

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (Formerly Advisory Committee for Pharmaceutical Science); Notice of Meeting**

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (formerly Advisory Committee for Pharmaceutical Science).

*General Function of the Subcommittee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on April 30, 2007, from 8:30 a.m. to 5 p.m.

*Location:* Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

*Contact Person:* Victoria Ferretti-Aceto, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: [Victoria.FerrettiAceto@fda.hhs.gov](mailto:Victoria.FerrettiAceto@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572) in the Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The subcommittee will do the following: (1) As an awareness topic, discuss issues pertaining to the stability of tablets split for patient use; (2) receive a general update and discuss current strategies on quality by design and the Office of Generic Drugs' question-based review; and (3) receive an update on and discuss the status of the Office of New Drug Quality Assessment Chemistry, Manufacturing, and Controls Pilot Program.

FDA intends to make background material available to the public no later than 1 business day before the meeting. If FDA is unable to post the background

material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2007 and scroll down to the appropriate advisory committee link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person on or before April 16, 2007. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 6, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 9, 2007.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Victoria Ferretti-Aceto at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 26, 2007.

**Randall W. Lutter,**

*Associate Commissioner for Policy and Planning.*

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**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Substance Abuse and Mental Health Services Administration****Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

*Project:* School Climate Survey for the National Cross-Site Evaluation of Safe School/Healthy Student (SS/HS) Initiative Grants—NEW.

The SS/HS Initiative is a collaborative grant program supported by three Federal departments—the U.S. Departments of Health and Human Services, Education, and Justice. The program is authorized under the Elementary and Secondary Education Act of 1965, as amended, and the Higher Education Act of 1965, Title IV, Part A, Subpart 2 (National Programs), Section 4121 (Federal Activities). It is also authorized under Section 581 of the Public Health Service Act.

This initiative, instituted by Congress following the murderous assaults at Columbine High School in Colorado, is designed to provide Local Educational Agencies (LEAs), including school districts and multi-district regional consortia, with 3 years of funding to simultaneously improve school safety, student access to mental health services, the reduction of violence and substance abuse, school relationships with the larger community, and early childhood preparation for learning. Collectively, Congress expects these changes to be reflected in improved school climate.

Local Education Agencies (LEAs) serve as the primary applicants for SS/HS grants, but the LEAs are required to establish formal partnerships with the local mental health system, the local law enforcement agency, and the local juvenile justice agency. Other partners often include public and private social services agencies, businesses, civic organizations, the faith community, and private citizens. As a result of these partnerships, comprehensive plans are developed, implemented, evaluated, and sustained with the goals of promoting the healthy development of children and youth, fostering their resilience in the face of adversity, and preventing violence.