Furlong, PA 18925. To register via the Internet go to *http://www.socra.org/FDA_Conference.htm*. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

The registrar will also accept payment by major credit cards. For more information on the meeting, or for questions on registration, contact 800–SoCRA92 (800–762–7292), or 215–345–7369 or via e-mail: *socramail@aol.com*. Attendees are responsible for their own accommodations. To make reservations at the Holiday Inn Fisherman's Wharf, at the reduced conference rate, contact the Holiday Inn (see *Location*) before December 21, 2004.

The registration fee will be used to offset the expenses of hosting the conference, including meals, refreshments, meeting rooms, and materials. Space is limited, therefore interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration.

If you need special accommodations due to a disability, please contact Marcia Madrigal at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The ''FDA Clinical Trials Statutory and Regulatory Requirements'' workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating researchers on proper conduct of clinical trials. FDA has made education of the research community a high priority to assure the quality of clinical data and protect research subjects.

The workshop helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

Dated: November 18, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26092 Filed 11–24–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0509]

Draft Guidance and Protocol for Industry and Food and Drug Administration Staff: Certification of Fish and Fishery Products for Export to the European Union and the European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) is announcing the availability of the draft guidance entitled ''Guidance and Protocol for Industry and Food and Drug Administration Staff: Certification of Fish and Fishery Products for Export to the European Union and the European Free Trade Association.'' The draft guidance describes how health certificates required for shipments of fish and fishery products from the United States to the European Union (EU), EU Accession Partnership Countries, and members of the European Free Trade Association (EFTA) should be issued. 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. Submit written or electronic comments on the collection of information provisions by January 25, 2005.

ADDRESSES: Submit written requests for single copies of the 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 and the proposed information collection provisions 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 and the proposed information collection provisions 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. The FDA also signs certificates for shipments of fish and fishery products to EU Accession Partnership Countries and EFTA Members. A certificate is issued if it is determined that the establishment[1] is in regulatory good standing with FDA. The Seafood Inspection Program of the National Oceanic and Atmospheric Administration (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.

II. Significance of Guidance

FDA is providing this draft guidance to clarify the internal processes that FDA uses to issue these EU Export Certificates, the procedures that industry seeking these certificates should follow, the criteria that FDA

[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.

generally intends to consider in determining whether to issue an EU Export Certificate, and related matters. This guidance, when finalized, is intended to supersede all previous protocols that were written by the various districts offices that provide EU certification for seafood products.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Health Certificate for Fishery and Aquaculture Products Intended for Export to the European Community

Description: This draft guidance describes the procedures FDA staff should use to issue the EU certificates, as well as the procedures industry should use for requesting a certificate. As discussed in detail in the draft guidance, the EU requires that each shipment have a certificate issued by a ''competent authority'' in the exporting country. The respondent (shipper) is asked to fill out a certificate-form (as required by the EU) that provides the following information: (1) The identity of the fishery product in terms of its physical state, type of packaging, number of packages, net weight, temperature required during storage and transport; (2) origin of the product, to include the name and registration number of the establishment(s) that processed, stored or harvested the product and is registered with FDA for export to the EU; (3) destination of the product and place of dispatch from the United States, the means of transport, the name and address of the dispatcher, the name of the consignee, and address at destination; and (4) date of certificate. Certifying agencies will retain this information for a reasonable period of time in case it becomes necessary to respond to questions about the shipment by officials in the importing country.

The proposed collection of information will take place when an establishment fills out a certificate and submits it to FDA for signature. Certificates in different languages may be downloaded from the Internet at: *http://www.cfsan.fda.gov/~dms/eucert.html*.

Description of Respondents: The respondents to this collection of information are seafood industry firms that export seafood products to one or more of the countries within the EU. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Item	No. of respondents	No. of responses per respondent	Total annual responses	Hours per response	Total hours
Health Certificate for Fishery and Aquaculture Products Intended for Export to the European Community	928	26	24,500	0.25	6,125

[1] There are no capital and/or operating and maintenance costs associated with this collection of information.

Estimates of the annual FDA reporting burden were made using the number of firms that are currently on the EU Shippers List (928 respondents after subtracting the number of firms contracting with NOAA SIP in 2003), and the approximate total number of EU Health Certificates issued in 2003 by FDA (approximately 24,500). The estimated annual total hour burden is likely to be more accurate than the estimated number of responses per respondent, because the latter figure is the average obtained by dividing the recent total annual certificates by the current number of potential respondents (928). In practice, the frequency of shipments to the EU may vary widely among approved firms; some firms may export weekly to the EU, others may export only a few times a year or not at all.

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.

V. Electronic Access

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

Dated: November 17, 2004.

Jeffrey Shuren,

Associate Commissioner for Policy.

[FR Doc. 04–26138 Filed 11–22–04; 1:33 pm]

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