

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/comments>. 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

worksheets and supporting documents will be retained by the State agency.

II. Significance of Program Standards

These draft program standards represents the agency’s current thinking on how to build a uniform foundation for managing 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.

III. Electronic Access

Persons with access to the Internet may obtain the draft program standards at either http://www.fda.gov/ora/fed_state/default.htm or <http://www.fda.gov/ohrms/dockets/default.htm>.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection of OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Manufactured Food Regulatory Program Standards

Description: The elements of the draft program standards are intended to ensure that the States have the best practices of a high-quality regulatory program to use for self-assessment and continuous improvement and innovation. The ten standards describe the critical elements of a regulatory program designed to protect the public from foodborne illness and injury. These elements include the State program’s regulatory foundation, staff training, inspection, quality assurance, food defense preparedness and response, foodborne illness and incident investigation, enforcement, education and outreach, resource management, laboratory resources, and program assessment. Each standard has corresponding self-assessment worksheets, and certain standards have supplemental worksheets and forms that will assist State programs in determining their level of conformance with the standard. The State program is not required to use the forms and

worksheets contained herein; however, alternate forms should be equivalent to the forms and worksheets in the draft program standards. These draft program standards do not address the performance appraisal processes that a State agency may use to evaluate individual employee performance. When finalized, FDA will use the program standards as a tool to improve contracts with State agencies. The program standards will assist both FDA and the States in fulfilling their regulatory obligations.

The implementation of the program standards will be negotiated as an option for payment under the State contract. States that are awarded this option will receive up to \$5,000 to perform the self assessment and to maintain an operational plan for self improvement. FDA recognizes that full use and implementation of the program standards by those States will take several years. Such States will, however, be expected to implement improvement plans to demonstrate that their programs are moving toward full implementation. Those self assessments and improvement plans will be audited as a part of the program oversight of the FDA state contracts.

The goal is to enhance food safety by establishing a uniform basis for measuring and improving the performance of manufactured food regulatory programs in the United States. The development and implementation of these program standards will help Federal and State programs better direct their regulatory activities at reducing foodborne illness hazards in plants that manufacture, process, pack, or hold foods. Consequently, the safety and security of the food supply in the United States will improve.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
40	0.5	20	40	800

¹ Because State agencies already keep records of the usual and customary activities required by their inspection programs, the burden from compiling these records is not included in the burden chart.

TABLE 2.—ESTIMATED 5-YEAR SELF ASSESSMENT BURDEN

No. of Respondents	5-Year Frequency per Response	Total 5-Year Responses	Hours per Response ¹	Total Hours ¹
40	1	40	100/40	4,000/1,600

¹ The initial self assessment is estimated at 100 hours per respondent. Subsequent updates of the self assessments will be conducted every 5 years and should be completed in 40 hours or less.

TABLE 3.—ESTIMATED ANNUAL “IMPROVEMENT PLAN” BURDEN

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
40	1	40	5	200

V. Comments

The draft program standards are being distributed for comment purposes only and are not intended for implementation at this time. 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. A copy of the draft program standards and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m. Monday through Friday.

Dated: July 14, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-11539 Filed 7-19-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL).

Dates and Times: (Face-to-face meeting). July 24, 2006, 8:30 a.m. to 5 p.m. July 25, 2006, 8:30 a.m. to 3 p.m.

Place: Doubletree Hotel, 1750 Rockville Pike, Rockville, MD 20852, Telephone: 301-468-1100.

Status: The meeting will be open to the public.

Purpose: The Committee will be focusing on interdisciplinary training and education, specifically examining evidence-based models/research as regards interdisciplinary training. In addition, the Committee will be looking at the potential impact of interdisciplinary training programs on health service delivery networks including how such training programs address the needs of

various underserved populations. Included in the meeting will be discussions of community-based training initiatives. The meeting will allow the Committee to formulate appropriate recommendations for the Secretary and Congress regarding interdisciplinary training, and community-based training.

Agenda: The agenda includes an overview of the Committee's general business activities. The Committee will hear presentations from experts on interdisciplinary training and community-based training, and will discuss best practices to formulate recommendations for the Secretary and the Congress.

Agenda items are subject to change as priorities indicate.

Supplementary Information: This meeting notice is delayed due to the resolution of fiscal year 2006 budget issues and the status of Committee membership.

For Further Information Contact: Anyone requesting information regarding the Committee should contact Lou Coccodrilli, Federal Official for the ACICBL, and Acting Director of the Division of State, Community & Public Health, Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Maryland 20857; Telephone (301) 443-7774.

Dated: July 17, 2006.

Cheryl R. Dammons,

Director, Division of Policy Review and Coordination.

[FR Doc. 06-6382 Filed 7-17-06; 3:39 pm]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Division of Extramural Research and Training; Submission for OMB Review; Comment Request; Hazardous Waste Worker Training

Summary: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 5, 2006, page 17119, and allowed 60 days for public

comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Hazardous Waste Worker Training—42 CFR Part 65. *Type of Information Collection Request:* Revision of OMB No. 0925-0348, expiration date August 31, 2006. *Need and Use of Information Collection:* This request for OMB review and approval of the information collection is required by regulation 42 CFR part 65(a)(6). The National Institute of Environmental Health Sciences (NIEHS) has been given major responsibility for initiating a worker safety and health training program under section 126 of the Superfund Amendments and Reauthorization Act of 1986 (SARA) for hazardous waste workers and emergency responders. A network of non-profit organizations that are committed to protecting workers and their communities by delivering high-quality, peer-reviewed safety and health curricula to target populations of hazardous waste workers and emergency responders has been developed. In seventeen years (FY 1987-2004), the NIEHS Worker Training program has successfully supported 20 primary grantees that have trained more than 1.3 million workers across the country and presented over 69,000 classroom and hands-on training courses, which have accounted for nearly 18 million contact hours of actual training. Generally, the grant will initially be for one year, and subsequent continuation awards are also for one year at a time. Grantees must submit a separate application to have the support continued for each subsequent year. Grantees are to provide information in accordance with S65.4(a), (b), (c) and 65.6(b) on the nature, duration, and purpose of the training, selection criteria for trainees' qualifications and competency of the project director and staff, cooperative agreements in the case of joint applications, the adequacy of training plans and resources, including budget and curriculum, and response to