

unauthorized access to sensitive customer information, issues of confidentiality may arise if the Board were to obtain a copy of a customer notice during the course of an examination, a copy of a SAR, or other sensitive customer information. In such cases, the information would likely be exempt from disclosure to the public under the Freedom of Information Act (5 U.S.C. 552(b)(3), (4), (6), and (8)). Also, a federal employee is prohibited by law from disclosing a SAR or the existence of a SAR (31 U.S.C. 5318(g)).

Board of Governors of the Federal Reserve System, September 6, 2017.

Ann E. Misback,

Secretary of the Board.

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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 October 5, 2017.

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

1. *Central Bancshares, Inc.* to acquire, through its newly formed subsidiaries, CBI Midco, Inc. and CBI Merger Sub, Inc., all of Cambridge, Nebraska, up to 100 percent of the voting shares of Republic Corporation, and thereby indirectly acquire United Republic Bank, both of Omaha, Nebraska.

In connection with this application CBI Midco, Inc. and CBI Merger Sub, Inc., have applied to become bank holding companies.

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

1. *Pacific Premier Bancorp, Inc.*; to acquire 100 percent of Plaza Bancorp, and thereby indirectly acquire Plaza Bank, all of Irvine, California.

Board of Governors of the Federal Reserve System, September 6, 2017.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2017-19211 Filed 9-11-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4765]

Center for Devices and Radiological Health Premarket Approval Application Critical to Quality Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency or we) Center for Devices and Radiological Health (CDRH or Center), Office of Compliance (OC) and Office of In Vitro Diagnostics and Radiological Health (OIR) is announcing its Premarket Approval Application Critical to Quality (PMA CtQ) pilot program. Participation in the PMA CtQ pilot program is voluntary and the program aims to evaluate device design and manufacturing process quality information early on to assist FDA in its review of the PMA manufacturing section and post-approval inspections. This voluntary pilot program is part of the FDA's ongoing Case for Quality effort to apply innovative strategies that promote medical device quality and is a joint effort between the FDA's CDRH and Office of Regulatory Affairs (ORA). The pilot program is intended to provide qualifying PMA applicants with the option to engage FDA on

development of CtQ controls for their device and forego the standard PMA preapproval inspection. FDA would in turn, focus on the PMA applicant's implementation of the CtQ controls during a postmarket inspection.

DATES: FDA is seeking participation in the voluntary PMA CtQ pilot program starting from September 29, 2017. See the "Participation" section for instructions on how to submit a request to participate. This pilot program will run from September 29, 2017, to December 31, 2018. The voluntary PMA CtQ pilot program will accept the first nine participants with submissions that meet the acceptance criteria.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-