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 either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: January 21, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–1516 Filed 1–26–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0420] (formerly Docket No. 2007D–0365)

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 guidance for industry entitled "The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2—Current Good Manufacturing Practice (CGMP)." This guidance recommends an alternative method for manufacturers to comply with FDA's CGMP regulations that require laboratory apparatus be calibrated at suitable intervals in accordance with established written specifications. The guidance is intended to aid drug manufacturers (including ancillary testing laboratories) in calibrating U.S. Pharmacopeia (USP) Dissolution Apparatus 1 and 2 to help assure that critical parameters associated with the dissolution apparatus meet certain mechanical calibration (MC) tolerances.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Larry A. Ouderkirk, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4228, Silver Spring, MD 20993–0002, 301–796–1585.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2—Current Good Manufacturing Practice (CGMP)." The guidance recommends an alternative method for manufacturers to comply with the CGMP regulations that require laboratory apparatus be calibrated at suitable intervals in accordance with established written specifications (§§ 211.160(b)(4) and 211.68 (21 CFR 211.160(b)(4) and 211.68)).

Historically, both MC and chemical (tablet) calibration procedures have been employed to assure that reproducible and repeatable data are obtained with dissolution test apparatus. Recent studies performed in FDA and USP laboratories have identified several significant sources of variation within Apparatus 1 and 2 that can be minimized by employing an enhanced MC procedure. The enhanced MC procedure recommended in the guidance can be used as an alternative to the current Apparatus Suitability procedure for USP Dissolution Apparatus 1 and 2 described in USP General Chapter <711> *Dissolution* that employs basic MC with a performance verification test (PVT) using USP Reference Standard tablets.

In the **Federal Register** of October 19, 2007 (72 FR 59298), FDA published a notice announcing the availability of a draft guidance entitled "The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2—Current Good Manufacturing Practice (CGMP)." The notice gave interested persons an opportunity to submit comments by January 17, 2008. Comments received during the comment period have been carefully reviewed, and changes were made to the draft guidance in an effort to make the document clearer. Also, as a result of the received comments, the guidance provides advice on controlling the following recognized sources of significant variability in dissolution testing: Dissolved gases, vibration, and vessel dimensions.

In finalizing this guidance, FDA has made changes to the draft guidance to reflect the most recent changes to USP General Chapter <711> *Dissolution*. On August 1, 2007, USP revised its Chapter <711> as follows: (1) Changed the terminology "calibrator tablets" to "reference standard (RS) tablets," which is the term used to describe tablets used to establish system suitability; and (2) renamed the "Apparatus Suitability Test, Apparatus 1 and 2" to "Performance Verification Test, Apparatus 1 and 2." In making these revisions, USP has explicitly stated, "USP's RS tablets are not calibrator tablets."[1] USP has also announced its intention as of December 1, 2009, to discontinue use of its Salicylic Acid Tablets RS in the Performance Verification Test for Dissolution Apparatus 1 and 2 in <711> (but USP will retain use of its Prednisone Tablets RS). Although USP <711> establishes critical tolerances and parameters for dissolution apparatus, it does not describe enhanced MC practices that can optimize and assure consistent apparatus performance. In October 2007, USP posted to its Web site a "toolkit" to aid practitioners in performing apparatus MC. However, we note that neither the mechanical tolerances specified in USP <711> nor the MC procedure described in the USP toolkit is as comprehensive or stringent as the enhanced MC procedure recommended in the agency guidance.

