Investment Limited, and New York Global Partners, L.P., all of New York, New York, is revised to read as follows:

A. Federal Reserve Bank of Atlanta (Andre Anderson, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30303:

1. York Capital Management, L.P., York Investment Limited, York Global Value Partners, L.P., York Global Value Holdings, LLC, Dinan Management, LLC, York Offshore Holdings, Limited, Dinan Management, L.P., Dinan Management Corporation, and James G. Dinan (collectively, ''York''), all of New York, New York, and York Global Value Holdings, L.P., York Global Value Holdings, LLC and James G. Dinan, individually and on behalf of the York group, to acquire up to 24.9 percent of the voting shares of PanAmerican Bancorp, Miami, Florida, and thereby indirectly acquire voting shares of PanAmerican Bank, Miami, Florida.

Comments on this application must be received by October 4, 2005.

Board of Governors of the Federal Reserve System, September 14, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 05–18597 Filed 9–16–05; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Federal Open Market Committee; Domestic Policy Directive of August 9, 2005

In accordance with § 271.25 of its rules regarding availability of information (12 CFR part 271), there is set forth below the domestic policy directive issued by the Federal Open Market Committee at its meeting held on August 9, 2005.[1]

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. To further its long-run objectives, the Committee in the immediate future seeks conditions in reserve markets consistent with increasing the federal funds rate to an average of around 3½ percent.

The vote encompassed approval of the paragraph below for inclusion in the statement to be released shortly after the meeting:

''The Committee perceives that, with appropriate monetary policy action, the upside and downside risks to the attainment of both sustainable growth and price stability should be kept roughly equal. With underlying inflation expected to be contained, the Committee believes that policy accommodation can be removed at a pace that is likely to be measured. Nonetheless, the Committee will respond to changes in economic prospects as needed to fulfill its obligation to maintain price stability.''

By order of the Federal Open Market Committee, September 6, 2005.

Vincent R. Reinhart,

Secretary, Federal Open Market Committee.

[FR Doc. 05–18559 Filed 9–16–05; 8:45 am]

BILLING CODE 6210–01–P

[1] Copies of the Minutes of the Federal Open Market Committee Meeting on August 9, 2005, which includes the domestic policy directive issued at the meeting, are available upon request to the Board of Governors of the Federal Reserve System, Washington, DC 20551. The minutes are published in the Federal Reserve Bulletin and in the Board's annual report.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panels (SEP): Surveillance Review, Program Announcement PAR–04–106

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Surveillance Review, Program Announcement PAR–04–106.

Times and Dates: 8 a.m.–5 p.m., November 2, 2005 (Closed), 8 a.m.–5 p.m., November 3, 2005 (Closed).

Place: Marriott Inner Harbor at Camden Yard, 110 South Eutaw Street, Baltimore, MD 21201, Telephone Number 410.962.0202.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to: Surveillance Review, Program Announcement PAR–04–106.

Contact Person For More Information: Steve Olenchock, PhD, Scientific Review Administrator, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, WV 26506, Telephone 304.285.6127.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: September 13, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–18527 Filed 9–16–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0262]

Submission of Chemistry, Manufacturing, and Controls Information in a New Drug Application Under the New Pharmaceutical Quality Assessment System; Extension of Application and Comment Deadlines

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice to extend application and comment deadlines.

SUMMARY: The Food and Drug Administration (FDA) is announcing an extension in the deadlines for submitting requests to participate in and comment on a pilot program involving the submission of chemistry, manufacturing, and controls (CMC) information consistent with the new pharmaceutical quality assessment system.

DATES: Submit written requests to participate in the pilot program by March 31, 2006. Submit eligible new drug applications (NDAs) by March 31, 2007. Submit written or electronic comments on the pilot program by March 31, 2007.

ADDRESSES: Submit written requests to participate in the pilot program and comments on the pilot program to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests to participate in and comments on the pilot program to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Michael Folkendt, Center for Drug Evaluation and Research (HFD–800), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5918, e-mail: *folkendtm@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 14, 2005 (70 FR 40719), FDA announced

that it is seeking pharmaceutical companies to participate in a pilot program involving the submission of CMC information consistent with a new pharmaceutical quality assessment system. The Office of New Drug Chemistry (ONDC) in the Office of Pharmaceutical Science, Center for Drug Evaluation and Research, is establishing a modern, risk-based pharmaceutical quality assessment system, as described in a September 2004 White Paper, ''ONDC's New Risk-Based Pharmaceutical Quality Assessment System'' (*http://www.fda.gov/cder/gmp/gmp2004/ondc_reorg.htm*). The pilot program will provide additional information for ONDC to use in implementing the new quality assessment system. The pilot program will provide participating pharmaceutical companies an opportunity to submit critical CMC information that demonstrates their understanding of quality by design, product knowledge, and process understanding of the drug substance and drug product at the time of submission of an NDA. The pilot program will also enable the public and regulated industry to provide feedback that will assist FDA in developing guidance for industry on the new quality assessment system.

The July 14, 2005 (70 FR 40719), notice provided deadlines related to the submission of certain information related to the pilot program. To ensure inclusive and relevant results from the pilot program, this notice extends the deadlines as follows: Requests to participate in the pilot program to March 31, 2006, from October 31, 2005, and submission of eligible New Drug Applications (NDA) to March 31, 2007, from December 31, 2006. This notice also extends the comment period on the pilot program to March 31, 2007, from December 31, 2006. See the process section (II.B) in the July 14, 2005 (70 FR 40719) notice for instructions on submitting requests to participate in the pilot program. All requests to participate in the pilot program, both written and electronic, should be marked confidential.

II. Comments

Interested persons may submit written comments on this pilot program to the Division of Dockets Management (see **ADDRESSES**). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. While detailed information on participating NDAs will not be publicly available, names of participating applicants will be made public.

Dated: September 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–18515 Filed 9–16–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–02–1000]

Memorandum of Understanding Between the Food and Drug Administration, Center for Biologics Evaluation and Research, and the National Institutes of Health, National Institute of Neurological Disorders and Stroke

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Food and Drug Administration, Center for Biologics Evaluation and Research (FDA/CBER), and the National Institutes of Health, National Institute of Neurological Disorders and Stroke (NIH/NINDS). The purpose of this MOU is to provide a framework for coordination and collaborative efforts between these two entities, which are both components of the Department of Health and Human Services. This MOU also provides the principles and procedures by which information sharing between FDA/CBER and NIH/NINDS units shall take place.

DATES: The agreement became effective February 12, 2002.

FOR FURTHER INFORMATION CONTACT: *For FDA/CBER*: Kimberly Benton, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, WOC1/rm. 209N, Rockville, MD 20852, 301–827–5102.

For NIH/NINDS: Robert Finkelstein, Extramural Research, Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., rm. 2143, Bethesda, MD 20892, 301–496–9248.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: September 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S