

**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.

From FY 1999 through FY 2004, grants of \$1 million to \$3 million annually for 3 years were awarded to 190 LEAs, for a total of \$916 million. Approximately 40 new SS/HS grants were awarded in FY 2005. These grants are providing support for rural, tribal, suburban, and urban communities that include diverse racial and ethnic groups across the country.

In compliance with the Government Performance and Results Act (GPRA) of 1993, grantees are required to collect and report data that measure the results of the programs implemented with this grant. Specifically, grantees are required to collect and report information on the following GPRA indicators:

1. The percentage of SS/HS grant sites that experience a decrease in the number of violent incidents at schools.
2. The percentage of SS/HS grant sites that experience a decrease in substance abuse.
3. The percentage of SS/HS grant sites that improve school attendance.

4. The percentage of SS/HS grant sites that increase mental health services to students and families.

In addition to GPRA measures, the Federal Evaluation Work Group of the Safe School/Healthy Students (SS/HS) Initiative national evaluation, comprised of Federal officials representing the U.S. Departments of Education, Health and Human Services, and Justice, determined that information on changes in school climate is also required to provide a direct basis of comparison for performance with subsequent cohorts of grantees. Although GPRA measures monitor changes in individual outcomes among students, GPRA measures have been found to provide an incomplete metric of performance in terms of observed in changes in overall "school climate."

The SS/HS National Evaluation Team proposes to adopt the staff version of the California Healthy Kids Survey for this purpose. This instrument contains 43 multiple choice questions that are used to obtain school staff perceptions of student behavior and attitudes, school

programs and policies, and the overall school climate as they relate to student well-being and learning. It deals with such issues as truancy, safety, harassment, substance abuse, school connectedness and learning supports. The instrument, modified slightly to form the SS/HS School Climate Survey, will track changes in school climate in schools targeted for program services under the SS/HS Initiative. In the absence of the School Climate Survey, there would be no common, cross-site measure of performance across SS/HS initiative grantees. In practice, the School Climate Survey will be administered electronically among approximately 67,500 local educational system employees. These employees will be encouraged to log onto a Web site during each year that their school benefits from the grant to answer questions concerning their perception of student behavior and safety at the school.

*The burden estimate for the annual survey is as follows:*

| Number of respondents | Responses per respondent | Burden/response (hours) | Total annual burden (hours) |
|-----------------------|--------------------------|-------------------------|-----------------------------|
| 70,875 .....          | 1                        | 0.117                   | 8,269                       |

Written comments and recommendations concerning the proposed information collection should be sent by April 4, 2007 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202-395-6974.

Dated: February 27, 2007.  
**Patricia S. Bransford,**  
*Acting Director, Office of Program Services.*  
[FR Doc. E7-3764 Filed 3-2-07; 8:45 am]  
BILLING CODE 4162-20-P

**DEPARTMENT OF HOMELAND SECURITY**  
  
**U.S. Citizenship and Immigration Services**  
  
**Agency Information Collection Activities: Revision of an Existing Information Collection; Comment Request**  
  
**ACTION:** 60-day notice of information collection under review; Form I-824,

Application for Action on an Approved Application or Petition; OMB Control No. 1615-0044.

The Department of Homeland Security, U.S. Citizenship and Immigrations Services (USCIS) has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until May 4, 2007.

Written comments and suggestions regarding items contained in this notice, and especially with regard to 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, NW., 3rd Floor, Suite 3008, 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). When submitting comments by e-mail, please add the OMB Control No. 1615-0044 in the subject box.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

- (1) Evaluate whether the 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 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**  
  
(1) *Type of Information Collection:* Revision of an existing information collection.