FOR FURTHER INFORMATION CONTACT: Michelle Atkinson, Executive Secretary, by telephone at 410–786–2881 or by e-mail at *Matkinson@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION: On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) to describe the Medicare Coverage Advisory Committee (MCAC), which provides advice and recommendations to us about clinical issues. This notice announces a public meeting of the Committee.

Meeting Topic: The Committee will address the data from and the quality of clinical evidence pertaining to the effects of lifestyle modification such as diet, exercise, stress reduction and group counseling as it relates to reversal or resolution of diseases such as coronary heart disease and diabetes.

Background information about this topic, including panel materials, is available on the Internet at *http://www.cms.hhs.gov/coverage/*.

Procedure: This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the Executive Secretary named in the **FOR FURTHER INFORMATION CONTACT** section and submit the following by the *Deadline for Presentations and Comments* date listed in the **DATES** section of this notice: a brief statement of the general nature of the evidence or arguments you wish to present, and the names and addresses of proposed participants. A written copy of your presentation must be provided to each Committee member before offering your public comments. Your presentation must address the questions asked by us to the Committee. The questions will be available on our Web site at *http://www.cms.hhs.gov/mcac/default.asp#meetings*. If the specific questions are not addressed, your presentation will not be accepted. We request that you declare at the meeting whether or not you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the public and CMS presentations, the Committee will deliberate openly on the topic. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15 minute unscheduled open public session for any attendee to address issues specific to the topic. At the conclusion of the day, the members will vote and the Committee will make its recommendation.

Registration Instructions

The Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register by contacting Maria Ellis at 410–786–0309, mailing address: Coverage and Analysis Group, OCSQ; Centers for Medicare & Medicaid Services; 7500 Security Blvd, Mailstop: C1–09–06; Baltimore, MD 21244, or by e-mail at *Mellis@cms.hhs.gov*. Please provide your name, address, organization, telephone and fax number, and e-mail address.

You will receive a registration confirmation with instructions for your arrival at the CMS complex. You will be notified if the seating capacity has been reached.

Because the meeting is located on Federal property, for security reasons, any persons wishing to attend this meeting must register by close of business on January 17, 2005. In order to gain access to the building and grounds, participants must show to the Federal Protective Service or guard service personnel, government-issued photo identification and a copy of their registration confirmation. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify the Executive Secretary by January 3, 2005 (*see* **FOR FURTHER INFORMATION CONTACT**).

Authority: 5 U.S.C. App. 2, section 10(a).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 17, 2004.

Sean R. Tunis,

Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

[FR Doc. 04–26173 Filed 11–24–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Industry Exchange Workshop on Food and Drug Administration Clinical Trial Requirements; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Pacific Region, in cooperation with the Society of Clinical Research Associates (SoCRA), is announcing a workshop on FDA Clinical trial statutory and regulatory requirements. Topics for discussion include: Pre-IND (investigational new drug application) meetings and FDA meeting process, medical device, drug and biological product aspects of clinical research, investigator initiated research, informed consent requirements, adverse event reporting, how FDA conducts bioresearch inspections, ethics in subject enrollment, FDA regulation of Institutional Review Boards, FDA and confidence in the conduct of clinical research, and what happens after the FDA inspection. This 2-day workshop for the clinical research community targets sponsors, monitors, clinical investigators, institutional review boards, and those who interact with them for the purpose of conducting FDA regulated clinical research. The workshop will include both industry and FDA perspectives on proper conduct of clinical trials regulated by FDA.

Date and Time: The public workshop is scheduled for Wednesday, January 12, 2005, from 8:15 a.m. to 4:15 p.m. and Thursday, January 13, 2005, from 8:15 a.m. to 4 p.m.

Location: The public workshop will be held at the Holiday Inn Fisherman's Wharf, 1300 Columbus Ave., San Francisco, CA 94133, 415–771–9000, FAX: 415–771–7006.

Contact: Marcia Madrigal, Small Business Representative, FDA, 1301 Clay St., suite 1180–N, Oakland, CA 94612–5217, FAX: 510–637–3977, e-mail: *marcia.madrigal@fda.gov*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of $485 (member) or $560 (nonmember), $460 (government employee nonmember) (includes a 1 year membership). The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA, P.O. Box 101,

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]

BILLING CODE 4160–01–S

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.