

**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 July 13, 2015.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001:

1. *Southwest Bancorp, Inc.*, Stillwater, Oklahoma; to acquire 100 percent of the voting shares of First Commercial Bancshares, Inc., and thereby indirectly acquire voting shares of First Commercial Bank, both in Edmond, Oklahoma.

Board of Governors of the Federal Reserve System, June 15, 2015.

**Michael J. Lewandowski,**

*Associate Secretary of the Board.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2015-D-1777]

**Factors To Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions; Draft Guidance for Investigational Device Exemption Sponsors, Sponsor-Investigators, and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions (IDEs).” The purpose of this draft guidance is to provide greater clarity for FDA staff and IDE sponsors and sponsor-investigators regarding the principal factors that FDA considers when assessing the benefits and risks of IDE applications for human clinical study. The draft guidance also characterizes benefits in the context of investigational research, which includes direct benefits to the subjects and benefits to others (to the extent they are indirect benefits to subjects or reflect the importance of knowledge to be gained). This draft guidance is not final nor is it in effect at this time.

**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 of 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 September 16, 2015.

**ADDRESSES:** An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance entitled “Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions (IDEs)” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and

Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

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. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Sugato De, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5435, Silver Spring, MD 20993-0002, 301-796-6270; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

A primary goal of this guidance is to clarify the factors that FDA considers when assessing risks and anticipated benefits for IDE studies, and how uncertainty may be offset by a variety of risk mitigation measures that can assure appropriate patient and participant protections in investigational research settings. At earlier stages of device development, FDA considers appropriate mitigation measures for anticipated possible risks and unanticipated risks, whereas in later stages, risk mitigation focuses increasingly on the most probable risks. Another important goal of this guidance is to characterize benefits in the context of investigational research, which includes direct benefits to the subjects and benefits to others (to the extent they are indirect benefits to subjects or reflect the importance of knowledge to be gained).

As with the benefit-risk framework for evaluating marketing applications, FDA assessment of benefits and risks for an IDE application takes into account the contextual setting in which the study is being proposed, including but not limited to characterization of the disease or condition being treated or diagnosed, the availability of alternative treatments or diagnostics, and the risks associated with them. When available, information characterizing subject tolerance for risk