

The initial decision of the presiding officer in this proceeding shall be issued by January 6, 2017 and the final decision of the Commission shall be issued by July 20, 2017.

**Karen V. Gregory,**  
Secretary.

[FR Doc. 2016-00516 Filed 1-12-16; 8:45 am]

**BILLING CODE 6731-0AA-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, 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 Web site ([www.fmc.gov](http://www.fmc.gov)) or by contacting the Office of Agreements at (202) 523-5793 or [tradeanalysis@fmc.gov](mailto:tradeanalysis@fmc.gov).

*Agreement No.:* 011787-001.

*Title:* NSCSA/NYK Middle East/  
Europe Space Charter Agreement

*Parties:* National Shipping Company of Saudi Arabia and Nippon Yusen Kaisha.

*Filing Party:* Robert Shababb; NYK Line (North America) Inc.; 300 Lighting Way, 5th Floor; Secaucus, NJ 07094.

*Synopsis:* The amendment adds the Mediterranean Coast of Europe to the geographical scope of the agreement, and updates language in the agreement concerning routine operational and administrative matters.

By Order of the Federal Maritime Commission.

Dated: January 8, 2016.

**Karen V. Gregory,**  
Secretary.

[FR Doc. 2016-00515 Filed 1-12-16; 8:45 am]

**BILLING CODE 6731-AA-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 February 8, 2016.

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

1. *NCAL Bancorp, Los Angeles, California;* to acquire Commercial Bank of California, Irvine, California.

Board of Governors of the Federal Reserve System, January 8, 2016.

**Margaret McCloskey Shanks,**  
Deputy Secretary of the Board.

[FR Doc. 2016-00511 Filed 1-12-16; 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:** Notice is hereby given of the final approval of a proposed information collection by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority. 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.

**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.

Final approval under OMB delegated authority to revise and extend for three years the following report:

*Report title:* Annual Company-Run Stress Test Report for State Member Banks, Bank Holding Companies, and Savings and Loan Holding Companies with Total Consolidated Assets Greater Than \$10 Billion and Less Than \$50 Billion.

*Agency form number:* FR Y-16.

*OMB control number:* 7100-0356.

*Frequency:* Annual.

*Reporters:* Bank holding companies (BHCs) and savings and loan holding companies (SLHCs) with average total consolidated assets of greater than \$10 billion but less than \$50 billion, and any affiliated or unaffiliated state member bank (SMB) with average total consolidated assets of more than \$10 billion but less than \$50 billion, excluding SMB subsidiaries of covered companies.

*Estimated annual reporting hours:* BHCs: 24,388 hours; SLHCs: 3,283 hours; SMBs: 4,690 hours; One-time implementation: 7,200 hours.

*Estimated average hours per response:* BHCs: 469 hours; SLHCs: 469 hours; SMBs: 469 hours; One-time implementation: 3,600 hours.

*Number of respondents:* BHCs: 52; SLHCs: 7; SMBs: 10; One-time implementation: 2.

*General description of report:* This information collection is authorized pursuant section 165(i)(2) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), which specifically authorizes the Board to issue regulations implementing the annual stress testing requirements for its supervised institutions (12 U.S.C. 5365(i)(2)(C)). More generally, with respect to BHCs, section 5(c) of the Bank

Holding Company Act (12 U.S.C. 1844(c)), authorizes the Board to require a BHC and any subsidiary “to keep the Board informed as to—(i) its financial condition, [and] systems for monitoring and controlling financial and operating risks . . . .” Section 9(6) of the Federal Reserve Act (12 U.S.C. 324), requires SMBs to make reports of condition to their supervising Reserve Bank in such form and containing such information as the Board may require. Finally, with respect to SLHCs, under section 312 of the Dodd-Frank Act (12 U.S.C. 5412), the Board succeeded to all powers and authorities of the Office of Thrift Supervision, U.S. Department of the Treasury, and its Director, including the authority to require SLHCs to “file . . . such reports as may be required . . . in such form and for such periods as the [agency] may prescribe” (12 U.S.C. 1467a(b)(2)).

The obligation to respond is mandatory. Section 165(i)(2)(A) provides that “financial companies that have total consolidated assets [meeting the asset thresholds] . . . and are regulated by a primary Federal financial regulatory agency shall conduct annual stress tests.” Section 165(i)(2)(B) provides that a company required to conduct annual stress tests “shall submit a report to the Board and to its primary financial regulatory agency at such time, in such form, and containing such information as the primary financial regulatory agency shall require” (12 U.S.C. 5365(i)(2)(B)).

As noted under section 165(i)(2)(C)(iv), companies conducting annual stress tests under these provisions are “require[d] . . . to publish a summary of the results of the required stress tests.” (12 U.S.C. 5365(i)(2)(C)(iv)). Regarding the information collected by the Board, however, as such information will be collected as part of the Board’s supervisory process, it may be accorded confidential treatment under Exemption 8 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(8)). This information also is the type of confidential commercial and financial information that may be withheld under Exemption 4 of FOIA (5 U.S.C. 552(b)(4)).

*Abstract:* The FR Y–16 applies to BHCs, SLHCs,<sup>1</sup> and SMBs, excluding SMB subsidiaries of covered

companies,<sup>2</sup> with average total consolidated assets of greater than \$10 billion but less than \$50 billion. The annual FR Y–16 report collects quantitative projections of revenues, losses, assets, liabilities, and capital across three scenarios provided by the Federal Reserve (baseline, adverse, and severely adverse) and qualitative supporting information on the methodologies and processes used to develop these internal projections. The FR Y–16 collects data through two primary schedules: (1) The Results Schedule (which includes the quantitative results of the stress tests under the baseline, adverse, and severely adverse scenarios for each quarter of the planning horizon) and (2) the Scenario Variables Schedule. In addition, respondents are required to submit a summary of the qualitative information supporting its quantitative projections. The qualitative supporting information must include:

- A description of the types of risks included in the stress test;
- a summary description of the methodologies used in the stress test;
- an explanation of the most significant causes for the changes in regulatory capital ratios, and
- the use of the stress test results.

