

efficient and effective acquisition and grant programs.

- Advises and assists the Administrator, senior staff, and Agency components on acquisition and grant related issues.

- Plans, develops, and interprets comprehensive policies, procedures, regulations, and directives for CMS acquisition functions.

- Represents CMS at departmental acquisition and grant forums and functions, such as the Executive Council on Acquisition and the Executive Council for Grants Administration Policy.

- Serves as the CMS contact point with HHS and other Federal agencies relative to grant and cooperative agreement policy matters.

- Coordinates and/or conducts training for contracts and grant personnel, as well as project officers in CMS components.

- Develops agency-specific procurement guidelines for the utilization of small and disadvantaged business concerns in achieving an equitable percentage of CMS' contracting requirements.

- Provides cost/price analyses and evaluations required for the review, negotiation, award, administration, and closeout of grants and contracts. Provides support for field audit capability during the pre-award and closeout phases of contract and grant activities.

- Develops and maintains the OAGM automated procurement management system. Manages procurement information activities (i.e., collecting, reporting, and analyzing procurement data).

26. Office of Policy (FLA)

- Assists the Policy Council with immediate/rapid response on timely issues and transform concepts into institutionalized processes.

- Assists the MMA Council as requested to develop, implement, and coordinate a policy process for the agency for key major cross-cutting and policy issues resulting from MMA legislation and subsequent issues.

- Advises the Administrator on medical technical innovation and health information technology matters.

- Plans and develops future CMS program policy. Assists OL in the development of legislative strategies by providing analytic support for legislative options and proposals. Conducts legislative, economic, and policy analyses related to the overall structure of health care financing. Translates research findings into policy applications.

- Performs environmental scanning, identifying, evaluating, and reporting emerging trends to health care delivery and financing. Works with Agency components and outside organizations to obtain relevant information on emerging trends. Analyzes trends for their interactions with Agency programs and implications for future policy development and planning. Identifies emerging trends and policy issues that would benefit the Office of Research, Development, and Information's research, evaluation, and survey enterprises.

- Conducts management and development of the long-term strategic plan for the Agency. Provides analytic support and information to the Administrator and Senior Leadership needed to establish the Agency's goals and directions. Conducts special studies and analyses concerning Agency-wide planning issues.

- Provides data analyses, graphics presentations, briefing materials, and analyses on short notice to support the immediate needs of the Administrator and Senior Leadership.

- Manages strategic, cross-cutting initiatives as assigned by the Office of the Administrator.

- Facilitates policy development by providing analytic liaison with other components in HHS and elsewhere in the Administration.

- Serves as CMS' contact for international visitors. Responds to requests from intergovernmental agencies and the international community for information related to the United States health care system.

Dated: December 20, 2005.

Karen Pelham O'Steen,

*Director, Office of Operations Management,
Centers for Medicare & Medicaid Services.*

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BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction

Program (the Site Tours Program). The purpose of this notice is to invite pharmaceutical companies interested in participating in this program to contact CDER.

DATES: Pharmaceutical companies may submit proposed agendas to the agency by February 27, 2006.

FOR FURTHER INFORMATION CONTACT: Beth Duvall-Miller, Office of New Drugs (HFD-020), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 22, rm. 6466, Silver Spring, MD 20903, 301-796-0700, FAX: 301-796-9858.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, the Center has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) First hand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. Regulatory Project Management Site Tours and Regulatory Interaction Program

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and

industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, tracking mechanisms, and regulatory submission operations.

The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the site tours will be the responsibility of CDER, therefore, selection will be based on the availability of funds and resources for each fiscal year.

Firms interested in offering a site tour or learning more about this training opportunity should respond within 60 days of this notice by submitting a proposed agenda to Beth Duvall-Miller (see **FOR FURTHER INFORMATION CONTACT**).

Dated: December 21, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E5-8017 Filed 12-28-05; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2005-23422]

Collection of Information Under Review by Office of Management and Budget: OMB Control Number 1625-0073

AGENCY: Coast Guard, DHS.

ACTION: Request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to seek the approval of OMB for the renewal of an Information Collection Request (ICR). The ICR is 1625-0073, Alteration of Unreasonably Obstructive Bridges Under the Truman-Hobbs (T-H) Act. Before submitting the ICR to OMB, the Coast Guard is inviting comments on them as described below.

DATES: Comments must reach the Coast Guard on or before February 27, 2006.

ADDRESSES: To make sure that your comments and related material do not enter the docket [USCG-2005-23422] more than once, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility, U.S. Department of Transportation (DOT), room PL-401, 400 Seventh Street, SW., Washington, DC 20590-0001.

(2) By delivery to room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(3) By fax to the Docket Management Facility at 202-493-2251.

(4) Electronically through the Web Site for the Docket Management System at <http://dms.dot.gov>.

The Docket Management Facility maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://dms.dot.gov>.

Copies of the complete ICR is available through this docket on the Internet at <http://dms.dot.gov>, and also from Commandant (CG-611), U.S. Coast Guard Headquarters, room 1236 (Attn: Mr. Arthur Requina), 1900 Half Street, SW., Washington, DC 20593-0001. The telephone number is 202-475-3523.

FOR FURTHER INFORMATION CONTACT: Mr. Arthur Requina, Office of Information Management, telephone 202-475-3523, or fax 202-475-3929, for questions on these documents; or telephone Ms. Renee V. Wright, Program Manager, Docket Operations, 202-493-0402, for questions on the docket.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to respond to this request for comments by submitting comments and related materials. We will post all comments received, without change, to <http://dms.dot.gov>; they will include any personal information you have provided. We have an agreement with DOT to use the Docket Management Facility. Please see the paragraph on DOT's "Privacy Act Policy" below.

Submitting Comments

If you submit a comment, please include your name and address, identify the docket number [USCG-2005-23422], indicate the specific section of

the document to which each comment applies, and give the reason for each comment. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit them by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change the documents supporting this collection of information or even the underlying requirements in view of them.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this notice as being available in the docket, go to <http://dms.dot.gov> at any time and conduct a simple search using the docket number. You may also visit the Docket Management Facility in room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act

Anyone can search the electronic form of all comments received in dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Privacy Act Statement of DOT in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit <http://dms.dot.gov>.

Information Collection Request

Title: Alteration of Unreasonably Obstructive Bridges Under the Truman-Hobbs (T-H) Act.

OMB Control Number: 1625-0073.

Summary: The collection of information is a request to determine if a bridge is unreasonably obstructive to navigation.

Need: 33 U.S.C. 494, 502, 511, 513, 514, 516 and 517 authorize the Coast Guard to alter bridges and causeways that go over navigable waters of the United States deemed to be unreasonably obstructive.

Respondents: Public and private owners of bridges over navigable waters of the United States.

Frequency: On occasion.