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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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In the **Federal Register** of December 30, 1998 (63 FR 71932), FDA announced the availability for comment of a draft guidance entitled ''Guidance for Premarket Submissions for Tests for Screening Drugs of Abuse to Be Used By The Consumer.'' FDA invited interested persons to comment on the draft guidance by March 30, 1999. FDA is replacing that draft guidance document with a new draft guidance entitled ''Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications.'' This second draft guidance provides more detailed recommendations on what to include in a premarket notification for this device, and includes new information addressing the relevant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The draft guidance recommends including in the premarket notification: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The draft guidance also seeks public comment on premarket review of OTC alcohol tests.

The draft guidance also addresses labeling for these devices.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This draft guidance represents the agency's current thinking on submissions for OTC screening tests for drugs of abuse.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 February 12, 2001. 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: November 2, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–29109 Filed 11–8–00; 4:21 pm]

BILLING CODE 4160–01–F

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.

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 February 12, 2001.

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 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 February 12, 2001. 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: November 2, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–29110 Filed 11–8–00; 4:21 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: October 2000

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of October 2000, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs.

In addition, no program payment is made to any business or facility, *e.g.,* a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject, city, state	Effective date
PROGRAM-RELATED CONVICTIONS	
ASKARI, SOHEILA MONTGOMERY, AL	11/20/2000
BEN, ERIC S PORT ST LUCIE, FL	11/20/2000
CARNEVALI, STEVEN ERNEST JR PITTSBURGH, PA	11/20/2000
CASPER, FRANCES C VIRGINIA BCH, VA	11/20/2000
CHACON, RAUL ENRIQUE VALRICO, FL	11/20/2000
CHAMBERS, CHARLES ROOSEVELT, NY	11/20/2000
CUCHEZ, MARIA BELL GARDENS, CA	11/20/2000
CULLINAN, MICHAEL JOSEPH MORGANTOWN, WV	11/20/2000
DE LOS SANTOS, RAMIRO EAGLE PASS, TX	11/20/2000
DE LOS SANTOS GARCIA, MARILU EAGLE PASS, TX	11/20/2000
DEL TORO PHARMACY MIAMI, FL	11/20/2000
DENIS, ALFONSO EL MONTE, CA	11/20/2000
DIAZ, RACHEL M HIALEAH, FL	11/20/2000
DONALDSON, JAMES FRED BERRIEN SPRINGS, MI	11/20/2000
FERREIRO, CARLOS M MIAMI, FL	11/20/2000
FISHER, STEPHEN NEAL PITTSBURGH, PA	11/20/2000
FLORES, JOSE MARTIN DOWNEY, CA	11/20/2000
GALE, STACEY R DONALSONVILLE, GA	11/20/2000
GALIANO, CARMEN SOCORRO MIAMI, FL	11/20/2000
GARCIA, EDUARDO G	11/20/2000