DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0510]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or agency) is announcing the availability of the draft guidance entitled ''Proposed Referral Program from the Food and Drug Administration to the National Oceanic and Atmospheric Administration Seafood Inspection Program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.'' The draft guidance proposes a 24-month Referral Program in which European Union (EU) Export Certificates for all shipments of live and perishable fish and fishery products destined for the EU, EU Accession Partnership Countries, and members of the European Free Trade Association (EFTA) would be issued by the National Oceanic and Atmospheric Administration Seafood Inspection Program (NOAA SIP) under the Agricultural Marketing Act (AMA). This draft guidance is not final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by December 27, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this draft guidance to Bruce Wilson, Center for Food Safety and Applied Nutrition (HFS–417), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1425, e-mail: *bwilson1@cfsan.fda.gov*. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments concerning the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Tim Hansen, Center for Food Safety and Applied Nutrition (HFS–415), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1405, e-mail: *thansen@cfsan.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Since 1993, the EU has required that an EU Export Certificate accompany all shipments of fish and fishery products that are shipped to the EU. For fish and fishery products generally, the certificates that FDA signs essentially attest that the products have been produced in accordance with a Hazard Analysis Critical Control Point (HACCP)-based safety system that is at least equivalent to the EU system of control. The FDA HACCP regulations have been deemed by the European Commission to be equivalent, in principle, to the EU system of control. In 1996, the EU also began requiring a different certificate specifically for shipments of live molluscan shellfish (e.g., oysters, clams, mussels). These certificates are based partly on equivalence to, and partly on consistency with, EU requirements.

In 1993, to ensure the smooth flow of trade in fish and fishery products to the EU, FDA began signing certificates for shipments of fish and fishery products to the EU. FDA also signs certificates for shipments of fish and fishery products to EU Accession Countries and EFTA Members. A certificate is issued if it is determined that the establishment[1] is in regulatory good standing with FDA. The NOAA SIP of the U.S. Department of Commerce also signs EU Export Certificates as one service that it offers U.S. seafood processors and other entities in its voluntary, fee-for-service seafood inspection program.

The demand for EU Export Certificates by industry has risen dramatically in recent years and has caused significant resource allocation problems for FDA. The diversion of resources to lower priority, discretionary activities diminishes the agency's ability to carry out public health activities and regulatory oversight that are intended to protect the U.S. consuming public.

II. Significance of Guidance

In order to expedite the exportation of live and perishable fish and fishery products, FDA is considering what parts of its current EU certification activities related to fish and fishery products could be conducted by NOAA SIP. FDA is, therefore, proposing 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 all shipments of live and perishable fish and fishery products destined for the EU, EU Accession Partnership Countries, and EFTA Members would be issued by the NOAA SIP under the AMA. The basis for issuing EU Export Certificates under the Referral Program would be, as it is now, whether the establishment or establishments in question are in regulatory good standing with FDA. FDA intends to cease to issue EU Export Certificates for live and perishable fish and fishery products during this period. FDA seeks 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. During this 24-month period, however, both agencies intend to continue to issue EU Export Certificates for shipments of canned, frozen, dried, vacuum packed, etc., products, as requested by appropriate parties.

III. Electronic Access

An electronic version of this guidance is available on the Internet at *http://www.cfsan.fda.gov/guidance.html*.

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

[1] ''Establishment'' refers to any structure, or structures, under one ownership at one general physical location, or, in the case of a mobile establishment, traveling to multiple locations, that manufactures/processes, packs, or holds food. Transport vehicles are not establishments if they hold food only in the usual course of business as carriers. An establishment may consist of one or more contiguous structures, and a single building may house more than one distinct establishment if the establishments are under separate ownership.

Dated: November 17, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26139 Filed 11–22–04; 1:33 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for the opportunity for public comment on proposed data collection projects [Section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13], the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on (a) whether the agency needs to collect the proposed information to properly perform its functions and whether the information has any practical utility; (b) whether the agency's estimate of the burden of the proposed collection of information is accurate; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information for respondents (*e.g.*, by using automated collection techniques or other forms of information technology).

Proposed Project: Ryan White CARE Act Dental Reimbursement Program (OMB No. 0915–0151)—Revision

The Dental Reimbursement Program (DRP) under Part F of the Ryan White CARE Act offers grants to accredited dental schools and programs that provide non-reimbursed oral health care to patients with HIV disease. The Ryan White CARE Act Amendments of 2000 expanded eligibility of this program to accredited schools of dental hygiene, in addition to previously funded schools of dentistry and post-doctoral dental education programs.

HRSA requests clearance to revise the DRP Application as the Dental Services Report that schools and programs will use, either to apply for funding of non-reimbursed costs incurred in providing oral health care to patients with HIV, or to report annual program data. Awards are authorized under section 2692(b) of the Public Health Service Act (42 U.S.C. § 300ff–111(b). The Dental Services Report is intended to collect data in four different areas: program information, patient demographics and services, funding, and training. It also requests applicants to provide narrative descriptions of their services and facilities, as well as their links and collaboration with community-based providers of oral health services.

The primary purpose of collecting this information annually, as part of the Dental Services Report, is to verify eligibility and determine reimbursement amounts for DRP applicants as well as to document the program accomplishments of Community-Based Dental Partnership Program (CBDPP) grant recipients. This information also allows HRSA to learn about (1) the extent of the involvement of dental schools and programs in treating patients with HIV, (2) the number and characteristics of clients who receive CARE Act-supported oral health services, (3) the types and frequency of the provision of these services, (4) the non-reimbursed costs of oral health care provided to patients with HIV, and (5) the scope of grant recipients' community-based collaborations and training of providers. In addition to meeting the goal of accountability to Congress, clients, advocacy groups, and the general public, information collected in the Dental Services Report is critical for HRSA, State and local grantees, and individual providers, to help assess the status of existing HIV-related health service delivery systems.

The reporting burden for reviewing the Dental Services Report Instructions and completing the Report is estimated as:

Collection	Number of respondents	Hours per application	Total burden hours
Dental Services Report	125	20	2500

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 18, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–26142 Filed 11–24–04; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[CGD 01–04–093]

Notice, Announcement of Public Meeting and Extension of Comment Period; Letter of Recommendation, LNG Facility Weaver's Cove, Fall River, MA

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting; and extension of public comment period.

SUMMARY: In response to public comments on the proposed LNG facility at Weaver's Cove, Fall River, MA, the Coast Guard is sponsoring a public hearing. Additionally, the Coast Guard is reopening the public comment period an additional 60 days. These actions will afford the public and the owner or operator additional time and opportunity to provide the Coast Guard with information regarding the proposed Weaver's Cove LNG Facility.

DATES: Comments and related material must reach the Coast Guard on or before January 25, 2005.

ADDRESSES: The Commanding Officer, U.S. Coast Guard Marine Safety Office Providence maintains the public docket for this notice. Comments and documents will become part of this docket and will be available for inspection and copying at the same address between 8 a.m. and 3 p.m. Monday through Friday, except Federal holidays. You may submit comments and related material by:

(1) Mail or delivery to Commanding Officer, U.S. Coast Guard Marine Safety