

**Register.** FDA is publishing a final rule to classify remote medication management systems into class II (special controls). This guidance document is being immediately implemented as the special control for remote medication management systems, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

**DATES:** Submit written or electronic comments on the guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled "Class II Special Controls Guidance Document: Remote Medication Management System" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-276-3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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 either <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Richard Chapman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-2585.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying remote medication management systems into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for remote medication management systems. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order

classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the time frames established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Thus, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

**II. Significance of Guidance**

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the agency's current thinking on remote medication management systems. 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 "Class II Special Controls Guidance Document: Remote Medication Management System," you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1621 to identify the guidance you are requesting.

Persons interested in obtaining a copy of the guidance may 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 refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

**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 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.

Dated: October 3, 2007.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. E7-20635 Filed 10-18-07; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2007D-0365]

**Draft Guidance for Industry on the Use of Mechanical Calibration of Dissolution Apparatus 1 and 2 – Current Good Manufacturing Practice; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (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)." 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.*

[FR Doc. E7-20664 Filed 10-18-07; 8:45 am]

**BILLING CODE 4160-01-S**

**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.*

[FR Doc. 07-5158 Filed 10-18-07; 8:45 am]

**BILLING CODE 4160-01-M**

**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.