

availability of a draft guidance for industry entitled "The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2 – Current Good Manufacturing Practice (CGMP)." The draft guidance is intended to aid drug manufacturers and ancillary testing laboratories in using mechanical calibration as an alternate approach to the use of calibrator tablets in calibrating an apparatus used for dissolution testing. The guidance provides references to information on critical tolerances that should be achieved with mechanical calibration.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 17, 2008.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 either <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Albinus D'Sa, Center for Drug Evaluation and Research (HFD-320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301-827-9044.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2 – Current Good Manufacturing Practice (CGMP)." FDA regulations require that laboratory apparatus be calibrated at suitable intervals in accordance with established written specifications (21 CFR 211.160(b)(4)). Historically, both chemical and mechanical means have been used in calibrating dissolution apparatuses. Since 1978, chemical calibration has been the predominant method of calibration, consistent with chapter 711 of the U. S. Pharmacopeia

(USP), which describes the use of calibrator tablets. Chemical calibration of an apparatus is usually performed, in addition to mechanical calibration, every 6 months. Because the use of USP chemical calibration tablets can lead to variability in the dissolution measurement system, FDA is providing guidance on mechanical calibration as an alternate approach to calibrating dissolution equipment. As stated in the draft guidance, instead of using an external calibrator tablet, a firm can use an appropriately rigorous method of mechanical calibration as an alternative to ensure ongoing acceptability of the dissolution apparatus.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the use of mechanical calibration of dissolution apparatus 1 and 2 as related to CGMP. 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 statutes and regulations.

**II. 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 copy. 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.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: October 15, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Public Health Service; Notice of Listing of Members of the Substance Abuse and Mental Health Services Administration's Senior Executive Service Performance Review Board (PRB)**

The Substance Abuse and Mental Health Services Administration (SAMHSA) announces the persons who will serve on the Substance Abuse and Mental Health Services Administration's Performance Review Board. This action is being taken in accordance with Title 5, U.S.C., Section 4314(c)(4), which requires that members of performance review boards be appointed in a manner to ensure consistency, stability, and objectivity in performance appraisals, and requires that notice of the appointment of an individual to serve as a member be published in the **Federal Register**.

The following persons will serve on the SAMHSA Performance Review Board, which is responsible for making recommendations on performance appraisal ratings, pay adjustments, and performance awards for SAMHSA's Senior Executive Service (SES) members:

Eric Broderick, D.D.S.—Chairperson.  
Westley Clark, M.D., J.D., M.P.H.  
Randy Grinnell.  
Anna Marsh, Ph.D.  
Dennis Romero, M.A.

For further information about the SAMHSA Performance Review Board, contact the Division of Management Systems, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Room 3-1017, Rockville, Maryland 20857, telephone (240) 276-1124 (not a toll-free number).

Dated: October 15, 2007.

**Terry L. Cline,**

*Administrator, SAMHSA.*

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**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

[Docket No. USCG-2007-0006]

**Commercial Fishing Industry Vessel Safety Advisory Committee**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of meeting.

**SUMMARY:** The Commercial Fishing Industry Vessel Safety Advisory Committee (CFIVSAC) will meet in Seattle, WA, to discuss various issues relating to commercial vessel safety in the fishing industry. The meetings are open to the public.

**DATES:** CFIVSAC will meet on November 13 and 14, 2007, from 8 a.m. to 5 p.m. The meetings may close early if all business is finished. Requests to make oral presentations should reach the Coast Guard on or before October 12, 2007. Written material for distribution at the meeting should reach the Coast Guard on or before November 7, 2007. Requests to have a copy of your material distributed to each member of the committee should reach the Coast Guard on or before October 30, 2007. Send written material with 25 copies and requests to make oral presentations to Lieutenant Commander Kenneth Vazquez, Commandant (CG-543-3), U.S. Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593-0001. This notice is available on the Internet at <http://www.regulations.gov>.

**ADDRESSES:** CFIVSAC will meet in the Court Room on the 5th Floor (Room 514), at the Jackson Federal Building, 915 Second Avenue, Seattle, Washington 98174.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant Commander Kenneth Vazquez, Assistant to the Executive Director, by telephone at 202-372-1247, fax 202-372-1918, e-mail: [Kenneth.Vazquez@uscg.mil](mailto:Kenneth.Vazquez@uscg.mil).

**SUPPLEMENTARY INFORMATION:** Information about the CFIVSAC up to date meeting information and a listing of the past meeting minutes is available through the following World Wide Web address (i.e., Uniform Resource Locator or URL): <http://www.FishSafe.info> ("Advisory Committee") or <http://homeport.uscg.mil/mycg/portal/ep/channelView.do?channelId=-18425&channelPage=%2Fep%2Fchannel%2Fdefault.jsp&pageTypeId=13489&BV>.

CFIVSAC will meet to discuss various issues relating to commercial vessel safety in the fishing industry. The meetings are open to the public. Notice of the meetings is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92-463).

#### Agenda of Meeting

The agenda includes the following:

- (1) Approval of last meeting's minutes.
- (2) Update on past recommendations.
- (3) Status report on the NPRM.
- (4) WPI project.

(5) Meeting of communication subcommittee.

(6) Meeting of risk management subcommittee.

(7) Status of Legislative proposals: The House and Senate fishing vessel safety related proposals discussed in their versions of the Coast Guard authorization bills; Pending final bills outcomes.

(8) Discussions and working group sessions by the committees on long term strategies and future plans.

#### Procedural

The meetings are open to the public. Please note the meetings may close early if all business is finished. At the Chair's discretion, members of the public may make presentations during the meeting. If you would like to make an oral presentation at the meeting, please notify the Executive Director no later than October 12, 2007. Written material for distribution at the meeting should reach the Coast Guard no later than November 7, 2007. If you would like a copy of your material distributed to each member of the committee in advance of the meeting, please submit 25 copies to the Executive Director no later than October 30, 2007.

#### Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the Executive Director as soon as possible but no later than November 5, 2007.

Dated: October 15, 2007.

**J.G. Lantz,**

*Director of Commercial Regulations and Standards, Assistant Commandant for Marine Safety, Security, and Stewardship.*

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#### DEPARTMENT OF HOMELAND SECURITY

#### U.S. Citizenship and Immigration Services

#### Agency Information Collection Activities: Form I-539, Revision of an Existing Information Collection; Comment Request

**ACTION:** 30-Day Notice of Information Collection Under Review: Form I-539, Application to Extend/Change Nonimmigrant Status. OMB Control Number: 1615-0003.

The Department of Homeland Security, U.S. Citizenship and

Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on July 16, 2007, at 72 FR 38841. The notice allowed for a 60-day public comment period. No comments were received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until November 19, 2007. This process is conducted in accordance with 5 CFR 1320.10.

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 Department of Homeland Security (DHS), USCIS, Chief, Regulatory Management Division, Clearance Office, 111 Massachusetts Avenue, 3rd floor, Washington, DC 20529. Comments may also be submitted to DHS via facsimile to 202-272-8352 or via e-mail at [rfs.regs@dhs.gov](mailto:rfs.regs@dhs.gov), and to the OMB USCIS Desk Officer via facsimile at 202-395-6974 or via e-mail at [kastrich@omb.eop.gov](mailto:kastrich@omb.eop.gov).

When submitting comments by e-mail please make sure to add OMB Control Number 1615-0003 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

*Overview of this information collection:*