application Form FMC–18, and the related foreign-based unlicensed NVOCC registration/renewal Form FMC–65.

Type of Request: Reinstatement, with changes of a previously approved collection for which approval has expired.

Proposed Changes: The proposed changes to the collection reflect proposed changes to Part 515 in a recent rulemaking, which include: (a) Removing optional paper license application process and related reference to fee amounts; (b) clarifying language specifying who can be the Qualifying Individual in a partnership between entities other than individuals; (c) updating description of processes regarding renewals, bonds, and terminations; (d) expanding the types of applications subject to direct Commission review to include applicants employing the same officers, managers, or members of an OTI whose license was revoked or denied within the previous three years; (e) clarifying that sureties provide the organization number of OTIs with claim details for registered NVOCCs; (f) adding the submission of Form FMC–1 prior to being licensed; and (g) deleting reference to availability of the Regulated Person's Index (RPI) upon request.

Most of the proposed changes seek to streamline licensing, registration, renewal, and termination processes so that the Commission, licensees and registrants can receive and transmit documents electronically; remove references to paper license application and registration forms on the basis that no requests for waivers of electronic filing requirement were received; and assist carriers in verifying an NVOCC's compliance with OTI licensing, tariff, and financial responsibility requirements by adding the requirement that Form FMC–1 be submitted prior to issuance of an OTI license. Electronic filing of applications, registrations, and financial responsibility documents reduces cost to OTIs and the Commission and facilitates Commission review and issuance of OTI licenses and registrations. The Commission currently issues OTI licenses upon receipt of evidence of financial responsibility. Licensees that are NVOCCs must publish a tariff and notify the Commission using Form FMC–1, prior to commencing NVOCC service. The proposed change to issue an NVOCC OTI license upon receipt of financial responsibility and Form FMC–1 will assist common carriers in determining an NVOCC's compliance with the OTI licensing, tariff, and financial responsibility requirements. Foreign-registered NVOCCs submit a Form FMC–65, Form FMC–1, and evidence of financial responsibility to the Commission prior to commencing NVOCC service. The Commission is clarifying that sureties provide the organization number of OTIs with claim details for registered NVOCCs. The sureties currently provide similar identifying information for licensed OTIs. Data contained in the RPI can be downloaded at no cost from the Commission's website, and therefore the Commission is proposing to delete reference to availability of the RPI upon request.

Purpose: The Commission uses information obtained under this part and through Form FMC–18 to determine the qualifications of OTIs and their compliance with the Act and regulations, and to enable the Commission to discharge its duties under the Act by ensuring that OTIs maintain acceptable evidence of financial responsibility. If the collection of information were not conducted, there would be no basis upon which the Commission could determine if applicants are qualified for licensing. The Commission would also not be able to effectively assess the compliance of foreign-based, unlicensed NVOCCs without the required registration information.

Frequency: This information is collected when applicants apply for a license or submit a registration, complete the triennial renewal, or when existing licensees or registrants change certain information in their application forms.

Type of Respondents: The types of respondents are persons desiring to obtain or maintain a license or registration to act as an OTI. Under the Act, OTIs may be either an ocean freight forwarder, a non-vessel-operating common carrier, or both.

Number of Annual Respondents: The Commission estimates a potential annual respondent universe of 6,475 entities.

Estimated Time per Response: The time per response to complete application Form FMC–18 averages 2 hours and to complete the triennial renewal is 10 minutes. The time to complete a financial responsibility form averages 20 minutes. The time to complete Form FMC–65 to submit or renew a registration as a foreign-based, unlicensed NVOCC averages 10 minutes.

Total Annual Burden: The Commission estimates the total annual burden at 3,918 hours.

Rachel Dickon,

Secretary.

[FR Doc. 2019–20614 Filed 9–23–19; 8:45 am]

BILLING CODE 6731–AA–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 October 24, 2019.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Central Bancshares, Inc., Muscatine, Iowa;* to acquire the outstanding voting shares of Walcott Trust & Savings Bank, Walcott, Iowa, pursuant to section 3 of the Bank Holding Company Act. In connection with this application, Central

Bancshares, Inc., has applied to acquire Hail, Inc., Walcott, Iowa, and thereby engage in the sale of insurance in a town of less than 5,000 in population pursuant to section 4 of the Bank Holding Company Act and 12 CFR 225.28(b)(11)(iii)(A).

Board of Governors of the Federal Reserve System, September 18, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–20564 Filed 9–23–19; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1215]

Post-Marketing Pediatric-Focused Product Safety Reviews; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice, establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to collect comments related to the post-marketing pediatric-focused safety reviews of products posted between April 12, 2019, and September 23, 2019, on FDA's website but not presented at the September 26 or 27, 2019, Joint Pediatric Advisory Committee (PAC) and Drug Safety and Risk Management (DSaRM) Advisory Committee meeting. These reviews are intended to be available for review and comment by members of the PAC, interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public.

DATES: Submit either electronic or written comments by October 7, 2019.

ADDRESSES: FDA is establishing a docket for public comment on this document. The docket number is FDA–2019–N–1215. The docket will close on October 7, 2019. Submit either electronic or written comments by that date. Please note that late, untimely comments will not be considered. Electronic comments must be submitted on or before October 7, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 7, 2019. 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.

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 make 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–N–1215 for ''Post-Marketing Pediatric-Focused Product Safety Reviews; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.'' FDA 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: Marieann Brill, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 240–402–3838, *marieann.brill@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our Nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

FDA is establishing a public docket, Docket No. FDA–2019–N–1215, to receive input on post-marketing pediatric-focused safety reviews of