FEDERAL MARITIME COMMISSION

Sunshine Act Meeting


TIME AND DATE: November 17, 2016—10 a.m.

PLACE: 800 North Capitol Street NW., First Floor Hearing Room, Washington, DC.

STATUS: The meeting agenda originally published November 15, 2016, 81 FR 80055, is revised to add item 4 in the Closed Session. The change was made upon a unanimous vote of the Commission. The first portion of the meeting will be held in Open Session and will be streamed live at http://fmc.capitolconnection.org/; the second portion in closed session.

MATTERS TO BE CONSIDERED:

Open Session
1. Briefing by the Chairman on the World Shipping Summit
2. Staff Briefing on OTI License Renewals

Closed Session
1. Staff Briefing on Hanjin Bankruptcy and Shipping Disruptions
2. Update on the PierPASS Third-party Audit and Extended Gate Workshop
3. Empirical Analysis of Changing Alliance Structures in the Transpacific Trade
4. THE Alliance Agreement, FMC Agreement No. 012439

CONTACT PERSON FOR MORE INFORMATION:
Rachel E. Dickon, Assistant Secretary, (202) 523 5725.

Rachel E. Dickon, Assistant Secretary.

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 December 6, 2016.

A. 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. Jeffrey Harris Lowery, M.D., Eads, Tennessee; to acquire more than 10 percent of the shares of Germantown Capital Corporation, Inc., and thereby indirectly control more than 10 percent of the voting shares of First Capital Bank, both in Germantown, Tennessee.

Yao-Chin Chao,
Assistant Secretary of the Board.

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 December 13, 2016.

A. 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. Central Bank and Central Acquisition Sub, Inc., both in Little Rock, Arkansas; to become bank holding companies through the merger of Central Acquisition Sub, Inc. with and into Pinnacle Bancshares, Inc., Rogers, Arkansas, Simultaneously with the merger, Pinnacle Bank, Rogers, Arkansas, will be merged with and into Central Bank.
2. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198—0001:
   1. Equity Bancshares, Inc. and Prairie Merger Sub, Inc., both in Wichita, Kansas; for Prairie Merger Sub, Inc. to become a bank holding company for a moment in time by acquiring Prairie State Bancshares, Inc., and thereby indirectly acquiring State Bank, both in Hoxie, Kansas. Immediately thereafter, Prairie State Bancshares, Inc. will merge into Equity Bancshares, Inc.

Yao-Chin Chao,
Assistant Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA—2016–D–2241]

Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling: Draft Guidance for Industry; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice of availability; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the notice, published in the Federal Register of September 9, 2016 (81 FR 62509), announcing the availability of the draft guidance for industry entitled “Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling.” We are reopening the comment period in response to a request...
for an extension to allow interested persons additional time to submit comments.

**DATES:** Submit either electronic or written comments by February 21, 2017.

**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–2016–D–2241 for “Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling.” 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.” We will review this copy, including the claimed confidential information, in our 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 docket, 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 electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOREIGN INFORMATION CONTACT:** Gizlan Robert-Baldo, Center for Food Safety and Applied Nutrition (HFS–850), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1451.

**SUPPLEMENTARY INFORMATION:** In the Federal Register of September 9, 2016 (81 FR 62509), we published a notice announcing the availability of a draft guidance entitled, “Substantiation for Structure/Function Claims Made in Infant Formula Labels and Labeling.” Although you can comment on any guidance at any time, to ensure that we consider comments on this draft guidance before we begin work on the final version, interested persons were originally given until November 8, 2016, to comment on the draft guidance.

Following publication of the September 9, 2016, notice of availability, we received a request for a 90-day extension of the comment period. The request expressed concern that the current 60-day comment period does not allow sufficient time to develop a thoughtful and comprehensive response to the draft guidance. We have considered the request and are reopening the comment period for an additional 90 days, until February 21, 2017. We believe that this reopening allows adequate time for interested persons to submit comments without significantly delaying finalizing the guidance.

Dated: November 15, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–27941 Filed 11–18–16; 8:45 am]

**BILLING CODE 4164–01–P**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Food and Drug Administration**

[Docket No. FDA–2014–N–1050]

**Report of the Center for Veterinary Medicine Working Group on the Regulation of Animal Drug Availability Act Combination Drug Medicated Feeds; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a report of a Center for Veterinary Medicine (CVM) working group proposing possible changes to the current review processes for new animal drug applications (NADAs) providing for the use of multiple new animal drugs in combination drug medicated feeds. This report was developed for the use of the CVM committee that will be participating in discussions concerning the reauthorization of the animal drug user fee program for 5 additional years through fiscal year 2023 (per the Animal Drug User Fee Amendments (ADUFA) IV).

**ADDRESSES:** For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.