TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
822.31	10	1	10	20	200
822.32	30	1	30	10	300
Total					500

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

FDA estimates that, based on current staffing and resources and experience with five actual PS actions over the past 3 years, five PS actions will be issued for generic devices, comprised of approximately five manufacturers. Each manufacturer will be required to submit a PS plan (§§ 822.9 and 822.10) and interim and final reports on the progress of the PS (§ 822.38). FDA anticipates that, on a case-by-case basis, requests for additional information may be made from a manufacturer. FDA expects that a small number of respondents will propose changes to their PS plans (§ 822.21), request a waiver of a specific requirement of this regulation (§ 822.29), or request exemption from the requirement to conduct PS of their device (§ 822.30). FDA's experience has shown that a few respondents will go out of business (§ 822.26) or cease marketing the device subject to PS (§ 822.28) each year. In addition, manufacturers must certify transfer of records when ownership changes (§ 822.34).

FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year clinically-based PS plan, using three investigators. These estimates are based on FDA's knowledge and experience with limited implementation of section 522 under the Safe Medical Device Act of 1990. Therefore, FDA would expect that the recordkeeping requirements would apply to a maximum of 10 manufacturers (3 to 4 added each year) and 30 investigators (3 per PS plan). After 3 years, FDA would expect these numbers to remain level as the PS plans conducted under the earliest orders reach completion and new orders are issued.

Dated: December 7, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–21167 Filed 12–12–06; 8:45 am]

BILLING CODE 4160–01–S

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.

The Food and Drug Administration (FDA) Los Angeles District, in cooperation with the Society of Clinical Research Associates (SoCRA), is announcing a workshop on FDA clinical trial statutory and regulatory requirements. 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, February 7, 2007, from 8:30 a.m. to 5 p.m. and Thursday, February 8, 2007, from 8:30 a.m. to 4:30 p.m.

Location: The public workshop will be held at the Wyndham San Diego at Emerald Plaza, 400 West Broadway, San Diego, CA 92101, 619–239–4500, FAX: 619–239–3274.

Contact: Marshalette Edwards, Food and Drug Administration, 1431 Harbor Bay Parkwy., Alameda, CA 94502, 510–337–6794, FAX: 510–337–6703 e-mail: *MO.Edwards@fda.hhs.gov*.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) and the registration fee of $575 (member), $650 (nonmember), $525 (Government employee nonmember) or $450 (Government employee member) to SoCRA , P.O. Box 101, Furlong, PA 18925. The registration fee for nonmembers includes a 1-year membership). The registration fee for FDA employees is waived. Make the registration fee payable to SoCRA.To register via the Internet go to *http://www.socra.org/html/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 215–822–8644, or via e-mail: *socramail@aol.com*. Attendees are responsible for their own accommodations. To make reservations at the Wyndham San Diego at Emerald Plaza at the reduced conference rate, contact the hotel (see *Location*) before January 7, 2007. 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 Marshalette Edwards (see *Contact*) at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The workshop on FDA clinical trials statutory and regulatory requirements 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. Topics for discussion include the following: (1) FDA regulation of the conduct of clinical research; (2) medical device, drug, biological product and food aspects of clinical research; (3) investigator initiated research; (4) pre-investigational new drug application meetings and the FDA meeting process; (5) informed consent requirements; (6) ethics in subject enrollment; (7) FDA regulation of institutional review boards; (8) electronic records requirements; (9) adverse event reporting; (10) how FDA conducts

bioresearch inspections; and (11) what happens after the FDA inspection.

FDA has made the education of the research community a high priority to ensure 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: December 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–21138 Filed 12–12–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[COTP Houston-Galveston 06–037]

Houston-Galveston Area Maritime Security Committee; Vacancies

AGENCY: Coast Guard, DHS.

ACTION: Solicitation for membership.

SUMMARY: Under the Maritime Transportation Security Act of 2002, the Secretary of Homeland Security has established an Area Maritime Security (AMS) Committee under the direction of the Houston-Galveston Captain of the Port (COTP)/Federal Maritime Security Coordinator (FMSC). The Houston-Galveston COTP/FMSC hereby requests qualified individuals interested in serving on this committee to apply for AMS Committee membership.

