

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "FDA and Industry Actions on Premarket Approval Applications: Effect on FDA Review Clock and Performance Assessment" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

For Device Issues: Thinh Nguyen, CDRH (HFZ-402), 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2186.

For Biologics Issues: Sayah Nedjar, Center for Biologics Evaluation and Research (CBER) (HFM-380), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-3524.

SUPPLEMENTARY INFORMATION:

I. Background

The Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250), signed into law on October 26, 2002, allows FDA to assess user fees for certain premarket reviews. Performance goals, existing outside of the statute, accompany the authorization of medical device user fees. These goals represent a realistic projection of what FDA's CDRH and CBER offices can accomplish with industry cooperation.

The guidance describes premarket review cycle and decision actions and goals for original PMAs, original expedited PMAs, panel-track supplements, and 180-day PMA supplements. Although it was not feasible to obtain comments before issuing the guidance due to tight statutory deadlines, in accordance with this agency's GGP procedures, FDA will

accept comments on the guidance at any time.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGP regulation (21 CFR 10.115). The guidance represents the agency's current thinking on PMA 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 Approval Applications: 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 (1218) 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. 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 (the PRA) (44 USC 3501-3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket

approval applications (21 CFR part 814, OMB control number 0910-0231).

V. 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. 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.

To receive "FDA and Industry Actions on Premarket Approval Applications: 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 (1218) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Dated: September 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2003-16200]

National Boating Safety Activities: Funding for National Nonprofit Public Service Organizations

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability.

SUMMARY: The Coast Guard seeks applications for fiscal year 2004 grants and cooperative agreements from national, nongovernmental, nonprofit, public service organizations. These grants and cooperative agreements would be used to fund projects on various subjects promoting recreational boating safety on the national level. This notice provides information about the grant and cooperative agreement application process and some of the subjects of particular interest to the Coast Guard.

DATES: Application packages may be obtained on or after October 8, 2003. Proposals for the fiscal year 2004 grant

cycle must be received before 3 p.m. eastern time, January 15, 2004.

ADDRESSES: Application packages may be obtained by calling the Coast Guard Infoline at 800-368-5647. Submit proposals to: Commandant (G-OPB-1), U.S. Coast Guard Headquarters, 2100 Second Street SW., Room 3100, Washington, DC 20593-0001. This notice is available from the Coast Guard Infoline and on the Internet at <http://dms.dot.gov> in docket USCG-2003-16200 or at the Web site for the Office of Boating Safety at <http://www.uscgboating.org>.

FOR FURTHER INFORMATION CONTACT: Ms. Vickie Hartberger, Office of Boating Safety, U.S. Coast Guard (G-OPB-1/room 3100), 2100 Second Street, SW., Washington, DC 20593-0001; 202-267-0974. The points of contact for the nine project areas are listed at the end of the description of each project area.

SUPPLEMENTARY INFORMATION: Title 46, United States Code, section 13103, allocates funds available from the Aquatic Resources Trust Fund for boating safety grants. The majority of funds are allocated to the States, and up to 5 percent of these funds may be distributed by the Coast Guard for grants and cooperative agreements to national, nonprofit, public service organizations for national recreational boating safety activities. It is anticipated that up to \$2,950,000 will be made available for fiscal year 2004. Thirty-two awards totaling \$2,994,500 were made in fiscal year 2003 ranging from \$7,000 to \$370,000. Nothing in this announcement should be construed as committing the Coast Guard to dividing available funds among qualified applicants or awarding any specified amount.

It is anticipated that several awards will be made by the Director of Operations Policy, U.S. Coast Guard. Applicants must be national, nongovernmental, nonprofit, public service organizations and must establish that their activities are, in fact, national in scope. An application package may be obtained by writing or calling the point of contact listed in **ADDRESSES** on or after October 8, 2003. The application package contains all necessary forms, an explanation of how the grant program is administered, and a checklist for submitting a grant application. Specific information on organization eligibility, proposal requirements, award procedures, and financial administration procedures may be obtained by contacting the person listed in **FOR FURTHER INFORMATION CONTACT**.

Prospective grantees may propose up to a 5-year grant with 12-month (fiscal

year) increments. In effect, an award would be made for the first year and thereafter renewal is optional. Each annual increment would not be guaranteed. Under a continuation (multi-year) grant type of award the Coast Guard agrees to support a grant project at a specific level of effort for a specified period of time, with a statement of intention to provide certain additional future support, provided funds become available, the achieved results warrant further support, and are in support of the needs of the government. Award of continuation grants will be made on a strict case-by-case basis to assist planning certain large scale projects and ensure continuity. Procedures also provide for awarding noncompetitive grants or cooperative agreements on a case-by-case basis. This authority is judiciously used to fund recurring annual projects or events which can only be carried out by one organization, and projects that present targets of opportunity for timely action on new or emerging program requirements or issues.

