Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202)–523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 011488–005.

Title: CSVV/Cool Carriers Space Charter Agreement.

Parties: Cool Carriers AB and CSAV Sud Americana De Vapores S.A.

Filing Party: David F. Smith, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006.

Synopsis: The Amendment changes the name of Agreement party NYKCool AB to Cool Carriers AB and makes related conforming changes.

Agreement No.: 012287–001.

Title: Siem Car Carriers AS/Mitsui O.S.K Lines Ltd. Space Charter Agreement.

Parties: Siem Car Carriers AS and Mitsui O.S.K Lines, Ltd.

Filing Party: Ashley W. Craig, Esq. and Elizabeth K. Lowe, Esq.; Venable LLP; 575 Seventh Street NW., Washington, DC 20004.

Synopsis: The Amendment adds Germany and the U.S. Gulf Coast to the geographic scope of the Agreement.

Agreement No.: 012317.

Title: MOL/''K'' Line U.S. Atlantic and China Sailing Agreement.

Parties: Mitsui O.S.K. Lines, Ltd. and Kawasaki Kisen Kaisha, Ltd.

Filing Party: Eric. C. Jeffrey, Esq.; Nixon Peabody LLP; 401 9th Street NW., Suite 900; Washington, DC 20004.

Synopsis: The Agreement authorizes the Parties to coordinate their sailings and space requirements in the trade, and to discuss and agree upon the volumes, cargo characteristics, shipping requirements, and other transportation features of service for a specific shipper, when such shipper has given written authorization for such discussion and agreement.

By Order of the Federal Maritime Commission.

Dated: February 13, 2015.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2015–03506 Filed 2–18–15; 8:45 am]

BILLING CODE 6730–01–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 March 5, 2015.

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

1. *Bruce M. Williams and Joyce L. Williams, Anaheim, California; Brian Edward Williams, Yorba Linda, California; Ashley Maureen Williams, Orange, California; Brooke Ann Williams, Anaheim, California; Michael Robert Williams, Las Vegas, Nevada; Rebecca Kristy Williams, Fullerton, California; the Gladys M. Bryant Living Trust, Anaheim, California; and Bruce M. Williams as Trustee of the Gladys M. Bryant Living Trust, Anaheim, California;* to acquire and retain 10 percent or more of the shares of CalWest Bancorp and thereby indirectly South County Bank National Association, both of Rancho Santa Margarita, California.

Board of Governors of the Federal Reserve System, February 13, 2015.

Michael J. Lewandowski,

Assistant Secretary of the Board.

[FR Doc. 2015–03426 Filed 2–18–15; 8:45 am]

BILLING CODE 6210–01–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 March 16, 2015.

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

1. *First Mercantile Financial Corporation,* to become a bank holding company by acquiring 100 percent of the outstanding shares of Putnam 1st Mercantile Bank, both of Cookeville, Tennessee.

Board of Governors of the Federal Reserve System, February 13, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015–03427 Filed 2–18–15; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1399]

Guidance for Entities Considering Whether To Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' This draft guidance is intended to inform entities that are considering registering as outsourcing facilities under section 503B of the Federal Food,

Drug, and Cosmetic Act (the FD&C Act), as added by the Drug Quality and Security Act (DQSA), of the regulatory implications of registration as an outsourcing facility.

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 May 20, 2015.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993. 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–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Guidance for Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' On November 27, 2013, President Obama signed the DQSA (Pub. L. 113–54) into law. The DQSA added a new section 503B to the FD&C Act that created a category of entities called ''outsourcing facilities.'' Section 503B(d)(4) of the FD&C Act (21 U.S.C. 353b(d)(4)) defines an outsourcing facility, in part, as a facility that complies with all of the requirements of section 503B, including registering with FDA as an outsourcing facility and paying associated fees. If the conditions outlined in section 503B(a) of the FD&C Act are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from certain sections of the FD&C Act, including section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs).

FDA has received questions about whether entities engaged in various types of activities (*e.g.,* a facility that is compounding only non-sterile drugs or only repackaging biological products) should register as an outsourcing facility. Because entities that register as outsourcing facilities in fiscal year 2015 (beginning October 1, 2014) must pay a registration fee and FDA has determined that fees paid pursuant to sections 503B and 744K of the FD&C Act will not be refunded, FDA is issuing this guidance to answer some of these questions and to provide potential registrants additional information about the regulatory impact of registering as an outsourcing facility.

Elsewhere in this volume of the **Federal Register**, FDA is announcing the availability of separate FDA guidance documents on (1) mixing, diluting, or repackaging biological products outside the scope of an approved biologics license application, and (2) repackaging certain human drug products by pharmacies and outsourcing facilities. These guidance documents describe FDA's compliance policies with respect to biological products that are mixed, diluted, or repackaged outside the scope of an approved biologics license application and repackaged human drugs.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on registering as an outsourcing facility under section 503B of the FD&C Act. 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *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 document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: February 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03416 Filed 2–18–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2138]

Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled ''Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' Under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), an outsourcing facility must submit adverse event reports to FDA. This guidance explains FDA's current thinking on adverse event reporting for outsourcing facilities.

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 to finalize the guidance, submit either electronic or written comments on this draft guidance by May 20, 2015. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by May 20, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building,