DATES: Requests for membership should reach the Captain of the Port on or before January 24, 2007.

ADDRESSES: Requests for membership should be submitted to Sector Houston-Galveston, AMSC Executive Administrator, 9640 Clinton Drive, Houston TX 77029.

FOR FURTHER INFORMATION CONTACT: For questions about the Houston-Galveston AMS Committee or its charter, contact Ms. Tobi Moore, AMSC Executive Administrator, at (713) 671–5118.

SUPPLEMENTARY INFORMATION:

Authority

Section 102 of the Maritime Transportation Security Act (MTSA) of 2002 (Pub. L. 107–295) added section 70112 to Title 46 of the U.S. Code, and authorizes the Secretary of the Department in which the Coast Guard is operating to establish an AMS Committee for any port area of the United States. The MTSA includes a provision exempting these AMS Committees from the Federal Advisory Committee Act (FACA), Public Law 92–436, 86 Stat. 470 (5 U.S.C. App.2).

The Houston-Galveston AMS Committee assists the COTP/FMSC in the review and update of the AMS Plan for the Houston, Galveston, Freeport, and Texas City area of responsibility. Such matters may include, but are not limited to:

(1) Identifying critical port infrastructure and operations;

(2) Identifying risks (threats, vulnerabilities, and consequences);

(3) Determining mitigation strategies and implementation methods;

(4) Developing and describing the process to continually evaluate overall port security by considering consequences and vulnerabilities, how they may change over time, and what additional mitigation strategies can be applied; and

(5) Providing advice to, and assisting the COTP/FMSC in, reviewing and updating the Houston-Galveston Area Maritime Security Plan.

The Houston-Committee AMS Committee meets the last Thursday of odd-numbered months. Subcommittees, work groups and task forces convene between meetings of the parent committee. The AMS Committee meeting location is currently at the Port of Houston Authority, 111 East Loop North, Houston, TX. Committee meetings start at 9 a.m.

AMS Committee Membership

Applicants for AMS Committee membership should possess at least 5 years of experience related to maritime or port security operations. The total number of members of the AMS Committee shall be determined by the COTP/FMSC. Applicants may be required to pass an appropriate security background check prior to appointment to the committee.

The following appointed membership vacancies currently exist:

(1) *Docks & Terminals*—Alternate;

(2) *City Police Departments*—Primary and Alternate;

(3) *County Sheriffs*—Primary and Alternate;

(4) *Fleets*—Alternate;

(5) *Labor*—Primary and Alternate;

(6) *Port Police Departments*—Primary and Alternate;

(7) *Port Rail*—Alternate;

(8) *Shipyards*—Primary and Alternate; and

(9) *Trucking Industry*—Alternate.

Members' term of office will be for 5 years. Members are eligible to serve an additional term of office. Members will not receive any salary or other compensation for their service on the AMS Committee.

In support of the policy of the USCG on gender and ethnic diversity, we encourage qualified women and members of minority groups to apply.

Request for Applications

Applicants seeking AMS Committee membership are not required to submit formal applications to the COTP/FMSC, however, because we do have an obligation to ensure that a specific number of members have the prerequisite maritime security experience, we encourage the submission of resumes highlighting experience in the maritime and security industries.

Dated: November 22, 2006.

William J. Diehl,

Captain, U.S. Coast Guard, Federal Maritime Security Coordinator/Captain of the Port, Houston-Galveston.

[FR Doc. E6–21134 Filed 12–12–06; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Notice of Proposed Information Collection

AGENCY: Office of the Secretary, Office of Acquisition and Property Management.

ACTION: Notice and request for comments.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary of the Department of the Interior announces the proposed extension of an information collection required by Office of Management and Budget (OMB) Circular A–45 (Revised): ''Private Rental Survey,'' OMB Control No. 1084–0033, and that it is seeking comments on its provisions. After public review, the Office of the Secretary will submit the information collection to OMB for review and approval.

DATES: Consideration will be given to all comments received by February 12, 2007.

ADDRESSES: Written comments and recommendations on the proposed