

this second notice to request comments regarding the following: (1) Whether the collection of information is necessary for the proper performance of FHFA functions, including whether the information has practical utility; (2) the accuracy of FHFA's estimates of the burdens of the collection of information; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Dated: July 26, 2018.

Kevin Winkler,

Chief Information Officer, Federal Housing Finance Agency.

[FR Doc. 2018-16350 Filed 7-30-18; 8:45 am]

BILLING CODE 8070-01-P

FEDERAL MARITIME COMMISSION

Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments on the agreement to the Secretary by email at Secretary@fmc.gov, or by mail, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreement are available through the Commission's website (www.fmc.gov) or by contacting the Office of Agreements at (202)-523-5793 or tradeanalysis@fmc.gov.

Agreement No.: 201263.

Agreement Name: Maersk/MSC/Zim Cooperative Working Agreement.

Parties: Maersk Line A/S; Mediterranean Shipping Company S.A.; and Zim Integrated Shipping Services Ltd.

Filing Party: Wayne Rohde, Cozen O'Connor.

Synopsis: The Agreement authorizes the parties to share space and cooperate on the provision of service strings in the trade between Asia and the U.S. East Coast.

Proposed Effective Date: 9/8/2018.

Location: <https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/14256>.

Dated: July 25, 2018.

Rachel Dickon,

Secretary.

[FR Doc. 2018-16280 Filed 7-30-18; 8:45 am]

BILLING CODE P

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 August 23, 2018.

A. Federal Reserve Bank of Minneapolis (Mark A. Rauzi, Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. *Mackinac Financial Corporation, Manistique, Michigan*; to acquire 100 percent of the voting shares of Lincoln Community Bank, Merrill, Wisconsin.

Board of Governors of the Federal Reserve System, July 26, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018-16337 Filed 7-30-18; 8:45 am]

BILLING CODE P

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 August 24, 2018.

A. Federal Reserve Bank of Minneapolis (Mark A. Rauzi, Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. *Citizens Community Bancorp, Inc., Eau Claire, Wisconsin*; to acquire 100 percent of United Bank, Osseo, Wisconsin.

B. Federal Reserve Bank of St. Louis (David L. Hubbard, Senior Manager), P.O. Box 442, St. Louis, Missouri 63166-2034. Comments can also be sent electronically to

Comments.applications@stls.frb.org:

1. *Old National Bancorp, Evansville, Indiana*; to merge with Klein Financial, Inc., Chaska, Minnesota, and thereby indirectly acquire KleinBank, also of Chaska, Minnesota.

Board of Governors of the Federal Reserve System, July 25, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018-16377 Filed 7-30-18; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities; Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, with revision, the Financial Statements for Holding Companies (FR Y-9 family of reports) (OMB No. 7100-0128).

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452-3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263-4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

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.

SUPPLEMENTARY INFORMATION: On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Final approval under OMB delegated authority the extension for three years, with revision, of the following reports:

Report title: Financial Statements for Holding Companies.

Agency form number: FR Y-9C, FR Y-9LP, FR Y-9SP, FR Y-9ES, and FR Y-9CS.

OMB control number: 7100-0128.

Effective Date: June 30, 2018.

Frequency: Quarterly and semiannually.

Respondents: Bank holding companies, savings and loan holding companies, securities holding companies, and U.S. intermediate holding companies (collectively, holding companies (HCs)).

Estimated number of respondents: FR Y-9C (non-advanced approaches

holding companies): 638; FR Y-9C (advanced approaches holding companies): 18; FR Y-9LP: 775; FR Y-9SP: 3,837 FR Y-9ES: 82; FR Y-9CS: 236.

Estimated average hours per response: FR Y-9C (non-advanced approaches holding companies): 46.29 hours; FR Y-9C (advanced approaches holding companies HCs): 47.54 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.

Estimated annual burden hours: FR Y-9C (non-advanced approaches holding companies): 118,132 hours; FR Y-9C (advanced approaches holding companies): 3,423 hours; FR Y-9LP: 16,337 hours; FR Y-9SP: 41,440 hours; FR Y-9ES: 41 hours; FR Y-9CS: 472 hours.

General description of report: The FR Y-9C, FR Y-9LP, and FR Y-9SP serve as standardized financial statements for the consolidated holding company. The FR Y-9ES is a financial statement for HCs that are Employee Stock Ownership Plans. The Board uses the FR Y-9CS (a free-form supplement) to collect additional information deemed to be critical and needed in an expedited manner. The FR Y-9 family of reporting forms continues to be the primary source of financial data on HCs that examiners rely on between on-site inspections. Financial data from these reporting forms is used to detect emerging financial problems, review performance, conduct pre-inspection analysis, monitor and evaluate capital adequacy, evaluate HC mergers and acquisitions, and analyze an HC's overall financial condition to ensure the safety and soundness of its operations. The Board requires HCs to provide standardized financial statements to fulfill the Board's statutory obligation to supervise these organizations. HCs file the FR Y-9C on a quarterly basis, the FR Y-9LP quarterly, 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.

