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.

[FR Doc. 2017–19217 Filed 9–11–17; 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 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]

BILLING CODE 6210–01–P

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–

2017–N–4765 for ''Center for Devices and Radiological Health Premarket Approval Application Critical to Quality Pilot Program.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: 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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Bleta Vuniqi, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3463, Silver Spring, MD 20993, 301–796–5497, *Bleta.Vuniqi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

CDRH believes that proactive engagement with PMA applicants and a focused inspectional approach will promote quality in device design and manufacturing. CDRH plans to initiate the voluntary PMA CtQ pilot program focusing on activities critical to product and process quality starting September 29, 2017. The Center intends to work collaboratively with PMA applicants identified to participate in the PMA CtQ pilot program to define characteristics of the PMA device that are critical to product quality and how these characteristics are controlled in design and manufacturing prior to the postmarket inspection. PMA applicants can expect discussions during the inspection to relate to those factors most likely to impact device quality by working with FDA, before PMA approval, on defining activities critical to product and process quality. Improvements in overall device quality may reduce device failures and recalls, and translate into more efficient utilization of resources for CDRH, ORA, and the device industry. Previously, CDRH's OC completed the implantable devices containing batteries Critical to Quality Inspection pilot which established a collaborative framework for determining specific operations, design considerations, and controls that most impact the quality and safety of these devices (Ref. 1). Post-inspection feedback from ORA and CDRH's OC indicated that FDA can improve its approach for medical device inspections by focusing on areas critical to quality of the device, which in turn will change the compliance focus to influence better device quality. In addition, feedback received from industry participants indicated that many of the risks for devices reside in product and process design and post-production activities.

Whether firms are appropriate candidates for participation in this voluntary PMA CtQ pilot program is determined based on the factors listed in Section A. Participation Criteria. Upon applicant's pre-PMA q-submission meeting request, FDA will identify appropriate candidates to participate in this voluntary pilot program. Due to resource constraints, we intend to limit this voluntary pilot program to a maximum of nine participants. FDA intends to work with each participating applicant to identify characteristics of its device and its manufacture that are critical to its quality, which may include specific device features or quality control practices. The identified CtQ characteristics and controls will help focus FDA's post-approval inspectional approach.

The aim of the voluntary PMA CtQ pilot program is to have the applicant discuss device design and manufacturing process quality information with FDA early on to assist FDA in its review of the PMA manufacturing section and post-approval inspections. The goal of this voluntary pilot program is to streamline the premarket approval process while assuring that a firm's quality system includes rigorous controls for features and characteristics considered critical to the safety and effectiveness of the device. FDA believes that focusing on these activities may also lead to fewer device failures, a decrease in device recalls, and improved device innovation and efficiencies. For participants in the voluntary PMA CtQ pilot program, FDA intends to forego conducting a preapproval inspection, which it would usually conduct, and instead conduct a more focused post-approval inspection. That post-approval inspection would focus on the design, manufacturing, and quality assurance practices identified by the applicant in its PMA. In addition, this voluntary pilot program is part of the FDA's ongoing Case for Quality effort to apply innovative strategies that promote medical device quality instead of focusing only on compliance with the Quality System regulation (Ref. 2). This voluntary PMA CtQ pilot program does not represent a new requirement; instead, it is an opportunity to promote quality in device manufacturing, timely review of the PMA manufacturing section and more effective use of inspectional resources, and an enhanced opportunity to engage with firms regarding device quality prior to marketing of the device. This voluntary PMA CtQ pilot program augments the FDA's traditional Quality System Inspection Technique (QSIT) inspectional approach, and does not replace it (Ref. 3).

Combination products, products regulated by the Center for Biologics Evaluation and Research, and companion diagnostic In Vitro Diagnostic devices that require coordination with the Center for Drug Evaluation and Research are not within the scope of this voluntary PMA CtQ pilot program.