The CGMP regulations in §§ 211.160(b)(4) and 211.68 require that laboratory apparatus (mechanical equipment used in manufacturing) be calibrated at suitable intervals in accordance with an established written program of scheduled procedures containing provisions for remedial actions. The enhanced MC procedure recommended in the agency guidance satisfies these CGMP requirements and thus can be used as an alternative to the Apparatus Suitability procedure described in USP <711>. Furthermore,

[1] Deng G., A. J. Ashley, W. E. Brown, et al., 2008, "The USP Performance Verification Test, Part I: USP Lot P Prednisone Tablets—Quality Attributes and Experimental Variables Contributing to Dissolution Variance," *Pharmaceutical Research*; 25(5): 1100–1109.

the agency does not consider a reference tablet-based procedure such as a PVT to be a critical component when the enhanced MC procedures recommended in the agency guidance are followed.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on a new process for making available to sponsors FDA guidance on how to design product-specific bioequivalence studies to support ANDAs. 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 either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: January 21, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–1517 Filed 1–26–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Task Force on Community Preventive Services

Name: Task Force on Community Preventive Services meeting.

Times and Dates: 8 a.m.–5:30 p.m. EST, February 17, 2010; 8 a.m.–1 p.m. EST, February 18, 2010.

Place: Centers for Disease Control and Prevention, 2500 Century Parkway, Atlanta, Georgia 30345.

Status: Open to the public, limited only by space available.

Purpose: The mission of the Task Force is to develop and publish the *Guide to Community Preventive Services (Community Guide),* which is based on the best available scientific evidence and current expertise regarding essential public health and what works in the delivery of those services.

Matters To Be Discussed: Updates of reviews of interventions to increase screening for breast, cervical and colorectal cancer, interventions to increase vaccination rates, and interventions to increase physical activity; reviews of effectiveness of collaborative care for the management of depressive disorders and of interventions to reduce the overservice of alcohol; and the scope of reviews of interventions to reduce inequalities in health outcomes.

Agenda items are subject to change as priorities dictate.

Contact person or additional information: Nasheka Powell, Community Guide Branch, Centers for Disease Control and Prevention, 1600 Clifton Road, M/S E–69, Atlanta, GA 30333, phone: 404.498.1123.

Dated: January 20, 2010.

Tanja Popovic,

Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–1569 Filed 1–26–10; 8:45 a.m.]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of National Conversation on Public Health and Chemical Exposures Leadership Council Conference Call

Time and Date: 1 p.m.–3 p.m., Friday, January 29, 2010.

Location: Teleconference.

Status: The public is invited to listen to the meeting by phone, see "contact for additional information" below.

Purpose: This is the second meeting of the National Conversation on Public Health and Chemical Exposures Leadership Council. The National Conversation on Public Health and Chemical Exposures is a collaborative initiative through which many organizations and individuals are helping develop an action agenda for strengthening the nation's approach to protecting the public's health from harmful chemical exposures. The Leadership Council provides overall guidance to the National Conversation project and will be responsible for issuing the final action agenda. For additional information on the National Conversation on Public Health and Chemical Exposures, visit this Web site: *http://www.atsdr.cdc.gov/nationalconversation/.*

Meeting agenda: The call will include discussing (1) Revised project milestones and process elements, (2) revised National Conversation Operating Procedures, (3) the Policies and Practices work group charge, and (4) plans for developing and utilizing a community conversation toolkit on the issue of public health and chemical exposures.

Contact for additional information: If you would like to receive additional information on listening to the meeting by phone, please contact: *nationalconversation@cdc.gov* or Ben Gerhardstein at 770–488–3646.

Dated: January 19, 2010.

Tanja Popovic,

Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–1571 Filed 1–26–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0054]

Strengthening the Center for Devices and Radiological Health's 510(k) Review Process; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting entitled "Strengthening the Center for Devices and Radiological Health's 510(k) Review Process." The purpose of the public meeting is to identify actions that the Center for Devices and Radiological Health (CDRH) can consider taking to strengthen the premarket notification process for review of medical devices, also known as the 510(k) process. FDA is seeking input on a number of identified challenges associated with the 510(k) process and is requesting comments on this topic.

Dates and Time: The public meeting will be held on February 18, 2010, from 8 a.m. to 5:30 p.m. Persons interested in attending and/or participating in the meeting must register by 5 p.m. on