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/Guidance/ default.htm or http://www.regulations.gov.


David Dorsey,
Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–1571 Filed 1–26–10; 8:45 am]
BILLING CODE 4163–18–P

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.


Tanja Popovic,
Chief Science Officer, Centers for Disease Control and Prevention.

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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 Gerhardt at 770–488–3646.


Tanja Popovic,
Chief Science Officer, Centers for Disease Control and Prevention.

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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