Legal authorization and confidentiality: 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)), section 618 of the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank Act") (12 U.S.C. 1850a(c)(1)), and section 165 of the Dodd-Frank Act (12 U.S.C. 5365). The obligation of covered institutions to report this information is mandatory. With respect to the FR Y-9LP, FR Y-9SP, FR Y-9ES, and FR Y-9CS, as

well as most items on the FR Y-9C, the information collected would generally not be accorded confidential treatment. If confidential treatment is requested by a respondent, the Board will review the request to determine if confidential treatment is appropriate. With respect to the FR Y-9C, Schedule HI's item 7(g) "FDIC deposit insurance assessments," Schedule HC-P's item 7(a) "Representation and warranty reserves for 1-4 family residential mortgage loans sold to U.S. government agencies and government sponsored agencies," and Schedule HC-P's item 7(b) "Representation and warranty reserves for 1-4 family residential mortgage loans sold to other parties" are considered confidential. Such treatment is appropriate because the data is not publicly available and could cause substantial harm to the competitive position of the respondent. The public release of this confidential data may impair the Board's future ability to collect similarly confidential data. Thus, this information may be kept confidential under exemptions (b)(4) of the Freedom of Information Act, which exempts from disclosure "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential" (5 U.S.C. 552(b)(4)), and (b)(8) of the Freedom of Information Act, which exempts from disclosure information related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions (5 U.S.C. 552(b)(8)). If confidential treatment is requested by a respondent for other items in the FR Y-9C, the Board will review the request to determine if confidential treatment is appropriate.

Current Actions: On April 30, 2018, the Board published a notice in the **Federal Register** (83 FR 18843) requesting public comment for 60 days on the extension, with revision, of the FR Y-9C report, and the extension, without revision, of the FR Y-9LP, FR Y-9SP, FR Y-9ES, and FR Y-9CS report. The Board proposed to implement a number of revisions to the FR Y-9C requirements, most of which were consistent with changes now implemented on 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 included deleting certain data items and consolidating existing data items into new data items, as well as adding new or raising existing reporting

thresholds for certain data items to reduce reporting burden. The comment period expired June 29, 2018.

Detailed Discussion of Public Comments

The Federal Reserve received one comment from a banking association. The commenter noted several inconsistencies on the FR Y-9C report form and one inconsistency on the instructions when compared to the Call Report pertaining to Schedule HC-Q Memoranda items 4.b and 4.d, column A and Schedule HC-S Column G instructions and requested clarification on the proper reporting. The draft report form was inadvertently updated to reflect the removal of items 4.b and 4.d and a line item reference on the instructions for Schedule HC-S Column G was also inadvertently struck through. The Board has revised these items so that both the report form and instructions align with the Call Report. Additionally, the commenter noted an inconsistency between the caption on the report form and the caption on the instructions pertaining to *Equity investments without readily determinable fair values* on Schedule HC-F line item 4 on the FR Y-9C report. The Board has updated the instructions so that the report form and instructions align.

The revisions will be implemented as proposed, with the modifications described above, effective for the June 30, 2018, report date.

Board of Governors of the Federal Reserve System, July 25, 2018.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2018-16265 Filed 7-30-18; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Relinquishment From Diagnostic Quality Assurance

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of delisting.

SUMMARY: The Patient Safety Rule authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be “delisted” by the Secretary if it is found to no longer

meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO’s listing expires. AHRQ has accepted a notification of voluntary relinquishment from Diagnostic Quality Assurance of its status as a PSO, and has delisted the PSO accordingly. Diagnostic Quality Assurance, PSO number P0170, submitted this request for voluntary relinquishment after receiving a Notice of Preliminary Finding of Deficiency.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on July 1, 2018.

ADDRESSES: Both directories can be accessed electronically at the following HHS website: <http://www.pso.ahrq.gov/> listed.

FOR FURTHER INFORMATION CONTACT:

Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Room 06N94B, Rockville, MD 20857; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; Email: psa@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to b-26, (Patient Safety Act) and the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, 73 FR 70732-70814, establish a framework by which hospitals, doctors, and other health care providers may voluntarily report information to Patient Safety Organizations (PSOs), on a privileged and confidential basis, for the aggregation and analysis of patient safety events.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be “delisted” if

it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO’s listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

AHRQ has accepted a notification from Diagnostic Quality Assurance, a component entity of Quality Star, LLC, to voluntarily relinquish its status as a PSO. Accordingly, Diagnostic Quality Assurance was delisted effective at 12:00 Midnight ET (2400) on July 1, 2018. AHRQ notes that that Diagnostic Quality Assurance submitted this request for voluntary relinquishment following receipt of the Notice of Preliminary Finding of Deficiency sent on April 10, 2018.

More information on PSOs can be obtained through AHRQ’s PSO website at <http://www.pso.ahrq.gov>.

Francis D. Chesley, Jr.,

Acting Deputy Director.

[FR Doc. 2018-16327 Filed 7-30-18; 8:45 am]

BILLING CODE 4160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0007]

Biosimilar User Fee Rates for Fiscal Year 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for biosimilar user fees for fiscal year (FY) 2019. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Biosimilar User Fee Amendments of 2017 (BsUFA II), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development; review of certain applications for approval of biosimilar biological products; and each biosimilar biological product approved in a biosimilar biological product application.

BsUFA II directs FDA to establish, before the beginning of each fiscal year, the amount of initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application and