

and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go

to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Table 5 follows:

TABLE 5.—INCORPORATION BY REFERENCE

Service Bulletin No.	Page	Revision	Date
RB.211-72-AD344 Total Pages: 11	All	7	March 12, 2004.
RB.211-72-AD344, Appendices 1 through 5 Total Pages: 18	All	7	March 12, 2004.
RB.211-72-D672 Total Pages: 24	All	Original	February 1, 2002.

Related Information

(l) Civil Aviation Authority (CAA) airworthiness directive G-2004-0008, dated April 29, 2004, also addresses the subject of this AD.

Issued in Burlington, Massachusetts, on September 6, 2005.

Peter A. White,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.
[FR Doc. 05-17976 Filed 9-9-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2005D-0356]

Guidance for Industry: Questions and Answers Regarding the Final Rule on Establishment and Maintenance of Records; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability of guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Questions and Answers Regarding Establishment and Maintenance of Records.” The guidance responds to various questions raised about the recordkeeping provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency’s implementing regulation, which requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled “Questions and Answers Regarding Establishment and Maintenance of Records” to Denise Beavers (see **FOR FURTHER INFORMATION CONTACT**). Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Denise Beavers, Center for Food Safety and Applied Nutrition (HFS-24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1721.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of December 9, 2004 (69 FR 71562), FDA issued a final rule to implement section 306 of the Bioterrorism Act (21 U.S.C. 350c). The regulation requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. Persons subject to the regulation are required to be in compliance by December 9, 2005, June 9, 2006, or December 11, 2006, depending on the size of the business.

The guidance for industry entitled “Questions and Answers Regarding Establishment and Maintenance of Records” responds to questions about the final rule on records. It is intended to help industry better understand and comply with the regulation in 21 CFR part 1, subpart J. FDA is issuing this guidance as a level 1 guidance. The guidance represents the agency’s current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the

public. Consistent with FDA’s good guidance practices regulation § 10.115(g)(2) (21 CFR 10.115(g)(2)), the agency will accept comments, but it is implementing the guidance document immediately, in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. As noted, the final rule requires that covered persons begin to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food by December 9, 2005, June 9, 2006, or December 11, 2006, depending on the size of the business. Clarifying the provisions of the final rule will facilitate prompt compliance with these requirements and ensure complete implementation of the final rule.

FDA continues to receive large numbers of questions regarding the records final rule, and is responding to these questions under § 10.115 as promptly as possible, using a question-and-answer format. The agency believes that it is reasonable to maintain all responses to questions concerning establishment and maintenance of records in a single document that is periodically updated as the agency receives and responds to additional questions. The following four indicators will be employed to help users of the guidance identify revisions: (1) The guidance will be identified as a revision of a previously issued document, (2) the revision date of the guidance will appear on its cover, (3) the edition number of the guidance will be included in its title, and (4) questions and answers that have been added to the original guidance will be identified as such in the body of the guidance.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any

mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments and the guidance may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at <http://www.cfsan.fda.gov/guidance.html>.

Dated: September 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-18039 Filed 9-7-05; 3:12 pm]

BILLING CODE 4160-01-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 228

[FRL-7967-7]

Ocean Dumping; LA-3 Ocean Dredged Material Disposal Site Designation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) today designates LA-3 as a permanent ocean dredged material disposal site (ODMDS) located offshore of Newport Beach, California, managed at a maximum annual dredged material disposal quantity of 2,500,000 cubic yards (yd³) (1,911,000 cubic meters [m³]), and adjusts the management of the permanently-designated LA-2 ODMDS at an increased maximum annual dredged material disposal quantity of 1,000,000 yd³ (765,000 m³) for the ocean disposal of clean dredged material from the Los Angeles County and Orange County regions. The availability of suitable ocean disposal sites to support ongoing maintenance and capital improvement projects is essential for the continued use and economic growth of the vital commercial and recreational areas in the region. Dredged material will not be allowed to be disposed of in the ocean

unless the material meets strict environmental criteria established by the EPA and U.S. Army Corps of Engineers (USACE).

