FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3260.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective February 10, 1997.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

Lacy E. Suiter,

Executive Associate Director, Response and Recovery Directorate.

[FR Doc. 97–4917 Filed 2–26–97; 8:45 am]

BILLING CODE 6718–02–M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than March 19, 1997.

A. Federal Reserve Bank of Atlanta (Lois Berthaume, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

1. Mr. O. H. Deshotels, Jr., Kaplan, Louisiana; to acquire an additional 2.9 percent, for a total of 12.6 percent, of the voting shares of Coastal Commerce Bancshares, Inc., Kaplan, Louisiana, and thereby indirectly acquire Kaplan State Bank, Kaplan, Louisiana.

Board of Governors of the Federal Reserve System, February 21, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–4828 Filed 2–26–97; 8:45 am]

BILLING CODE 6210–01–F

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than March 24, 1997.

A. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. AmeriBancShares, Inc., Wichita Falls, Texas; to become a bank holding company by acquiring 100 percent of the voting shares of AmeriBancShares of Delaware, Wilmington, Delaware, and thereby indirectly acquire American National Bank, Wichita Falls, Texas.

2. AmeriBancShares of Delaware, Inc., Wilmington, Delaware; to become a bank holding company by acquiring 100 percent of the voting shares of American National Bank, Wichita Falls, Texas.

Board of Governors of the Federal Reserve System, February 21, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–4829 Filed 2–26–97; 8:45 am]

BILLING CODE 6210–01–F

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies That are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.25 of Regulation Y (12 CFR 225.25) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. Once the notice has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than March 13, 1997.

A. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1413:

1. Shoreline Financial Corporation, Benton Harbor, Michigan; to acquire SJS Bancorp, Inc., St. Joseph, Michigan, and thereby indirectly acquire SJS Federal Savings Bank, St. Joseph, Michigan, and thereby engage in operating a savings association pursuant to § 225.25(b)(9) of the Board's Regulation Y and in insurance agency and underwriting activities pursuant to § 225.25(b)(8)(i) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, February 21, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–4830 Filed 2–26–97; 8:45 am]

BILLING CODE 6210–01–F

FEDERAL RETIREMENT THRIFT SUPERVISION INVESTMENT BOARD

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Federal Retirement Thrift Investment Board.

TIME AND DATE: 9:00 a.m., March 10, 1997.

PLACE: National Finance Center, First Floor, Conference Room 6, USDA/NFC Building No. 350, NASA Space Facility, 13800 Old Gentilly Road, New Orleans, Louisiana.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Approval of the minutes of the February 10, 1997, Board member meeting.
2. Thrift Savings Plan activity report by the Executive Director.
3. Briefings by National Finance Center and Board staff on:
   a. National Finance Center;
   b. Thrift Savings Plan system replacement effort;
   c. Thrift Savings Plan improvements;
   d. Capability maturity model;
   e. Software methodology;
   f. Project tracking and controls;
   g. Service Office enhancements;
   h. Local area network; and
   i. Thrift Savings Plan costs.

CONTACT PERSON FOR MORE INFORMATION: Tom Trabucco, Director, Office of External Affairs (202) 942–1640.

Dated: February 24, 1997.

Roger W. Mehle,

Executive Director, Federal Retirement Thrift Investment Board.

[FR Doc. 97–5013 Filed 2–25–97; 11:37 am]

BILLING CODE 6760–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95P–0110]

The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a document entitled ''Good Guidance Practices'' (GGP's), which sets forth the agency's policies and procedures for the development, issuance, and use of guidance documents. Issues relating to FDA's development and issuance of guidance documents were raised in a citizen petition submitted by the Indiana Medical Devices Manufacturers Council, Inc. (IMDMC) (see Docket No. 95P–0110). In an effort to improve its guidance document procedures, FDA has adopted the GGP's described and included in this notice.

