

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.

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Dated: September 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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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