Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Versailles IV Room, Bethesda, Maryland 20814.

Open February 18, 9:30 a.m. to 9:45 a.m. Closed for remainder of meeting.

Purpose: To review and evaluate grant applications.

Agenda: The open session of the meetings will be devoted to business covering administrative matters and reports. During the closed sessions, the Subcommittees will be reviewing and discussing grant applications dealing with health services research issues. In accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C., 552b(c)(6), the Administrator, Agency for Health Care Policy and Research, has made a formal determination that these latter sessions will be closed because the discussions are likely to reveal personal information concerning individuals associated with the applications. This information is exempt from mandatory disclosure.

Anyone wishing to obtain a roster of members, minutes of the meetings, or other relevant information should contact Ms. Jenny Griffith, Committee Management Officer, Office of Research Review, Education and Policy, Agency for Health Care Policy and Research, 2101 East Jefferson Street, Suite 400, Rockville, Maryland 20852, Telephone (301) 594–1847.

Agenda items for these meetings are subject to change as priorities dictate.

Dated: January 21, 1999.

John M. Eisenberg,

Administrator.

[FR Doc. 99–2106 Filed 1–28–99; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Change in Dates for Availability of Application Kits and Deadline for Receipt of Applications Under the Office of Community Services' Urban and Rural Community Economic Development Program for Fiscal Year 1999

AGENCY: Office of Community Services, ACF, DHHS.

ACTION: Notice.

SUMMARY: The Office of Community Services (OCS) published a **Federal Register** Notice on December 28, 1998 indicating that the application kit for the Urban and Rural Community Economic Development Program for FY 1999 would be available on January 22, 1999. This notice also indicated that the deadline for receipt of applications would be on April 23, 1999. These dates are no longer valid. When new dates are established, a follow-up notice will be published in the **Federal Register**. The deadline date will be adjusted accordingly. This application kit will be posted on the OCS Website after it becomes available. The OCS Website address is: http://www.acf.dhhs.gov/programs/ocs

FOR FURTHER INFORMATION CONTACT: Thelma Johnson (202) 401–5523.

Dated: January 22, 1999.

Donald Sykes,

Director, Office of Community Services.

[FR Doc. 99–2180 Filed 1–28–99; 8:45 am]

BILLING CODE 01–4184–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0446]

Agency Information Collection Activities; Submission for OMB Review; Postmarketing Reporting of Adverse Drug Experiences

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by March 1, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Postmarketing Reporting of Adverse Drug Experiences—21 CFR 310.305 and 314.80 (OMB Control Number 0910–0230—Reinstatement)

Section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) requires applicants to submit data showing whether a drug is safe and effective. FDA is authorized to issue regulations requiring the recordkeeping and reporting necessary to enable it to evaluate the safety or effectiveness of a drug product, including whether the product is misbranded or adulterated under sections 501 and 502 of the act (21 U.S.C. 351 and 352). Under §§ 310.305 and 314.80 (21 CFR 310.305 and 314.80), FDA set forth reporting and recordkeeping requirements regarding adverse drug experiences.

All applicants who have received marketing approval of drug products are required to file Alert Reports with FDA regarding serious, unexpected adverse drug experiences, as well as followup reports on the adverse drug experiences when the applicant receives new information or as requested by FDA (§ 314.80(c)(1)). The Alert Reports include reports of all foreign or domestic adverse experiences, as well as reports obtained in scientific literature (§ 314.80(d)), and if there is a reasonable possibility that the drug caused the adverse experience, reports from postmarketing studies (§ 314.80(e)). Under § 314.80(c)(2), applicants must provide periodic reports of adverse drug experiences. Under § 314.80(i), applicants must keep for 10 years records of all adverse drug experience reports known to the applicant.

For marketed prescription drug products without approved new drug applications or abbreviated new drug applications, manufacturers, packers, and distributors are required to report to FDA serious, unexpected adverse drug experiences, as well as followup reports on the adverse drug experiences when the applicant receives new information or as requested by FDA (§ 310.305(c)(1) and (c)(2)). Under § 310.305(f), each manufacturer, packer, and distributor shall maintain for 10 years records of all adverse drug experiences required to be reported.

