Families (ACF) before using CCDF funds for construction or major renovation. This information collection contains the statutorily-mandated uniform procedures for the solicitation and consideration of requests, including instructions for preparation of environmental assessments in conjunction with the National Environmental Policy Act. The proposed draft procedures update and clarify the original procedures that were issued in August 1997. Respondents will be CCDF tribal grantees requesting to use CCDF funds for construction or major renovation.

Respondents: Tribal Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number or responses per respondent	Average burden hours per response	Total burden hours
Construction and Renovation	25	1	20	500
Estimated Total Annual Burden Hours				500

Additional Information: In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Infant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Desk Officer for ACF.

Dated: August 25, 2000.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 22148 Filed 8–29–00; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nonprescription 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: Nonprescription 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 October 19, 2000, 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Ave., Gaithersburg, MD.

Contact Person: Sandra L. Titus, 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, or e-mail Tituss@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12541. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will consider safety issues regarding the use of Phenylpropanolamine (PPA) in over-the-counter (OTC) drug products. The discussion will focus on the reported results of an epidemiological study designed to assess the risk of hemorrhagic stroke associated with the use of PPA. The Consumer Health Products Association (CHPA) commissioned the study which was conducted by Yale University. The material which the committee will review will be available at least 1 business day before the meeting at: http://www.fda.gov/ohrms/dockets/ac/acmenu.htm. Click on the year 2000 and then locate the Nonprescription Drugs Advisory Committee meeting for October 20, 2000.

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 by October 9, 2000. 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 before October 9, 2000, 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.

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

Dated: August 21, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–22141 Filed 8–29–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Gastrointestinal 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 Committees: Nonprescription Drugs Advisory Committee and the Gastrointestinal Drugs Advisory Committee.

General Function of the Committees: To provide advice and

recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 20, 2000, 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Ave., Gaithersburg, MD.

Contact Person: Sandra L. Titus or Thomas H. Perez, 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, or e-mail: Perezt@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12541. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committees will consider new drug application (NDA) 21–229 proposing over-the-counter (OTC) use of Prilosec® (omeprazole), Astra-Zeneca with distribution by Procter and Gamble. This is proposed to: (1) Relieve heartburn, acid indigestion and sour stomach, and (2) prevent heartburn, acid indigestion, and sour stomach brought on by consuming food and beverages, or associated with events such as stress, hectic lifestyle, lying down, or exercise.

The background material that the committees will review will be available 1 business day before the meeting on the Internet at: http://www.fda.gov/ohrms/dockets/ac/acmenu.htm. Click on the year 2000 and then locate the Nonprescription Drugs Advisory Committee meeting for October 20, 2000.

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 by October 9, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. on October 20, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 9, 2000, 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.

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

Dated: August 21, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–22144 Filed 8–29–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1424]

Draft Guidance for Industry on Analytical Procedures and Methods Validation: Chemistry, Manufacturing, and Controls Documentation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Analytical Procedures and Methods Validation: Chemistry, Manufacturing, and Controls Documentation.'' This draft guidance is intended to provide recommendations to applicants on submitting analytical procedures, validation data, and samples to support the identity, strength, quality, purity, and potency of drug substances and drug products. The recommendations apply to drug substances and drug products covered in new drug applications (NDA's), abbreviated new drug applications (ANDA's), biologics license applications (BLA's), product license applications (PLA's), and supplements to these applications.

DATES: Submit written comments on the draft guidance by November 28, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1488, FAX 888–CBERFAX or 301–827–3844. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. To expedite FDA review of your comments to the docket on this draft guidance, CDER requests that, if possible, you also send an electronic copy of these comments by e-mail to cunninghamp@cder.fda.gov.

FOR FURTHER INFORMATION CONTACT:

Radhika Rajagopalan, Center for Drug Evaluation and Research (HFD–645), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5849, or

Alfred Del Grosso, Center for Biologics Evaluation and Research (HFM–250), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–435–4988.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Analytical Procedures and Methods Validation: Chemistry, Manufacturing, and Controls Documentation.'' This draft guidance is intended to assist applicants in assembling information, submitting samples, and presenting data to support analytical methodologies. The recommendations apply to drug substances and drug products covered in NDA's, ANDA's, BLA's, PLA's, and supplements to these applications. The principles also apply to drug substances and drug products covered in Type II drug master files.

The principles of methods validation described in this guidance apply to all types of analytical procedures; however, the specific recommendations in this guidance may not be applicable to certain analytical procedures unique to products such as biological, biotechnological, botanical, or radiopharmaceutical drugs.

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on analytical procedures and methods validation. 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 statute, regulations, or both.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the draft guidance by November 28, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be