The action would shift the center of the permanently-designated LA-3 site approximately 1.3 nautical miles (nmi) (2.4 kilometers [km]) to the southeast of the interim LA-3 site, and encompass a region that is already disturbed by dredged material. The permanent site also would be located on a flat, depositional plain, and away from the submarine canyons, that will be more amenable to surveillance and monitoring activities. The LA-2 site is a permanently designated ODMDS that has been historically managed at an average annual disposal quantity of 200,000 yd³ (153,000 m³) for the disposal of material dredged primarily from the Los Angeles/Long Beach Harbor complex. The action will allow an increased volume of dredged material to be disposed annually at this site. The annual disposal quantity has occasionally exceeded the historical annual average due to capital projects from both the ports of Los Angeles and Long Beach. Thus, the new maximum volume designation would accommodate the projected average annual volume requirements as well as provide for substantial annual volume fluctuations.

DATES: This final regulation is effective on October 12, 2005.

FOR FURTHER INFORMATION CONTACT: Mr. Allan Ota, Dredging and Sediment Management Team, U.S. Environmental Protection Agency, Region IX (WTR-8), 75 Hawthorne Street, San Francisco, CA 94105, telephone (415) 972-3476 or FAX: (415) 947-3537 or e-mail: ota.allan@epa.gov.

SUPPLEMENTARY INFORMATION: The supporting document for this site designation is the Final Environmental Impact Statement for the Site Designation of the LA-3 Ocean Dredged Material Disposal Site off Newport Bay, Orange County, California. This document is available for public inspection at the following locations:

1. EPA Region IX, Library, 75 Hawthorne Street, 13th Floor, San Francisco, California 94105.

2. EPA Public Information Reference Unit, Room 2904, 401 M Street, SW., Washington, DC 20460.

3. U.S. EPA, Southern California Field Office, 600 Wilshire Boulevard, Suite 1460, Los Angeles, CA 90017.

4. Lloyd Taber-Marina del Rey Library, 4533 Admiralty Way, Marina del Rey, CA 90292.

5. Long Beach Public Library, 101 Pacific Avenue, Long Beach, CA 90822.

6. Los Angeles Public Library, Central Library, 630 West 5th Street, Los Angeles, CA 90071.

7. Los Angeles Public Library, San Pedro Regional Branch Library, 931 South Gaffey Street, San Pedro, CA 90731.

8. Newport Beach Public Library, Balboa Branch, 100 East Balboa Boulevard, Balboa, CA 92661.

9. Newport Beach Public Library, Central Library, 1000 Avocado Avenue, Newport Beach, CA 92660.

10. Newport Beach Public Library, Corona del Mar Branch, 420 Marigold Avenue, Corona del Mar, CA 92625.

11. Newport Beach Public Library, Mariners Branch, 2005 Dover Drive, Newport Beach, CA 92660.

12. U.S. EPA Web site: <http://www.epa.gov/region9>.

13. U.S. Army Corps of Engineers' Web site: <http://www.spl.usace.army.mil>.

A. Potentially Affected Entities

Entities potentially affected by this action are persons, organizations, or government bodies seeking to dispose of dredged material in ocean waters at the LA-3 and LA-2 ODMDS, under the Marine Protection Research and Sanctuaries Act, 33 U.S.C. 1401 *et seq.* The Rule would be primarily of relevance to parties in the Los Angeles and Orange County areas seeking permits from the USACE to transport dredged material for the purpose of disposal into ocean waters at the LA-3 and LA-2 ODMDS, as well as the USACE itself (when proposing to dispose of dredged material at the LA-3 and LA-2 ODMDS). Potentially affected categories and entities seeking to use the LA-3 and LA-2 ODMDS and thus subject to this Rule include:

Category	Examples of potentially affected entities
Industry and General Public	Ports. Marinas and Harbors. Shipyards and Marine Repair Facilities. Berth owners.
State, local and tribal governments	Governments owning and/or responsible for ports, harbors, and/or berths. Government agencies requiring disposal of dredged material associated with public works projects.
Federal Government	U.S. Army Corps of Engineers Civil Works and O & M projects.