The following list includes items of specific interest to the Coast Guard, however, potential applicants should not be constrained by the list. We welcome any initiative that supports the organizational objectives of the Recreational Boating Safety Program to save lives, reduce the number of boating accidents, injuries and property damage, and lower associated health care costs. Some project areas of continuing and particular interest for grant funding include the following:

1. *Develop and Conduct a National Annual Safe Boating Campaign.* The Coast Guard seeks a grantee to develop and conduct the year 2005 National Annual Safe Boating Campaign that targets specific boater market segments and recreational boating safety topics. This year-round campaign must support the organizational objectives of the Recreational Boating Safety Program and the nationwide grassroots activities of the many volunteer groups who coordinate local media events, education programs, and public awareness activities, as well as compliment the Coast Guard "You're In Command" campaign. The major focus of the campaign will be to affect the behavior of all boaters with special focus on boat operators being responsible for their own safety as well as the safety of their passengers. A significant emphasis should be placed on life jacket wear, safety and security issues, and the dangers of carbon monoxide, as well as boating under the influence of alcohol or a dangerous drug. Efforts will also be coordinated,

year-round, with other national safety activities and special media events. Point of Contact: Ms. Jo Calkin, (202) 267-0994.

2. *Develop and Conduct a National Recreational Boating Safety Outreach and Awareness Conference.* The Coast Guard seeks a grantee to plan, implement, oversee, and conduct a National Recreational Boating Safety Outreach and Awareness Conference that supports the organizational objectives of the Recreational Boating Safety Program. The overall conference focus should have promotional strategies with special focus on boat operators being responsible for their own safety as well as the safety of their passengers. Significant emphasis should be placed on offering multiple subject matter areas that afford the participants professional development opportunities and educational enhancement. Areas should focus on, but not be limited to: life jacket wear, safety and security issues, the dangers of carbon monoxide, boating education, vessel safety, as well as boating under the influence of alcohol or a dangerous drug. Point of Contact: Ms. Jo Calkin, (202) 267-0994.

3. *State/Federal/Boating Organizations Cooperative Partnering Efforts.* The Coast Guard seeks a grantee to provide programs to encourage greater participation and uniformity in boating safety efforts. Applicants would provide a forum to encourage greater uniformity of boating laws and regulations, reciprocity among jurisdictions, and closer cooperation and assistance in developing, administering, and enforcing Federal and State laws and regulations pertaining to boating safety. Point of Contact: Ms. Audrey Pickup, (202) 267-0872.

4. *Voluntary Standards Development Support.* The Coast Guard seeks a grantee to carry out a program to encourage active participation by members of the public and other qualified persons in the development of technically sound voluntary safety standards for boats and associated equipment. Point of Contact: Mr. Peter Eikenberry, (202) 267-6984.

5. *Develop and Conduct Boating Accident Seminars.* The Coast Guard seeks a grantee to develop, provide instructional material, and conduct training courses nationwide for boating accident investigators, including three courses at the U.S. Coast Guard Reserve Training Center in Yorktown, Virginia. Point of Contact: Mr. Rick Gipe, (202) 267-0985.

6. *National Estimate of Personal Flotation Devices (PFDs) Wear Rate.* The Coast Guard seeks a grantee to develop

a statistically valid national estimate and evaluation of wear rates of PFDs by recreational boaters. Wear rate should be determined by actual observation of boaters rather than other means such as surveys. Point of Contact: Mr. Peter Eikenberry, (202) 267-6894.

7. *Recreational Boat Navigation Light Installation Practices.* The Coast Guard seeks a grantee to conduct a study of recreational boat navigation light installation practices. This study shall include both traditional incandescent and light emitting diode (LED) lights installed in recreational boats and/or available for sale as after market items. The study shall be focused on identifying issues related to compliance with Rules of the Road, and particularly instances in which the specific positioning of navigation lights may cause glare or other effects that interfere with the operator's visibility. The study shall identify instances in which compliance with Rules of the Road lighting requirements may not serve to enhance the safety of recreational boaters. The grantee shall make recommendations for changes to recreational lights that will enhance safety. Point of Contact: Mr. Richard Blackman, (202) 267-6810.

