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 January 17, 2018.

A. Federal Reserve Bank of Minneapolis (Brendan S. Murdin, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:
1. Alexandra Bosshard, Washington, DC; to both retain and acquire additional shares of Bosshard Banco, Ltd., La Crosse, Wisconsin, and thereby indirectly retain and acquire additional shares of First National Bank of Bangor, Bangor, Wisconsin, and Intercity State Bank, Schofield, Wisconsin, as a member of the Bosshard Family Group that controls Bosshard Banco, Ltd.

B. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:
1. Roy Thomas Pitcock, Jr., Graham, Texas; Medora Jacqueline Pitcock Eubank, Fort Worth, Texas; the Melissa Pitcock Trust, Graham, Texas; and Angela Allison Pitcock Adams, Aledo, Texas (together, the Pitcock Family Group): as a group acting in concert to both retain and acquire additional shares of Graham Savings Financial Corp., and thereby indirectly retain and acquire additional shares of Graham Savings and Loan SSB, both in Graham, Texas.

C. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:
1. Michael D. Werner, as trustee of the Michael D. Werner Revocable Trust, Key West, Florida; and Judith Werner, Waupun, Wisconsin: as a group acting in concert to retain voting shares of National Bancshares, Inc., and thereby indirectly retain voting shares of NBW Bank, both in Waupun, Wisconsin.


Ann E. Misback,
Secretary of the Board.

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 January 26, 2018.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:
1. Caldwell County Bancshares, Inc., Hamilton, Missouri; to acquire Horizon State Bank, Cameron, Missouri.

2. First State Holding Co., Lincoln, Nebraska; to acquire Wallco, Inc., and thereby indirectly acquire The Nehawka Bank, both in Nehawka, Nebraska.

B. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528.
Comments can also be sent electronically to Comments.applications@rich.frb.org:


Ann E. Misback,
Secretary of the Board.
SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, with revision, the mandatory Financial Statements for Holding Companies (FR Y–9; OMB No. 7100–0128).

On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

DATES: Comments must be submitted on or before March 5, 2018.

ADDRESSES: You may submit comments, identified by FR Y–9C, FR Y–9LP, FR Y–9SP, FR Y–9ES, or FR Y–9CS, by any of the following methods:


• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

• Email: regs.comments@federalreserve.gov. Include OMB number in the subject line of the message.

• Fax: (202) 452–3819 or (202) 452–3102.

• Mail: Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board’s website at http://www.federalreserve.gov/apps/foia/proposeregs.aspx as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room 3515, 1801 K Street (between 18th and 19th Streets NW) Washington, DC 20006 between 9:00 a.m. and 5:00 p.m. on weekdays.

Additionally, commenters may send a copy of their comments to the OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of the PRA OMB submission, including the proposed reporting form and instructions, supporting statement, and other documentation will be placed into OMB’s public docket files, once approved. These documents will also be made available on the Federal Reserve Board’s public website at: http://www.federalreserve.gov/apps/reportforms/review.aspx or may be requested from the agency clearance officer, whose name appears below.


SUPPLEMENTARY INFORMATION:

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Federal Reserve’s functions; including whether the information has practical utility;

b. The accuracy of the Federal Reserve’s estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Federal Reserve should modify the proposal prior to giving final approval.

Proposal To Approve Under OMB Delegated Authority the Extension for Three Years, With Revision, of the Following Report


OMB control number: 7100–0128.

Frequency: Quarterly and semiannually.

Reporters: Bank holding companies (BHCs), savings and loan holding companies (SLHCs), securities holding companies (SHCs), and U.S. Intermediate Holding Companies (IHCs) (collectively, holding companies (HCs)).

Estimated annual reporting hours: FR Y–9C (non-advanced approaches holding companies): 125,357 hours; FR Y–9C (advanced approached holding companies): 3,536 hours; FR Y–9LP: 16,969 hours; FR Y–9SP: 42,919; FR Y–9ES: 42 hours; FR Y–9CS: 472 hours.

