

N. Preservati Grandchildren's Trust, the co-trustees of which are Richard G. Preservati, II; Gina Preservati Boggess, both of Princeton, West Virginia; Nicholas S. Preservati, Charleston, West Virginia; and Arnold D. Lively, Venice, Florida; all acting in concert, and Richard G. Preservati, II, Princeton, West Virginia, individually, to acquire voting shares of New Peoples Bankshares, Inc., and thereby indirectly acquire voting shares of New Peoples Bank, Inc., both in Honaker, Virginia.

Board of Governors of the Federal Reserve System, October 21, 2013.

Margaret McCloskey Shanks,
Deputy Secretary of the Board.

[FR Doc. 2013-24994 Filed 10-23-13; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

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 shares of 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. The notices also will 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 November 7, 2013.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street, NE., Atlanta, Georgia 30309:

1. *Jane Bryant Banks, Mary Banks Garnand, James Banks Garnand, and Daniel Michael Garnand*, all of Eutaw, Alabama; to collectively retain voting shares of Merchants and Farmers Bankshares, Inc., and thereby indirectly retain voting shares of Merchants & Farmers Bank of Greene County, both in Eutaw, Alabama.

Board of Governors of the Federal Reserve System, October 18, 2013.

Margaret McCloskey Shanks,
Deputy Secretary of the Board.

[FR Doc. 2013-24855 Filed 10-23-13; 8:45 am]

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FEDERAL RESERVE SYSTEM

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. The applications 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 (12 U.S.C. 1843). 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 November 18, 2013.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. *Talmer Bancorp, Inc.*, Troy, Michigan; to acquire 100 percent of the voting shares of Michigan Commerce Bank, Ann Arbor, Michigan.

B. Federal Reserve Bank of San Francisco (Gerald C. Tsai, Director, Applications and Enforcement) 101 Market Street, San Francisco, California 94105-1579:

1. *Umpqua Holdings Corporation*, Portland, Oregon; to merge with Sterling Financial Corporation, and thereby indirectly acquire Sterling Savings Bank, both in Spokane, Washington.

Board of Governors of the Federal Reserve System, October 21, 2013.

Margaret McCloskey Shanks,
Deputy Secretary of the Board.

[FR Doc. 2013-24995 Filed 10-23-13; 8:45 am]

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FEDERAL RESERVE SYSTEM

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

This notice corrects a notice (FR Doc. 2013-24511) published on page 62363 of the issue for Monday, October 21, 2013.

Under the Federal Reserve Bank of Dallas heading, the entry for WCM-Parkway, Ltd, Dallas, Texas, is revised to read as follows:

A. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *WCM Holdings, Inc., and WCM-Parkway, Ltd.*, both in Dallas, Texas; to acquire up to 15 percent of the voting shares of Veritex Holdings, Inc., and thereby indirectly acquire voting shares of Veritex Community Bank, both in Dallas, Texas.

Comments on this application must be received by November 14, 2013.

Board of Governors of the Federal Reserve System, October 21, 2013.

Margaret McCloskey Shanks,
Deputy Secretary of the Board.

[FR Doc. 2013-24993 Filed 10-23-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1143]

Draft Guidance for Industry: Use of Nucleic Acid Tests To Reduce the Risk of Transmission of West Nile Virus From Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus From Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)," dated October 2013. The draft guidance document provides establishments that make donor eligibility determinations for donors of HCT/Ps, with recommendations for donor testing for West Nile Virus (WNV) using an FDA-licensed donor screening test. The guidance recommends the use of an FDA-licensed nucleic acid test

(NAT) for testing donors of HCT/Ps for infection with WNV. The draft guidance replaces the draft guidance entitled "Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus From Donors of Whole Blood and Blood Components Intended for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated April 2008, with respect to HCT/Ps. The testing recommendations in the guidance, when finalized, will supplement the donor screening recommendations for WNV (which will remain in place) that were made in the guidance entitled "Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated August 2007 (2007 Donor Eligibility Guidance).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 22, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Chacko, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of

West Nile Virus From Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)," dated October 2013. FDA is providing establishments that make donor eligibility determinations for donors of HCT/Ps with recommendations for donor testing for WNV using an FDA-licensed donor screening test. FDA believes that the use of an FDA-licensed NAT will reduce the risk of transmission of WNV from donors of HCT/Ps and therefore recommends that you use an FDA-licensed NAT for testing donors of HCT/Ps for infection with WNV. The 2007 Donor Eligibility Guidance indicated that FDA may recommend routine use of an appropriate, licensed donor screening test(s) to detect acute infections with WNV using NAT technology, once such tests were available.

The draft guidance announced in this notice replaces the draft guidance entitled "Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus From Donors of Whole Blood and Blood Components Intended for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated April 2008 (April 28, 2008; 73 FR 22958), with respect to HCT/Ps. The testing recommendations in the guidance, when finalized, will supplement the donor screening recommendations for WNV (which remain in place) that were made in the 2007 Donor Eligibility Guidance.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments regarding this document <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and

will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: October 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-24940 Filed 10-23-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0419]

Guidance for Industry on Active Controls in Studies To Demonstrate Effectiveness of a New Animal Drug for Use in Companion Animals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry #204 entitled "Active Controls in Studies to Demonstrate Effectiveness of a New Animal Drug for Use in Companion Animals." This guidance advises industry on the use of active controls in studies intended to provide substantial evidence of effectiveness of new animal drugs for use in companion animals. The intent of the guidance is to provide information to clinical investigators who conduct studies using active controls and have a basic understanding of statistical principles.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-