

Commissioned Corps promotion and awards programs; and (4) maintains liaison and coordinates personnel services for Commissioned Corps personnel with the Division of Commissioned Personnel.

Central Staffing Section (CAD536). (1) Implements a centralized staffing and placement program; (2) administers the delegated examining authority, the direct hiring authority, and the temporary limited appointment authority granted by USOPM; (3) oversees the overall staffing process and insures quality control; (4) reviews, evaluates, and makes recommendations on the application and implementation of the USOPM delegated authorities and merit promotion program rules and regulations; (5) provides guidance and consultation in job analyses and in development of knowledge/skills/abilities (KSAs) crediting plans; and (6) manages various staffing programs such as the CDC summer program, the Voluntary Employee Referral Program, the Interagency Career Transition Assistance Program, and the Career Transition Assistance Program.

Technical Services Section (CAD357). (1) Provides central personnel services and assistance in the areas of employee benefits, personnel action processing, data quality control/assessment, and files/records management; (2) services as liaison between CDC and the HHS payroll office resolving discrepancies with pay and leave; (3) administers the leave donor program and processes time and attendance amendments; (4) provides policy guidance and technical advice and assistance on retirement, the Thrift Savings Plan, health/life insurance, and savings bonds; (5) codes and finalizes all personnel actions in the automated personnel data system; (6) assists with new employee orientation; (7) establishes and maintains the official personnel files system and administers personnel records storage and disposal program; (8) responds to employment verification inquiries; (9) administers the personnel security program; (10) initiates suitability background checks and fingerprints for all CDC personnel; and (11) provides assistance in the implementation of the HHS Plan for a Drug Free Workplace.

Information Technology and Analysis Branch (CAD36). (1) Develops strategic plans for information technology and information systems to support CDC's and HRMO's personnel information requirements; (2) acquires and implements appropriate technology and develops information systems to meet CDC-wide information needs on personnel, staffing, and work force characteristics and trends; (3) provides

support to HRMO organizations and users in achieving automation of functions and use of information technology and systems; (4) develops, manages, and supports centralized information technology and systems in support of personnel activities, including the HHS personnel system; (5) researches and develops new sources of personnel information and access methods including computer-based CDC-wide surveys; (6) coordinates HRMO information resource management activities with IRMO and CDC information resource management committees; (7) conducts demographic analysis of the CDC work force and publishes results in management reports; and (8) develops methodologies to assess the impact of revised personnel policies and practices on the work force.

Outreach and Marketing Branch (CAD37). (1) Develops and implements human resource management marketing campaigns; (2) provides leadership in identifying the Centers/Institute/Offices' (CIOs) recruiting needs, and assesses, analyzes, and develops CDC's short- and long-range recruitment plans to meet these needs; (3) provides consultation, guidance, and technical advice on recruitment and special emphasis policies, practices, and procedures, including search committees; (4) strategizes on the best approach to recruitment at specific events, and designs and develops recruitment materials for events; (5) maintains and manages the Automated Applicant Listing System (AALS/Resumix) for storage and retrieval of applications of those individuals with education and experience appropriate for commonly needed and hard-to-fill positions; coordinates, with CIOs, the referral of appropriate candidates from the applicant pool for position vacancies; (6) provides leadership on recruitment activities through the development of policies and practices for effective communication of HRMO programs, coordinates the development and dissemination of information among HRMO and the CIOs, provides training and technical assistance to CIO staff; (7) manages and operates the CDC Job Information Center, including the automated telephone job line; (8) markets and manages special emphasis programs including the Program for Persons with Disabilities and the Disabled Veterans Affirmative Action Program, the Veterans Readjustment Appointment Program, the Federal Equal Opportunity Recruitment Program, and college relations and student employment programs; and (9)

provides leadership in assessing progress in achieving overall staffing, EEO, and Affirmative Action goals.

Delegations of Authority Statement

All delegations and redelegations of authority remain in effect until otherwise modified, superseded, or cancelled.

Section C-C, Order of Succession

Delete in its entirety Section C-C, Order of Succession, and insert the following:

During the absence or disability of the Director, CDC, or in the event of a vacancy in that office, the first official listed below who is available shall act as Director, except that during a planned period of absence, the Director may specify a different order of succession:

1. Deputy Director for Science and Public Health;
2. Deputy Director for Policy and Legislation;
3. Deputy Director for Program Management.

Dated: October 30, 2000.

Jeffrey P. Koplan,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1555]

Draft Guidance for Industry on Refusal of Inspection or Access to HACCP Records Pertaining to the Safe and Sanitary Processing of Fish and Fishery Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (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 draft guidance sets forth the agency's interpretation of its Hazard Analysis Critical Control Point (HACCP) regulations for fish and fishery products as they pertain to the inspection of facilities and records. The agency is clarifying that a processor's refusal to allow FDA to inspect its processing facilities, or to provide HACCP records or plans to an inspector during an inspection, violates the regulations and

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 requests. 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.

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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