**Results Schedule:** For each of the three supervisory scenarios (Baseline, Adverse, and Severely Adverse), data are reported on two supporting schedules: (1) the Income Statement Schedule and (2) the Balance Sheet Schedule. In addition, the Results Schedule includes a Summary Schedule, which summarizes key results from the Income Statement and Balance Sheet Schedules.

**Income statement data** are collected on a projected quarterly basis showing both projections of revenues and losses. These data are organized in a similar fashion to the mandatory Consolidated Financial Statements for Holding Companies (FR Y–9C; OMB No. 7100–0128), Schedule HI—Consolidated Income Statement, and the Consolidated Report of Condition and Income (FFIEC 031 and FFIEC 041; OMB No. 7100–0036) (Call Report), Schedule RI—Income Statement. For example, respondents project net charge-offs by loan type (stratified by twelve specific loan types), gains and losses on securities, pre-provision net revenue, and other key components of net

income (*i.e.*, provision for loan and lease losses, taxes, etc.).

**Balance sheet data** are collected on a quarterly basis for projections of certain assets, liabilities, and capital. These data are organized in a similar fashion to the FR Y–9C, Schedule HC—Consolidated Balance Sheet, and Call Report, Schedule RC—Balance Sheet. For example, respondents would project loans, allowance for loan and lease losses, securities, funding sources, and equity capital. Capital data are also collected on a projected quarterly basis and include components of regulatory capital, including the projections of risk weighted assets and capital actions such as common dividends and share repurchases.

**Scenario Variables Schedule:** To conduct the stress tests, an institution may choose to project additional economic and financial variables beyond the mandatory supervisory scenarios provided to estimate losses or revenues for some or all of its portfolios. In such cases, the institution would be required to complete the Scenario Variables Schedule for each scenario where the institution chooses to use additional variables. The Scenario Variables Schedule collects information on the additional scenario variables used over the planning horizon for each supervisory scenario.

**Current Actions:** The revisions to the FR Y–16 report would be effective for the 2016 stress test cycle and would: (1) Change the report as-of date from September 30 to December 31, (2) change the reporting submission or due date from March to July, and (3) modify the reporting instructions to make corresponding changes to the dates, reflect technical changes related to final implementation of BASEL III requirements, and to clarify certain of the instructions in coordination with the other federal regulatory agencies. None of the changes impose additional information collection requirements.

On July 8, 2015, the Federal Reserve published a notice in the **Federal Register** (80 FR 39117) requesting public comment for 60 days on the proposal to revise and extend for three years the Annual Company-Run Stress Test Report for \$10–50 Billion Companies. The comment period for this notice expired on September 8, 2015. The Federal Reserve did not receive any comments, and the information collection will be revised as proposed.

<sup>1</sup> The Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) annual company-run stress testing requirements do not apply to SLHCs until 2017, and will only apply to an SLHC that is subject to minimum regulatory capital requirements. See 12 CFR 252.13(b)(2)(iii).

<sup>2</sup> “Covered company” is defined in 12 CFR 252(g) as a BHC (other than a foreign banking organization (FBO)) with average total consolidated assets of \$50 billion or more; a U.S. intermediate holding company (IHC) subject to 12 CFR 252.153, and a nonbank financial company supervised by the Board.

Board of Governors of the Federal Reserve System, January 7, 2016.

**Robert deV. Frierson,**  
Secretary of the Board.

[FR Doc. 2016-00441 Filed 1-12-16; 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 January 28, 2016.

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

1. *Kristina Davidson, Greenwood Village, Colorado; and Zachary Davidson and Tiffany Davidson, both of Nine Mile Falls, Washington; Shauna Cumin and Macaulay Kerr, both of Billings, Montana; Robert Kerr, Spokane Washington; Scott Kerr, Satellite Beach, Florida; the Joshua K. Davidson Irrevocable Trust, Brighton, Colorado; and the Michelle M. Davidson Irrevocable Trust, Englewood, Colorado,* as members of the Davidson Family group and acting in concert; to retain voting shares of First American Bancorp, and thereby indirectly retain voting shares of First American State Bank, both in Greenwood Village, Colorado.

Board of Governors of the Federal Reserve System, January 8, 2016.

**Margaret McCloskey Shanks,**  
Deputy Secretary of the Board.

[FR Doc. 2016-00512 Filed 1-12-16; 8:45 am]

BILLING CODE 6210-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-5106]

#### Clinical Outcome Assessment Compendium

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

**ACTION:** Notice; establishment of docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the establishment of a docket to receive suggestions, recommendations, and comments from interested parties (including academic institutions, regulated industry, and patient groups) on our pilot "Clinical Outcome Assessment Compendium" (COA Compendium). FDA has developed a Web site that describes the purpose of the pilot COA Compendium and provides background information. Comments received on the pilot COA Compendium during its pilot phase will help FDA determine its utility, and may assist FDA in developing future iterations of the COA Compendium and identifying best methods for conveying COA Compendium information on FDA's Web site.

**DATES:** Submit either electronic or written comments by March 14, 2016.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner

detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2015-N-5106 for "Clinical Outcome Assessment Compendium." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the