A. Participation Criteria

Firms that are appropriate to participate in this voluntary PMA CtQ pilot program are those firms submitting an original PMA who follow the procedures set out in Section B and who also:

1. Submit a request for a pre-PMA q-submission meeting, and

a. Provide the recommended information identified in the guidance document, ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' dated February 18, 2014 (Ref. 4), along with a statement of interest for participation in this voluntary PMA CtQ pilot program in the applicant's cover letter.

b. Provide a list of PMA-related facilities responsible for the manufacture, processing, packing, or installation with the applicant's pre-PMA q-submission submission package.

c. If available, submit a draft list of critical characteristics for the device which is the subject of the PMA application.

2. As part of the PMA application, include the proposed list of critical characteristics as well as their associated controls for the device which is the subject of the PMA. The list should include characteristics where failure in meeting the characteristic would have a reasonable likelihood or a remote likelihood of causing a death or serious injury.

3. Have their PMA application accepted and filed for review by FDA (Ref. 5).

4. Have not had Quality System deficiencies identified in FDA's review of the manufacturing section of the applicant's PMA (Ref. 6).

5. Have had an FDA inspection of the PMA-related facilities conducted at least once within the last 5 years.

6. An FDA inspection of the PMA-related facilities has not been classified as Official Action Indicated or been subject to a judicial action (*e.g.,* seizure or injunction, including consent decrees) within the last 5 years (Ref. 7).

B. Procedures

Postmarket inspections under this proposed voluntary PMA CtQ pilot program will be conducted in accordance with FDA's general establishment inspection authority in section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)). FDA intends for the investigator to follow the current medical device inspection model as outlined in the 2017 FDA Investigations Operations Manual (IOM) Chapter 5 and FDA Compliance Program 7383.001 ''Medical Device Premarket Approval and Postmarket Inspections'' dated March 5, 2012, with the following exceptions: (1) The inspection is conducted in the postmarket setting and (2) the postmarket inspection includes an evaluation of critical control measures for the production of the device are implemented (Ref. 8–10). Section 5.1.2 of the IOM provides the inspection may be directed for ''obtaining specific information on new technologies, good commercial practices, or data for establishing food standards or other regulations.''

Additionally, FDA intends on soliciting feedback from ORA, industry participants, and CDRH's OC/OIR staff during the voluntary PMA CtQ pilot program. Feedback from participants will be gathered through meetings and questions proposed in Appendices A and B (Ref. 11).

The following captures FDA's expected process for the voluntary PMA CtQ pilot program:

1. A firm submits a pre-PMA q-submission meeting request at least 75–90 days in advance of submission of the PMA application following the recommendations outlined in the guidance document ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' (Ref. 4) dated February 18, 2014. Additional expectations, include:

a. Providing a statement in the pre-PMA q-submission to support being considered for participation in the voluntary PMA CtQ pilot program.

b. Providing a list of PMA-related facilities responsible for the manufacture, processing, packing, or installation for the device which is the subject of the PMA as part of the applicant's pre-PMA q-submission package.

c. If available, submitting a draft list of critical characteristics for the device which is the subject of the PMA application.

2. During the pre-PMA q-submission meeting, FDA clearly communicates the voluntary PMA CtQ pilot program expectations and discusses and provides the applicant's proposed draft list of critical characteristics for the PMA device and provide feedback.

3. Once a firm has expressed interest in participating in the voluntary PMA CtQ pilot program, CDRH determines whether:

a. all PMA-related facilities have been inspected within the last 5 years, and

b. all of the inspections of the PMA-related facilities have not been classified as Official Action Indicated and have not been subject to a judicial action (*e.g.,* a seizure or injunction action, including a consent decree) within the last 5 years.

4. The PMA application:

a. Is accepted and filed for review by FDA.

b. Includes as part of the manufacturing section the proposed list of device critical characteristics as well as their associated controls, which may include certain design, manufacturing, or quality assurance practices. The list of critical characteristics identified in 4(b) is based on risk to the patient or user, including whether failure in meeting the characteristic can have a reasonable likelihood or a remote likelihood of causing a death or serious injury.

c. Is accompanied by a streamlined process validation report to CDRH OC or OIR no later than day 45 within the PMA application process.

