similar data on other forms of assistance.

Annual Audit

The CWA requires a CWSRF to undergo an annual audit. Though an audit conducted under the Single Audit Act meets this requirement, the EPA still recommends that a CWSRF also undergo a separate independent audit as a best management practice. The audit must contain an opinion on the financial condition of the CWSRF program, a report on its internal controls, and a report on compliance with applicable laws and the CWA.

Clean Water National Information Management System (CWNIMS) and CWSRF Benefits Reporting (CBR)

To meet the CWA objective of ''promoting the efficient use of fund resources,'' states must enter financial data, including project disbursements, into the CWNIMS database on an annual basis. This publicly available information is used by the EPA to assess compliance with the CWSRFs' mandate to use all funds in an ''expeditious and timely'' manner and achieve the objectives of the CWA. Project level data is collected on a quarterly basis using the CBR System to record projected environmental results from CWSRF projects.

CWSRF Applications

The application is developed and used by the CWSRFs to determine the project's eligibility, to evaluate the borrower's financial capability to repay the CWSRF, and to ensure that the borrower will comply with all applicable program requirements. The information collected by the CWSRF applications is consistent with requirements set forth by the CWA.

Public Awareness Policy

Per EPA Grants Policy Issuance (GPI) 14–02: Enhancing Public Awareness of EPA Assistance Agreements, CWSRF borrowers must publicize the EPA's involvement in project funding only up to the funding amount in each year's capitalization grant. The CWSRFs have various options to meet this requirement.

Except for the public awareness policy and CWSRF applications, the respondents for the information collection activities are the state environmental departments and/or finance agencies responsible for operating the CWSRFs. The CWSRFs have procedures in place to assist borrowers in completing the applications. The public awareness policy directly impacts CWSRF borrowers that are designated as recipients of federal funds. The burden associated with the public awareness policy should not have an impact on small entities since the CWSRFs have flexibility in determining which borrowers must comply with this requirement.

Form numbers: None.

Respondents/affected entities: Entities affected by this action are state environmental departments and/or finance agencies responsible for operating the CWSRFs and eligible CWSRF borrowers.

Respondent's obligation to respond: Required to obtain or retain a benefit per Title VI of CWA as amended by WRRDA.

Estimated number of respondents: 51 state environmental departments and/or finance agencies (per year); 1,544 eligible CWSRF borrowers (per year).

Frequency of response: Varies by requirement (*i.e.,* quarterly and annually).

Total estimated burden: 659,390 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $33,199,314 (per year).

Changes in estimates: There is an increase of 72,004 hours (per year) in the total estimated reporting burden compared with the ICR currently approved by OMB. This increase is from an upward adjustment of the annual number of CWSRF applications expected to occur during this collection period. Specifically, the estimated annual number of CWSRF applications has been increased from 1,359 to 1,544 in response to recent activity.

Dated: December 20, 2019.

Andrew D. Sawyers,

Director, Office of Wastewater Management.

[FR Doc. 2020–00274 Filed 1–10–20; 8:45 am]

BILLING CODE 6560–50–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), and interested persons may express their views in writing on the standards enumerated in section 4. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th and Constitution Avenue NW, Washington, DC 20551–0001, not later than February 12, 2020.

A. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *L1 Holding Corporation, Minneapolis, Minnesota;* to become a bank holding company by acquiring Eagle Community Bank, Maple Grove, Minnesota. In connection with this application, L1 Holding Corporation has applied to engage in mortgage lending activities by acquiring LeaderOne Financial Corporation, Overland Park, Kansas, pursuant to section 4 of the BHC Act.

Board of Governors of the Federal Reserve System, January 8, 2020.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2020–00278 Filed 1–10–20; 8:45 am]

BILLING CODE 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 (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 applications listed below, as well as other related filings required by the Board, if any, 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 paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th and Constitution Avenue NW, Washington DC 20551–0001, not later than January 28, 2020.

A. Federal Reserve Bank of Atlanta (Kathryn Haney, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Kenneth Lee Barber, Villa Rica, Georgia; Greg Logan Lee, Birmingham, Alabama; Jeff Daniel Couey, Acworth, Georgia; Johnny Lee Blankenship, Douglasville, Georgia; Eric Leonard Johnson, Atlanta, Georgia; Paul David Orr, Fairburn, Georgia; and Douglas Craig Davidson, Johns Creek, Georgia;* to acquire voting shares of Peoples Bankshares, Inc., and thereby indirectly acquire voting shares of The Peoples Bank, both of Eatonton, Georgia.

Board of Governors of the Federal Reserve System, January 8, 2020.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2020–00277 Filed 1–10–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5422]

Peripheral Percutaneous Transluminal Angioplasty and Specialty Catheters—Premarket Notification (510(k)) Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters—Premarket Notification (510(k)) Submissions; Draft Guidance for Industry and Food and Drug Administration Staff.'' The FDA is issuing this draft guidance document to provide recommendations for 510(k) submissions for peripheral percutaneous transluminal angioplasty (PTA) balloons and specialty catheters (*e.g.,* infusion catheters, PTA balloon catheters for in-stent restenosis (ISR), scoring/cutting balloons). This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by March 13, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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–2019–D–5422 for ''Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters—Premarket Notification (510(k)) Submissions; Draft Guidance for Industry and Food and Drug Administration Staff.'' 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). An electronic copy of the guidance document is available for