The primary purpose of FDA's adverse drug experience reporting system is to provide a signal for potentially serious safety problems with marketed drugs. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the marketed drug provide, for the first time, the opportunity to collect

information on rare, latent, and long-term effects. Signals are obtained from a variety of sources, including reports from patients, treating physicians, foreign regulatory agencies, and clinical investigators. Information derived from the adverse drug experience reporting system contributes directly to increased public health protection because the information enables FDA to make important changes to the product's labeling (such as adding a new warning) and, when necessary, to initiate removal of a drug from the market.

Respondents to this collection of information are manufacturers, packers, distributors, and applicants.

In the **Federal Register** of December 30, 1997 (62 FR 67874), the agency requested comments on the proposed collection of information. FDA received one comment. The comment questioned the accuracy of several of the information collection burden estimates, and suggested higher estimates for annual frequency per response and hours per response. In light of this comment, the agency reevaluated its estimates and is revising its previous estimate of the number of periodic reports prepared per respondent, from the 1.5 originally reported to 18. On review, FDA determined that this number reflects the average number of periodic reports it receives. A periodic report includes a narrative summary, individual case safety reports, and history of actions taken. In addition, the agency is revising the hours per response for preparing a periodic report under § 314.80(c)(2) from 5 to 28 hours. The comment suggested, and FDA agrees, that 28 hours more accurately reflects the amount of time required to prepare a response.

The comment also suggested ways to enhance the quality, utility, and clarity of the information to be collected and ways to minimize the burden of the collection of information on respondents.

FDA is in the process of revising its safety reporting and recordkeeping regulations and will consider these comments in developing its rulemaking. The respondent has had and will have an opportunity for comment on these rulemaking initiatives. In the **Federal Register** of October 27, 1994 (59 FR 54046), FDA published a proposed rule to amend its postmarketing expedited and periodic safety reporting requirements, as well as others, to implement international standards and to facilitate the reporting of adverse drug experiences. In the **Federal Register** of October 7, 1997 (62 FR 52237), FDA published a final rule amending its expedited safety reporting regulations to implement certain recommendations in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) E2A guidance on definitions and standards for expedited reporting (58 FR 37408, July 9, 1993). At this time, the agency is further considering recommendations in the ICH E2A guidance for additional amendments to its postmarketing expedited safety reporting regulations. With respect to the proposed amendments to the periodic adverse drug experience reporting requirements in the proposal of October 27, 1994, FDA has decided to repropose these amendments based on recommendations in the ICH E2C guidance on periodic safety update reports (62 FR 27470, May 19, 1997). In developing the reproposal, FDA will also consider comments submitted in response to the proposed rule of October 27, 1994, regarding periodic adverse experience reports. FDA is also considering rulemaking concerning the electronic submission of postmarketing expedited and periodic safety reports using standardized medical terminology, data elements, and electronic transmission standards recommended by the ICH.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
310.305(c)(5)	1	1	1	1	1
314.80(c)(1)(iii)	5	1	5	1	5
314.80(c)(2)	683	18	12,300	28	344,400
Total					344,406

[1] The reporting burden for §§ 310.305(c)(1), (c)(2), (c)(3), and 314.80(c)(1)(i) and (c)(1)(ii) was reported under OMB control number 0910–0291. There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
310.305(f)	25	1	2	1	25
314.80(i)	683	1	683	1	683
Total					708

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The numbers in Tables 1 and 2 of this document are accurate as of the time of publication. FDA is in the process of revising its safety reporting and recordkeeping regulations. These numbers may change when the revisions to those regulations are finalized.

Dated: January 22, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–2160 Filed 1–28–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–1234]

New Monographs, Revisions of Certain Food Chemicals Codex Monographs, New General Analytical Procedures, and Revisions of General Analytical Procedures; Opportunity for Public Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on pending changes to certain Food Chemicals Codex specification monographs in the fourth edition and on proposed new specification monographs and proposed new and revised general analytical procedures. New specification monographs for certain substances used as food ingredients; additions, revisions, and corrections to current monographs; and new and revised general analytical procedures are being prepared by the National Academy of Sciences/Institute of Medicine (NAS/IOM) Committee on Food Chemicals Codex (the committee). This material is expected to be presented in the next publication of the Food Chemicals Codex (the second supplement to the fourth edition) at a date yet to be determined.

