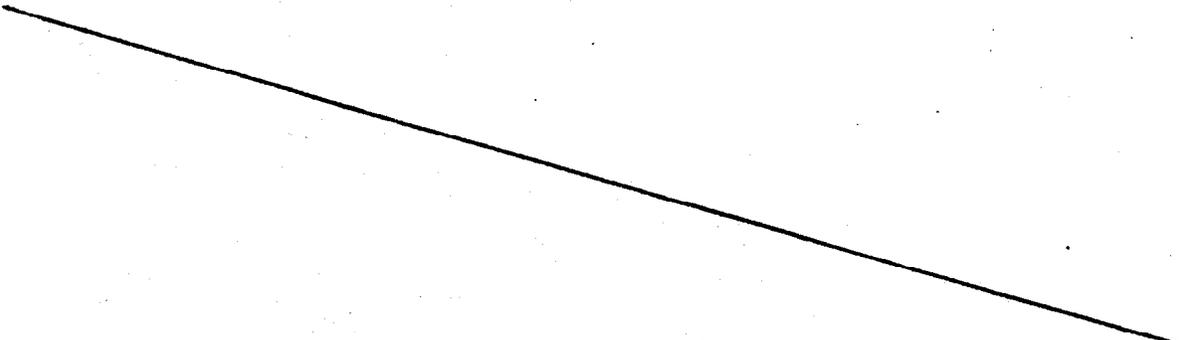
III. Electronic Access

In order to receive the draft guidance entitled "Guidance for Prescription Use Drugs of Abuse Assays 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 (152) 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>. "Guidance for Prescription Use Drugs of Abuse Assays Premarket Notifications" will be available at <http://www.fda.gov/cdrh/ode/guidance/152.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 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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