5. CDRH OC/OIR completes the following during review of the PMA application:

a. Checks the CtQ information for clarity, completeness, and relevance to the Quality System regulation within days 1–45, with the goal to have the list of device critical characteristics as well as their associated controls finalized by day 60 of the 180-day clock.

b. Reviews the manufacturing section of the PMA application within the first 30 days of the 180-day clock. If Quality System deficiencies are identified during this review, then the PMA application would no longer be appropriate for inclusion in this voluntary PMA CtQ pilot program. The reviewer would follow the current established procedures and place the PMA application on ''hold'' pending correction of the deficiencies.

c. Reviews the validation report identified in section B.4(c) within 30 calendar days of receipt. Any concerns raised by the validation report review may result in the issuance of a deficiency letter that will place the PMA on ''hold'' pending Good Manufacturing Practices corrections.

d. Provides an inspectional assignment to the investigator and makes necessary technical expertise available to the ORA. The critical characteristics and controls will help guide the investigator and appropriately focus their activities during the postmarket inspection. In addition, CDRH intends to include CtQ and control information in an inspectional assignment and contact the investigator(s) to discuss critical control measures and expectations prior to the inspection.

6. Following an approval decision, FDA conducts the postmarket inspection in accordance with the 2017 FDA IOM, Compliance Program 7382.845, and Compliance Program 7383.001 (Ref. 8–10) utilizing elements

of QSIT, and informed by the PMA CtQ information developed jointly by FDA and the PMA applicant.

7. Following completion of the inspection, participating FDA Offices and applicants provide the information/data needed to assess the voluntary PMA CtQ pilot program's impact on resource utilization and quality focus, utilizing the evaluation forms provided in Appendices A and B (Ref. 11).

During this voluntary PMA CtQ pilot program, CDRH staff intends to be available to answer questions or concerns that may arise. The voluntary PMA CtQ pilot program participants will be asked to comment on and discuss their experiences with the PMA CtQ pilot submission process. Comments and discussions may assist FDA in determining whether the goals of this voluntary PMA CtQ pilot program goal are clearly communicated and attainable.

II. Duration of the Premarket Approval Application Critical to Quality Pilot Program

FDA intends to accept requests for participation in the voluntary PMA CtQ pilot program from September 29, 2017, to December 31, 2018, or until such time as when a total of nine PMAs have been enrolled.

III. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814, subparts A through E have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756.

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *https://www.regulations.gov.* (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Implantable Devices that Contain Batteries Critical to Quality Inspection Pilot. Available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/UCM469128.pdf.*
2. FDA's Case for Quality, available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm.*
3. FDA's Guide to Inspections of Quality Systems, Quality System Inspection Technique, available at *http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074883.htm.*
4. FDA Guidance for Industry and FDA Staff ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' dated February 18, 2014. Available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm311176.pdf.*
5. FDA's Guidance for Industry and FDA Staff: Acceptance and Filing Reviews for Premarket Approval Applications (PMAs) at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm313368.pdf.*
6. FDA's Guidance for Industry and FDA Staff: Quality System Information for Certain Premarket Application Reviews, available at *http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm070897.htm.*
7. FDA's Official Action Indicated, available at *http://www.fda.gov/downloads/AboutFDA/Transparency/PublicDisclosure/GlossaryofAcronymsandAbbreviations/UCM212061.pdf.*
8. 2017 FDA Investigations Operations Manual (IOM) Chapter 5 at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-ice/documents/document/ucm123522.pdf.*
9. FDA Compliance Program 7383.001 at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/UCM295570.pdf.*
10. FDA Compliance Program 7382.845 at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM244277.pdf.*
11. Appendices A and B.

Dated: September 5, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–19258 Filed 9–11–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4515]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Ocfentanil, Carfentanil, Pregabalin, Tramadol, Cannabidiol, Ketamine, and Eleven Other Substances; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice that appeared in the **Federal Register** of August 14, 2017. In the notice, FDA requested comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of 17 drug substances. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice published August 14, 2017 (82 FR 37866). Submit either electronic or written comments by September 20, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 20, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 20, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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