projection of what CDRH and CBER can accomplish with industry cooperation.

The guidance describes premarket review cycle and decision actions and performance goals for premarket notification submissions (510(k)s). This guidance document is immediately in effect because the agency needs to provide guidance on how it intends to address the performance goals it has committed to meeting. On February 4, 2003, FDA published a notice in the **Federal Register** (68 FR 5643) to establish a public docket (02N–0534) so that we could share information on the implementation of MDUFMA and to provide interested persons an opportunity to share their views. On December 3, 2003, the agency held an open public meeting to update its stakeholders on its progress in implementing the new law, discuss some of MDUFMA's more challenging provisions, and obtain input from interested parties. During the drafting of this guidance, the agency specifically solicited comments to the docket on several aspects of the document in recognition of the interest in this issue. The agency has considered all comments received to date and will accept comments on the guidance at any time.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The guidance represents the agency's current thinking on 510(k) review cycle and decision actions and performance goals. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment'' by fax machine, call the CDRH Facts-on-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1219) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (the PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations premarket approval applications (21 CFR part 807, OMB control number 0910–0120).

V. Comments

Interested persons may submit to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written or electronic comments regarding this document. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 17, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–11503 Filed 5–20–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection: Comment Request; NIH Customer/Partner Satisfaction Survey of Modification in procedures for Applications and Awards of Research Project Grants

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of Extramural Research, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. The proposed information collection was previously published in the **Federal Register** on May 23, 2002, page 36202. No public comments were received. The purpose of this notice is to allow and additional 30 days for public comment. The NIH may not conduct or sponsor, and the respondent is not required to respond to, and information that has been extended, revised or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: NIH Customer/Partner Satisfaction Survey of Modification in procedures for Applications and Awards of Research Project Grants. *Type of Information Collection Request:* New request. *Need and Use of Information Collection:* The information collected in these surveys will be used by the Office of Extramural research to evaluate the re-engineering initiatives, including the Modular Grant Application Process and initiatives under the NIH Roadmap, Initiative, intended to facilitate application and award of Federal assistance programs administered by the NIH Modular Application/Grant process has been in effect for two years. At the outset of its implementation, the community was advised that the process would reduce administrative burden by focusing the efforts of investigators, institutional officials, and National Institutes of Health (NIH) staff on the science of the application. The NIH now believes it is an appropriate time to determine if these objectives have been met. *Frequency of response:* On occasion. *Affected Public:* Institutional Officials, Principal Investigators (PI's), Peer Reviewers, Program and Grants Management Staff, Institute Budget Officers. The annual reporting burden is as follows: *Estimated Number of Respondents:* 1,000; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:*

.334; and *Estimated Total Burden Hours Requested:* 334. Each year we will repeat the same survey with different respondents. There are no Capital Costs, Operating Costs/and or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Anthony Demsey, OD, NIH, Building 1, Room 152, Bethesda, MD 20892–7974, or call non-toll-free number (301) 496–0232, or E-mail your request, including your address to: [*Demseya@od.nih.gov*]

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: May 14, 2004.

Charles Mackay,

Chief, Project Clearance Branch, OPERA, OER, National Institutes olf Health.

[FR Doc. 04–11469 Filed 5–20–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2004–17621]

Commercial Fishing Industry Vessel Safety Advisory Committee; Vacancies

AGENCY: Coast Guard, DHS.

ACTION: Request for applications.

SUMMARY: The Coast Guard seeks applications for membership on the Commercial Fishing Industry Vessel Safety Advisory Committee (CFIVSAC). CFIVSAC advises and makes recommendations to the Coast Guard for improving commercial fishing industry safety practices.

DATES: Application forms should reach the Coast Guard at the location noted in **ADDRESSES** on or before August 15, 2004.

ADDRESSES: You may request an application form by writing to Commandant (G–MOC–3), U.S. Coast Guard, 2100 Second Street, SW., Room 1116, Washington, DC 20593–0001.

FOR FURTHER INFORMATION CONTACT: Captain Joseph A. Servidio, Executive Director of CFIVSAC, or David W. Beach, Assistant to the Executive Director, by telephone at 202–267–0505, fax 202–267–0506, e-mail: *dbeach@comdt.uscg.mil* or *http://www.uscg.mil/hq/g-m/cfvs/CFIVSAC.shtml*.

SUPPLEMENTARY INFORMATION: The Commercial Fishing Industry Vessel Safety Advisory Committee (CFIVSAC) is a Federal advisory committee under 5 U.S.C. App. 2. As required by the Commercial Fishing Industry Vessel Safety Act of 1988. The Coast Guard established CFIVSAC to provide advice to the Coast Guard on issues related to the safety of commercial fishing vessels regulated under Chapter 45 of Title 46, United States Code, which includes uninspected fishing vessels, fish processing vessels, and fish tender vessels. (*See* 46 U.S.C. 4508.)

CFIVSAC consists of 17 members as follows: (a) Ten members from the commercial fishing industry who reflect a regional and representational balance and have experience in the operation of vessels to which Chapter 45 of Title 46, United States Code applies, or as a crew member or processing line member on an uninspected fish processing vessel; (b) one member representing naval architects or marine surveyors; (c) one member representing manufacturers of vessel equipment to which Chapter 45 applies; (d) one member representing education or training professionals related to fishing vessel, fish processing vessels, or fish tender vessel safety, or personnel qualifications; (e) one member representing underwriters that insure vessels to which Chapter 45 applies; and (f) three members representing the general public, including whenever possible, an independent expert or consultant in maritime safety and a member of a national organization composed of persons representing the marine insurance industry.

CFIVSAC generally meets once a year. It may also meet for extraordinary purposes. Its subcommittees and working groups may meet intersessionally to prepare for meetings or develop proposals for the committee as a whole to address specific problems.

We will consider applications for five positions that expire or become vacant in October 2004 in the following categories: (a) Commercial Fishing Industry (two positions); (b) Insurance (one position); (c) Education (one position); (d) Public (one position).

Each member serves a 3-year term. Members may serve consecutive terms. All members serve at their own expense and receive no salary from the Federal Government, although travel reimbursement and per diem are provided.

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

You may request an application form by writing to Commandant (G–MOC–3), U.S. Coast Guard, 2100 Second Street, SW., Room 1116, Washington, DC 20593–0001; by calling 202–267–0478; by faxing 202–267–0506; or by e-mailing *Kvazquez@comdt.uscg.mil*. This notice and the application are also available on the Internet at *http://dms.dot.gov*.

If you are selected as a member representing the general public, you are required to complete a Confidential Financial Disclosure Report (OGE Form 450). We may not release the report or the information in it to the public, except under an order issued by a Federal Court or as otherwise provided under the Privacy Act (5 U.S.C. 552a).

Dated: April 29, 2004.

Joseph J. Angelo,

Director of Standards, Marine Safety, Security & Environmental Protection.

[FR Doc. 04–11588 Filed 5–20–04; 8:45 am]

BILLING CODE 4910–15–P