Estimated average hours per response: FR Y–9C (non-advanced approaches holding companies): 48.14 hours; FR Y–9C (advanced approached holding companies HC): 49.39 hours; FR Y–9LP: 5.27 hours; FR Y–9SP: 5.40 hours FR Y–9ES: 0.50 hours; FR Y–9CS: 0.50 hours.


General description of report:

Pursuant to the Bank Holding Company Act of 1956 (BHC Act), as amended, and the Home Owners’ Loan Act (HOLA), the Federal Reserve requires HCs to provide standardized financial statements to fulfill the Federal Reserve’s statutory obligation to supervise these organizations. HCs file the FRY–9C and FR Y–9LP quarterly, and the FR Y–9SP semiannually, the FR Y–9ES annually, and the FR Y–9CS on a schedule that is determined when this supplement is used.

Proposed revisions: The Board proposes a number of revisions to the FR Y–9C requirements, most of which are consistent with proposed changes to the Federal Financial Institutions Examination Council (FFIEC) Consolidated Reports of Condition and Income (Call Reports) (FFIEC 031, FFIEC 041, and FFIEC 051; OMB No. 7100–0036). The proposed revisions to the FR Y–9C include deletions and consolidations of existing data items into new data items, reductions in reporting frequency, and new and
revised reporting thresholds for certain data items. The Board also proposes to make changes to the reporting forms and instructions for the FR Y–9C, FR Y–9LP, and FR Y–9SP to implement accounting changes pertaining to equity securities under Accounting Standards update (ASU No. 2016–01, “Recognition and Measurement of Financial Assets and Financial Liabilities.”). The accounting changes pertaining to equity securities would be effective beginning with the reports reflecting the March 31, 2018, report date and June 30, 2018 for all other changes. The proposed changes include:

• Deleting and combining of certain data items pertaining to (1) Goodwill and Other intangible assets from Schedule HC, Balance Sheet; (2) U.S. Government agency obligations and structured financial products from Schedule HC–B, Securities; (3) Structured financial products and certain loans and the unpaid principal balance of such loans on Schedule HC–D, Trading Assets; (4) Certain counter-derivatives on Schedule HC–L, Derivatives and Off-Balance sheet items, and (5) Purchased credit card relationships and nonmortgage servicing assets from Schedule HC–M, Memoranda;

• Deleting two preprinted captions for other noninterest income on Schedule HI, Income Statement and certain data items on Schedule HC–D, Trading Assets and Liabilities;

• Deleting Column B (Domestic Office) from Schedule HC–D, Trading Assets and Liabilities;

• Reducing the reporting frequency from quarterly to semiannual and from quarterly to annual for certain data items on the FR Y–9C report;

• Increasing and adding reporting thresholds for certain data items in four FR Y–9C schedules;

• Revising the reporting forms and instructions to implement the reporting of equity securities under ASU–2016–01 and

• Moving “Goodwill” from Schedule HC to Schedule HC–M, Memoranda.

Legal authorization and confidentiality: The Board’s Legal Division has determined that the FR Y–9 family of reports is authorized by section 5(c) of the Bank Holding Company Act (12 U.S.C. 1844(c)), section 10 of Home Owners’ Loan Act (12 U.S.C. 1467a(b) and 1850a(c)(1)), section 165 of the Dodd-Frank Act (12 U.S.C. 5365), and section 252.153(b)(2) of Regulation YY (12 CFR 252.153(b)(2)). The obligation of covered HCs to report this information is mandatory. In general, the Board does not consider the financial data in these reports to be confidential. However, a respondent may request confidential treatment pursuant to sections (b)(4), (b)(6), and (b)(8) of the Freedom of Information Act (5 U.S.C. 552(b)(4), (b)(6), and (b)(8)). The applicability of these exemptions would need to be reviewed on a case by case basis.


Ann E. Mishack, Secretary of the Board.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0809]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that LUXTURNA (voretigene neparvovec), manufactured by Spark Therapeutics, Inc., meets the criteria for a priority review voucher. LUXTURNA (voretigene neparvovec) is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physician(s).


Leslie Kux, Associate Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6928]

Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pediatric Advisory Committee (PAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comments.

DATES: The meeting will be held on March 23, 2018, from 8:30 a.m. to 3:05 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due