thus may trigger a regulatory response by the agency. FDA is issuing this clarification because some domestic firms have questioned whether records can be made available after an inspection (rather than during) and some foreign firms have canceled scheduled inspections by FDA, but offered to make records available for review. This guidance applies to foreign processors that export fish and fishery products to the United States as well as to domestic processors.

DATES: Submit written comments on the draft guidance by December 14, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://vm.cfsan.fda.gov/dms/guidance.html. Submit written requests for single copies of the draft guidance to the Industry Activities Staff, Office of Constituent Operations (HFS–565), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Send one self-addressed adhesive label to assist that office in processing your reuqests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary I. Snyder, Center for Food Safety and Applied Nutrition (HFS–415), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3133.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products.'' This guidance is intended to clarify that on-site inspection of a processing facility and concurrent review of HACCP records are essential elements of FDA's Seafood HACCP program as set forth at part 123 (21 CFR part 123). These regulations require processors of fish and fishery products to operate preventive control systems for human food safety that incorporate the principles of HACCP. The regulations further provide that fish and fishery products are adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342(a)(4)) if their processor fails to have and implement a HACCP plan when one is necessary, or otherwise fails to meet any of the requirements of the regulations, including allowing the official review of records (§ 123.6(g)). Processors must make their HACCP records and plans available ''for official review and copying at reasonable times'' (§ 123.9(c)). The agency expects that it will regard the failure to provide records and plans by a domestic or foreign processor as a significant program violation, even if a firm volunteers the documents after the inspection.

FDA believes that the best way for a regulatory authority to determine whether a processor is effectively operating a HACCP system is by inspecting the processor to assess whether the system is operating properly and is appropriate for the circumstances. Review of monitoring and other records generated by the HACCP system is a critical component of an inspection because it allows the inspector to match records against practices and conditions being observed in the plant and it discourages fraud. Thus, FDA always has intended that its review of processors' HACCP plans and records would occur as part of an inspection of a processor's entire HACCP system.

For domestic processors, failure to allow an inspection would not only violate the HACCP regulations; it is also a prohibited act under section 301(f) of the act (21 U.S.C. 331(f)). Moreover, if a domestic processor refuses an FDA inspection, FDA can obtain an inspectional warrant from the U.S. district court in which the processor is located.

Failure to allow an FDA inspection by a foreign processor can also result in a regulatory response. The definition of ''processor'' at § 123.3(l) specifically includes persons in foreign countries. Thus, like domestic processors, foreign processors who ship to the United States must operate under conditions that satisfy FDA's HACCP regulations, including the requirement that records be made available during the course of an FDA inspection.

This draft guidance is being issued consistent with FDA's good guidance practices (65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on refusal of inspection or access to HACCP records that pertain to the safe and sanitary processing of fish and fishery products. 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 requirements of the applicable statutes and regulations.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the 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 are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 30, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–29011 Filed 11–13–00; 8:45 am]

BILLING CODE 4160–01–F

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.

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 February 12, 2001.

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 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]

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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