8. *Recreational Boating Study/Survey Analysis.* This project is a multiple phase project, with the first phase already in progress. The first phase of the project has been directed primarily at compiling and reviewing boating studies and reports, categorizing and summarizing research in a format that will encourage and facilitate its use by boating businesses and agencies, and in developing Web-based mechanisms to efficiently maintain this information (e.g., on-line boating research tracking form, boating research discussion page). Web-based tools are also being utilized to encourage research-related dialogue and future research partnerships, identify recreational boating research priorities and opportunities for multiple purpose studies, and widely publish and disseminate the resulting literature review and project deliverables. The second phase of the project will continue to identify, compile and analyze boating studies. During the second phase, more attention will be directed to encouraging dialogue focused on identifying future research agendas for boating research, and developing partnerships that will coordinate and make studies more comparable (e.g., comparable definitions, sampling, definitions). For example, instead of doing separate boating safety studies, safety issues and behaviors could be incorporated into existing research projects where

appropriate. These subsequent efforts will also identify and propose uniform definitions for boating-related terms and concepts, along with other common research variables that will enhance the potential of integration and comparability across recreational boating studies. In the second phase of the project, grantee is to convene a high-level symposium with representation from industry associations, marine trade associations, state and federal boating agencies, and university researchers to: establish boating research priorities, identify ways to encourage integrated multiple-sponsor studies, and to develop a funding strategy for encouraging and supporting these initiatives. Point of Contact: Mr. Bruce Schmidt, (202) 267-0955.

9. *Navigation Lighting On Barges.* The Coast Guard seeks a grantee to research and analyze the danger posed to recreational boaters by barges, both under tow and being pushed, under the conditions of reduced visibility. The grantee would provide recommendations for additional lighting or other means to increase the visibility of the barges. Any lighting recommendations must be consistent with Rule 20 of the Navigation Rules (33 U.S.C. 2020), that is, additional lights cannot be mistaken for the lights specified in the Rules and do not impair their visibility or distinctive character. Point of Contact: Mr. Rick Gipe, (202) 267-0985.

Potential grantees should focus on partnership, *i.e.*, exploring other sources, linkages, in-kind contributions, cost sharing, and partnering with other organizations or corporations. We encourage proposals addressing other boating safety concerns.

The Boating Safety Financial Assistance Program is listed in section 20.005 of the Catalog of Federal Domestic Assistance.

Dated: September 30, 2003.

Jeffrey J. Hathaway,

Rear Admiral, U. S. Coast Guard, Director of Operations Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2003-16252]

Senior Executive Service Performance Review Board Membership

AGENCY: Coast Guard, DHS.

ACTION: Notice of appointments.

SUMMARY: The Coast Guard is providing notice of the appointment of nine individuals to serve on its Performance Review Board.

FOR FURTHER INFORMATION CONTACT: David Hyde, Chief, Office of Civilian Personnel, (202) 267-0921.

SUPPLEMENTARY INFORMATION: Under 5 U.S.C. 4314(c)(4), the Coast Guard is required to publish the names of individuals appointed to serve on the Coast Guard Performance Review Board (CGPRB). The following nine persons have been selected to serve on the CGPRB:

Rear Admiral K. T. Venuto, Assistant Commandant for Human Resources, United States Coast Guard; Rear Admiral R. J. Papp, Director of Reserve and Training, United States Coast Guard; Rear Admiral E. M. Brown, Assistant Commandant for Systems, United States Coast Guard; Rear Admiral J. C. Olson, Director of Operations Capability, United States Coast Guard; Rear Admiral J. J. Hathaway, Director of Operations Policy, United States Coast Guard; Mr. John Matticks, Senior Planning Advisor, Federal Emergency Management Agency; Dr. Marjorie Budd, Assistant Commissioner for Training and Development, U.S. Customs and Border Protection; Mr. Thomas Grupski, Deputy Assistant Director, Protective Operations Office, U.S. Secret Service; Mr. James L. Dunlap, Deputy Assistant Director, Human Resources and Training, U.S. Secret Service.

Dated: October 1, 2003.

David Hyde,

Chief, Office of Civilian Personnel.

[FR Doc. 03-25417 Filed 10-7-03; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

List of Foreign Entities Violating Textile Transshipment and Country of Origin Rules

AGENCY: Bureau of Customs and Border Protection, Homeland Security.

ACTION: General notice.

SUMMARY: This document notifies the public of foreign entities which have been issued a penalty claim under section 592 of the Tariff Act of 1930, for certain violations of the customs laws. This list is authorized to be published by section 333 of the Uruguay Round Agreements Act.