DATES: Written comments by March 15, 1999. (The committee advises that comments received after this date may not be considered for the second supplement to the fourth edition. Comments received too late for consideration for the second supplement will be considered for later supplements or for a new edition of the Food Chemicals Codex.)

ADDRESSES: Submit written comments and supporting data and documentation to the NAS/IOM Committee on Food Chemicals Codex/FO–3042, National Academy of Sciences, 2101 Constitution Ave. NW., Washington, DC 20418. Copies of the new monographs, the proposed revisions to current monographs, and the proposed new and revised general analytical procedures may be obtained upon written request from NAS (address above) or from the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests for copies should specify by name the monographs or analytical procedures desired. Copies may also be obtained through the Internet at ''http://www2.nas.edu/codex''.

FOR FURTHER INFORMATION CONTACT:

Fatima N. Johnson/FO–3042, Committee on Food Chemicals Codex, Food and Nutrition Board, National Academy of Sciences, 2101 Constitution Ave. NW., Washington, DC 20418, 202–334–2580; or

Paul M. Kuznesof, Division of Product Manufacture and Use, Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–246), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3009.

SUPPLEMENTARY INFORMATION: By contract with NAS/IOM, FDA supports the preparation of the Food Chemicals Codex, a compendium of specification monographs for substances used as food ingredients. Before any specifications are included in a Food Chemicals Codex publication, public announcement is made in the **Federal Register**. All interested parties are invited to comment and to make suggestions for consideration. Suggestions should be accompanied by supporting data or other documentation to facilitate and expedite review by the committee.

In the **Federal Register** of December 3, 1996 (61 FR 64098), and March 28, 1997 (62 FR 14911), FDA announced that the committee was considering additional new monographs and a number of monograph revisions for inclusion in the first supplement to the fourth edition of the Food Chemicals Codex. The first supplement to the fourth edition of the Food Chemicals Codex was released by the National Academy Press (NAP) in September 1997. It is now available for sale from NAP (1–800–624–6242; 202–334–3313; FAX 202–334–2451; Internet ''http://www.nap.edu'') 2101 Constitution Ave. NW., Lockbox 285, Washington, DC 20055.

FDA now gives notice that the committee is soliciting comments and information on additional proposed new monographs, proposed changes to certain current monographs, and proposed new and revised general analytical procedures. These new monographs and analytical procedures and changes are expected to be published in the second supplement to the fourth edition of the Food Chemicals Codex. Copies of the proposed new monographs and analytical procedures and revisions to current monographs and analytical procedures may be obtained upon written request from NAS at the address listed above or through the Internet at ''http://www2.nas.edu/codex''.

FDA emphasizes, however, that it will not consider adopting and incorporating any of the committee's new monographs and general analytical procedures, or revisions to monographs or analytical procedures into FDA regulations without ample opportunity for public comment. If FDA decides to propose the adoption of new monographs or analytical procedures or changes that have received final approval of the committee, it will announce its intention and provide an opportunity for public comment in the **Federal Register**.

The committee invites comments and suggestions by all interested parties on specifications or analytical procedures to be included in the proposed new monographs (4), revisions of current monographs (30), and new and revised general analytical procedures (3) listed below:

I. Proposed New Monographs

Erythritol
Maltitol
Menhaden Oil, Hydrogenated
Menhaden Oil, Refined

II. Current Monographs to which the Committee Proposes to Make Revisions

L–Aspartic Acid (correct identification test)
Butadiene-Styrene 50/50 Rubber (delete arsenic specification)
Butadiene-Styrene 25/75 Rubber (delete arsenic specification)
Calcium Phosphate, Monobasic (correct limits for loss on drying and loss on ignition)
Carbon, Activated (reinstate arsenic specification)
Carmine (correct assay calculation; revise assay limit, description, and ash determination)
Dimethylpolysiloxane (modify identification test)
Disodium Inosinate (delete barium specification)