Federal agencies, state and local governments, schools of public health, colleges and universities, private industry, nonprofit foundations, professional associations, clinicians, researchers, administrators, and health planners. There are no costs to the respondents other than their time. The total estimated annualized burden hours are 8,645.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses/respondent	Avg. burden per response (in hrs)
Office-based physicians (eligible):			
Physician Induction Interview	2,662	1	35/60
Patient Record form	2,263	30	5/60
Pulling and re-filing Patient Record form	399	30	1/60
CCSS	712	1	15/60
Office-based physicians (ineligible):			
Patient Induction Interview	888	1	5/60
Community Health Center Directors:			
Community Health Center Induction Interview	104	1	20/60
CHC Providers:			
Physician Induction Interview	312	1	35/60
Patient Record Form	265	30	5/60
Pulling and re-filing Patient Record form	47	30	1/60
CCSS	312	1	15/60

Dated: July 11, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–11521 Filed 7–19–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Psychopharmacologic Drugs Advisory Committee; 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: Psychopharmacologic Drugs Advisory Committee.

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

Date and Time: The meeting will be held on September 7 and 8, 2006, from 8 a.m. to 5 p.m.

Location: Hilton Hotel,The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Cicely Reese, 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: *Cicely.Reese@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512544. Please call the Information Line for up-to-date information on this meeting. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* under the heading ''Psychopharmacologic Drugs Advisory Committee (PDAC).'' (Click on the year 2006 and scroll down to PDAC meetings.)

Agenda: On September 7, 2006, the committee will discuss new drug application (NDA) 21–999, paliperidone extended-release (ER) tablets, Janssen, L.P./Johnson & Johnson Pharmaceutical Research and Development, L.L.C., proposed indication for treatment of schizophrenia. On September 8, 2006, the committee will discuss NDA 21–992, desvenlafaxine succinate (DVS 233), ER tablets, Wyeth Pharmaceuticals, proposed indication for treatment of major depressive disorder.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 23, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. Time allotted for each presentation may be limited. 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 August 23, 2006.

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 Cicely Reese 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: July 13, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–11537 Filed 7–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Reproductive Health Drugs; 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: Advisory Committee for Reproductive Health Drugs.

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

Date and Time: The meeting will be held on August 29, 2006, from 8 a.m. to 5:30 p.m.

Location: Hilton Hotel, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Teresa Watkins, 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: *Teresa.Watkins@fda.hhs.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512537. Please call the Information Line for up-to-date information on this meeting. When available, background materials for this meeting will be posted 1 business day prior to the meeting on the FDA Website at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. Click on the year 2006 and scroll down to the Advisory Committee for Reproductive Health Drugs.)

Agenda: The committee will discuss new drug application (NDA) 21–945, proposed trade name Gestiva, 17 alpha-hydroxyprogesterone caproate injection, 250 mg/mL, Adeza Biomedical, for the proposed indication prevention of preterm delivery in women with a history of a prior preterm delivery.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 15, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. 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 August 15, 2006.

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 Teresa Watkins 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: July 13, 2006.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E6–11538 Filed 7–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0246]

Draft Manufactured Food Regulatory Program Standards; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Manufactured Food Regulatory Program Standards'' (draft program standards). The draft program standards, which establish a uniform foundation for the design and management of State programs responsible for regulation of plants that manufacture, process, pack, or hold foods in the United States, are being distributed for comment purposes only. This document is neither final nor is it intended for implementation at this time.

DATES: Written comments on the draft program standards may be submitted by September 18, 2006. General comments on the draft program standards are welcome at any time. Submit written comments on the information collection provisions by September 18, 2006.

ADDRESSES: Submit written comments on the information collection provisions 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.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

Submit written requests for single copies of the draft program standards to the Division of Federal-State Relations (HFC–150), Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your request, or fax your request to 716–551–3845. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft program standards.

FOR FURTHER INFORMATION CONTACT: Beverly Kent, Division of Federal-State Relations, Food and Drug Administration, 300 Pearl St., suite 100, Buffalo, NY 14202, 716–541–0331.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Manufactured Food Regulatory Program Standards.'' The standards were developed after the Department of Health and Human Services, Office of Inspector General (OIG) audited FDA's oversight of food firm inspections conducted by States through contracts. In June 2000, the OIG released its findings. The OIG recommended that FDA take steps to promote ''equivalence among Federal and State food safety standards, inspection programs, and enforcement practices.'' The report is on the Internet at *http://www.oig.hhs.gov/oei/reports/oei-01-98-00400.pdf*. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

In response to the OIG's findings, FDA established a committee to draft a set of quality standards for manufactured food regulatory programs. The committee was comprised of officials from FDA and from State agencies responsible for the regulation and inspection of food plants.

These draft program standards establish a uniform foundation for the design and management of a State program that is an operational unit(s) responsible for the regulatory oversight of food plants that manufacture, process, pack, or hold foods in the United States. The elements of the draft program standards describe best practices of a high-quality regulatory program. Achieving conformance with these program standards will require comprehensive self-assessment on the part of a State program and will encourage continuous improvement and innovation. All self-assessment