unnecessary. Rather than imposing excessive requirements that will force substantial costs on the parties, the Commission should have allowed the merger of Amoco and BP to proceed with antitrust relief limited to terminaling as well as the Ohio and the Pittsburgh, Pennsylvania wholesaling situation.

I therefore dissent from the aspects of this matter dealing with gasoline wholesaling in the southeastern United States markets identified in Paragraph 15 of the proposed complaint.

[FR Doc. 99–2073 Filed 1–28–99; 8:45 am]
BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has made a final finding of scientific misconduct in the following case:

Ms. Nellie Briggs-Brown, Rush-Presbyterian-St. Luke's Medical Center: Based on the report of an investigation conducted by Rush-Presbyterian-St. Luke's Medical Center dated December 3, 1997, ORI finds that Ms. Briggs Brown, former employee, Department of Neurology, engaged in scientific misconduct in clinical research supported by two National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH) grants.

Specifically, Ms. Briggs-Brown (1) falsified seven monthly screening logs for a NINDS funded study involving stroke victims (Randomized Trial of Org 10172 in Acute Ischemic Stroke Treatment) and submitted the same logs with altered dates on multiple occasions to the University of Iowa Coordinating Center; and (2) falsified several Human Investigation Committee research approval forms.

None of the questioned data has been included in publications.

ORI has implemented the following administrative actions for the three (3) year period beginning January 25, 1999:

(1) Ms. Briggs-Brown is prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) Any institution that submits an application for PHS support for a research project on which Ms. Briggs-Brown's participation is proposed or which uses her in any capacity on PHS supported research, or that submits a report of PHS-funded research in which she is involved, must concurrently submit a plan for supervision of her duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of Ms. Briggs-Brown's research contribution. The institution also must submit a copy of the supervisory plan to ORI.

FOR FURTHER INFORMATION CONTACT: Acting Director, Division of Research Investigations, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443–5330.

Chris B. Pascal,

Acting Director, Office of Research Integrity.

[FR Doc. 99–2158 Filed 1–28–99; 8:45 am]
BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has made a final finding of scientific misconduct in the following case:

Robert J. Thackeray, R.N., M.P.H., University of Pittsburgh: Based on an investigation report prepared by the University of Pittsburgh, dated June 24, 1998, and information obtained by ORI during its oversight review, ORI found that Mr. Thackeray, former program coordinator, Multi center AIDS Cohort Study (MACS), Department of Infectious Diseases and Microbiology, Graduate School of Public Health, University of Pittsburgh, engaged in scientific misconduct in research supported by the National Institutes of Health (NIH). The Pitt Men's Study is a component of the MACS funded by a cooperative agreement with the National Institute of Allergy and Infectious Diseases (NIAID), NIH.

Specifically, Mr. Thackeray falsified and/or fabricated research data that he recorded from various tests that he was responsible for conducting on subjects enrolled in the MACS.

Mr. Thackeray falsified and/or fabricated data for five subjects and reported that data on the ''Neurological Assessment Form 10'' and on the ''Instrumental Activities of Daily Living Scale'' questionnaire.

The fabricated and/or falsified research data were not compiled elsewhere and were not included in any publications.

Mr. Thackeray has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which he has voluntarily agreed, for the three (3) year period beginning January 19, 1999:

(1) To exclude himself from serving in any advisory capacity to the Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) That any institution that submits an application for PHS support for a research project on which his participation is proposed or which uses him in any capacity on PHS supported research, or that submits a report of PHS-funded research in which he is involved, must concurrently submit a plan for supervision of his duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of Mr. Thackeray's research contribution. The institution also must submit a copy of the supervisory plan to ORI.

FOR FURTHER INFORMATION CONTACT: Acting Director, Division of Research Investigations, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443–5330.

Chris B. Pascal,

Acting Director, Office of Research Integrity.

[FR Doc. 99–2157 Filed 1–28–99; 8:45 am]
BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Notice of Meetings

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C. Appendix 2) announcement is made of the following subcommittees scheduled to meet during the month of February 1999:

Name: Health Care Quality and Effectiveness Research.

Date and Time: February 9, 1999, 8:00 a.m.

Place: Bethesda Hyatt, 1 Bethesda Metro Center, Bethesda, Maryland 20814.

Open February 9, 8:30 a.m. to 8:45 a.m. Closed for remainder of meeting.

Purpose: To review and evaluate grant applications.

Name: Health Systems Research.

Date and Time: February 18, 1999, 9:30 a.m.

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