DATES: Although the agency already has begun to follow the procedures set forth in the GGP's, the GGP's will not be fully implemented until FDA's proposal to amend its regulations in part 10 (21 CFR part 10) to clarify that advisory opinions and guidelines do not bind the agency (57 FR 47314, October 15, 1992) is finalized and in effect.

FOR FURTHER INFORMATION CONTACT: Margaret M. Dotzel, Office of Policy (HF–22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION: The IMDMC petition requested that FDA control the initiation, development, and issuance of guidance documents by written procedures that assure the appropriate level of meaningful public participation. In response to the petition, FDA agreed to take steps to improve the agency's guidance document procedures. In the Federal Register of March 7, 1996 (61 FR 9181), FDA published a notice, which set forth its proposal on how best to improve its guidance document procedures and solicited comment on these and additional ideas for improvement (the March 7 Notice). On April 26, 1996, the agency held a public meeting to further discuss these issues (the April 26 public meeting). The comment period for the March 7 Notice closed on June 5, 1996. This notice: (1) Sets forth the agency's position on how it will proceed in the future with respect to guidance document development, issuance, and use; and (2) includes the agency's GGP's, which set forth the agency's policies and procedures for developing, issuing, and using guidance documents.

I. Definition of Guidance

In the March 7 Notice, FDA provided the following definition for guidance documents:

[T]he term ''guidance documents'' means: (1) Documents prepared for FDA review staff and applicants/sponsors relating to the processing, content, and evaluation/approval of applications and relating to the design, production, manufacturing, and testing of regulated products; and (2) documents prepared for FDA personnel and/or the public that establish policies intended to achieve consistency in the agency's regulatory approach and establish inspection and enforcement procedures. Guidance documents do not include agency reports, general information provided to consumers, documents relating to solely internal FDA procedures, speeches, journal articles and editorials, media interviews, warning letters, or other communications or actions taken by individuals at FDA or directed to individual persons or firms.

A number of the comments submitted in response to the March 7 Notice suggested alternative definitions for ''guidance document.'' One comment suggested that the term include all internal documents intended to direct activities of FDA staff. Another suggested that a guidance document be defined as any document or other communication that in effect announces a regulatory expectation to a broad audience. And yet another suggested that a guidance document be defined as any statement that may substantively impact a regulatory evaluation or determination.

Documents relating to internal procedures, warning letters, information directed at individuals or individual firms, and speeches, journal articles, editorials, media interviews, press materials, agency reports, and general information documents provided to consumers are not guidance documents. FDA disagrees with suggestions for a definition of guidance documents that would effectively broaden the scope of the term ''guidance document'' to include such documents. Definitions such as ''any document that announces a regulatory expectation,'' ''any statement that may substantively impact a regulatory evaluation or determination,'' or ''any agency-issued writing that establishes methods of compliance'' would include some or all of these excluded documents. A definition such as ''all internal documents that direct activities of FDA staff'' would include all documents relating to internal FDA procedures, even if they have no bearing on the regulated industry. Accordingly, FDA is rejecting these suggestions.

In the GGP document, attached to this notice, the agency is using the same basic definition as set forth in the March 7 Notice, with minor revisions to clarify what is and is not in the universe of guidance documents. It provides:

The term ''guidance documents'' includes documents prepared for FDA staff, applicants/sponsors, and the public that (1) relate to the processing, content, and evaluation/approval of submissions; (2) relate to the design, production, manufacturing, and testing of regulated products; (3) describe the agency's policy and regulatory approach to an issue; or (4) establish inspection and enforcement policies and procedures. ''Guidance documents'' do not include documents relating to internal FDA procedures, agency reports, general information documents provided to consumers, speeches, journal articles and editorials, media interviews, press materials, warning letters, or other communications directed to individual persons or firms.

Despite the agency's reluctance to broaden the definition of guidance, the agency is sensitive to the concern expressed during the April 26 public meeting and in the comments that too narrow a definition might permit agency employees to use documents or communications such as speeches, editorials, or journal articles to announce regulatory expectations without following the GGP's discussed herein. Although FDA employees should be able to respond to questions about how an established policy applies