guidance is streamlined and re-organized to make the information clearer and more accessible, but there are no major policy differences. The final guidance also omits much of the background discussion about the origin and nature of the adverse event reporting problem that the guidance addresses because that information is tangential to the goals of the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on adverse event reporting for the purpose of improving human subject protection. 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.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 56 have been approved under OMB control number 0910–0130; the collections of information in part 312 have been approved under OMB control number 0910–0014; and the collections of information in part 812 have been approved under OMB control number 0910–0078.

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 may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: December 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–683 Filed 1–14–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0043] (formerly Docket No. 2004D–0510)

Guidance for Industry: Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Fish and Fishery Products for Export to the European Union and the European Free Trade Association; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Fish and Fishery Products for Export to the European Union and the European Free Trade Association.'' The guidance provides information for seafood processors and other entities that are interested in obtaining export certificates for fish or fishery products that are to be shipped to the European Union (EU) and the European Free Trade Association (EFTA). FDA is also announcing that it intends to stop issuing EU Export Certificates after February 17, 2009.

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written comments concerning the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written requests for single copies of the guidance to the Office of Food Safety (HFS–300), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: William Jones, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–2300.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 26, 2004 (69 FR 68948) (the November 26 notice), FDA announced the availability of a draft guidance entitled ''Proposed Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program for the Certification of Live and Perishable Fish and Fishery Products for Export to the European Union and the European Free Trade Association.'' In the November 26 notice, FDA announced that it proposed to operate a Referral Program for a 24-month period to test the viability and effectiveness of such an arrangement. During this period, EU Export Certificates for shipments of live and perishable fish and fishery products destined for the EU, European Union Accession Partnership Countries (EUAPC), and EFTA Members would have been issued by the National Oceanic and Atmospheric Administration Seafood Inspection Program (NOAA SIP) under the Agricultural Marketing Act. In addition, FDA indicated that it intended to stop issuing EU Export Certificates for live and perishable fish and fishery products during this period. FDA sought comment on this referral program, including whether it should be expanded beyond live and perishable to all shipments of fish and fishery products destined for the EU, EU Accession Partnership Countries, and other countries with certificate requirements.

Interested persons were initially given until December 27, 2004, to comment on the draft guidance. The comment period was subsequently extended until January 25, 2005 (69 FR 78038, December 29, 2004). The agency considered and modified the guidance as appropriate.

The agency is announcing the availability of the final guidance document entitled ''Guidance for Industry: Referral Program from the Food and Drug Administration to the National Oceanic and Atmosphere Administration Seafood Inspection Program for the Certification of Fish and Fishery Products for the Export to the European Union and the European Free

Trade Association.'' In this final guidance, FDA is announcing that: (1) We intend to proceed with a Certification Referral Program to NOAA SIP, without a 24-month test period, (2) we intend to expand the program to include all fish and fishery products for export to the EU and EFTA, and (3) we intend to stop issuing EU Export Certificates effective February 17, 2009. The agency intends to adopt this approach because the industry's demand for EU Export Certificates continues to rise dramatically, and FDA can no longer justify the use of our limited food safety resources for issuance of EU Export Certificates. The implementation of this guidance should free up resources that the agency can allocate for higher priority public health activities that are intended to protect the U.S. consuming public, while still providing a mechanism for the industry to continue obtaining EU certification. Seafood processors and other entities involved in the exporting of seafood to the EU may obtain EU Export Certificates from the NOAA SIP.

FDA is issuing this guidance document as a level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA, NOAA SIP, or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

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. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

III. Electronic Access

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

Dated: January 9, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–785 Filed 1–14–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0661]

Unique Device Identification System; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: ''Unique Device Identification System.'' The purpose of the public workshop is to obtain information to help us better understand the issues involved in the establishment of a unique device identification system (UDI system) and request comments on this topic.

Dates and Time: The public workshop will be held on, February 12, 2009, from 9 a.m. to 5 p.m. See section V of this document for additional dates associated with registration and participation in the workshop.

Location: The public workshop will be held at the Marriott Gaithersburg Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD 20878, 301–590–0044.

Contact Person: Jay Crowley, Food and Drug Administration, Center for Devices and Radiological Health (HFZ–500), 1350 Piccard Dr., Rockville, MD 20852, 240–276–2389, or Stephen Ripley, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM–17), 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

Registration: Register electronically at *http://www.fda.gov/cdrh/ocd/udi/index.html*by January 30, 2009. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Jay Crowley (see *Contact Person*) by January 30, 2009.

Comments: Regardless of attendance at the public workshop, interested persons may submit written or electronic comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. 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. The deadline for submitting comments regarding this public workshop is February 27, 2009. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

A. What Does Section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) Require?

On September 27, 2007, President George W. Bush signed into law FDAAA (Public Law 110–85). Section 226 of FDAAA amended the Federal Food, Drug, and Cosmetic Act (the act) by requiring the establishment of a UDI system. Specifically, section 226(a) of FDAAA created a new section 519(f) of the act (21 U.S.C. 360i(f)) stating that ''The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.''

A UDI system may provide for early detection of the warning signs of a defective device and facilitate device recalls (Ref. 1) and other possible benefits of a UDI system have been suggested.

B. Why Are We Holding a Public Workshop?

The enactment of section 519(f) of the act has raised many questions for our consideration. For example, the statute requires the UDI to go on the device's label, but it also allows for ''alternative placement'' and for exceptions. Thus,