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 These dates are no longer valid.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