

Form Number: FCC Form 160.

Type of Review: Extension of a currently approved collection.

Respondents: Businesses or other for-profit entities; Individuals or households; Not-for-profit institutions; and State, Local, or Tribal Governments.

Number of Respondents and Responses: 145,726 respondents; 145,726 responses.

Estimated Time per Response: 10 minutes (0.167 hours).

Frequency of Response: One-time reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in the *Debt Collection Act of 1996* (DCCA), Public Law 104–134, Chapter 10, Section 31001.

Total Annual Burden: 24,366 hours.

Total Annual Costs: No Cost.

Needs and Uses: Respondents use FCC Form 160 to register in FCC's Commission Registration System (CORES). Entities must register in CORES to do regulatory transactions with FCC, including receiving licenses, paying fees, participating in auctions, etc. Without this collection of information, FCC would not have a database of the identity and contact information of the entities it does regulatory business with.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–07694 Filed 4–11–23; 8:45 am]

BILLING CODE 6712–01–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 public portions of 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(s) indicated below and at the offices of the Board of Governors. This information may also be obtained

on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

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 Street and Constitution Avenue NW, Washington DC 20551–0001, not later than May 12, 2023.

A. Federal Reserve Bank of Richmond (Brent B. Hassell, Assistant Vice President) P.O. Box 27622, Richmond, Virginia 23261, or electronically to Comments.applications@rich.frb.org:

1. *Churchill Bank Corporation, Clearwater, Florida*; to become a bank holding company by acquiring Miners Exchange Bank, Coeburn, Virginia.

B. Federal Reserve Bank of Minneapolis (Stephanie Weber, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291, or electronically to MA@mpls.frb.org:

1. *First Financial Corporation, Arthur, North Dakota*; to merge with HSB Financial Corporation, and thereby indirectly acquire Harwood State Bank, both of Harwood, North Dakota.

Board of Governors of the Federal Reserve System.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2023–07715 Filed 4–11–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–0362]

A Risk-Based Approach To Monitoring of Clinical Investigations—Questions and Answers; Guidance for Industry; 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 a final guidance for industry entitled “A Risk-Based Approach to Monitoring of Clinical Investigations—Questions and Answers.” This guidance provides information on risk-based approaches to

monitoring investigational studies of human drug and biological products, medical devices, and combination products. The guidance contains recommendations on planning a monitoring approach, developing the content of a monitoring plan, and addressing and communicating monitoring results. This guidance expands on the guidance for industry entitled “Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring” (August 2013) by providing additional information to facilitate sponsors’ implementation of risk-based monitoring. This guidance finalizes the draft guidance entitled “A Risk-Based Approach to Monitoring of Clinical Investigations: Questions and Answers,” issued on March 15, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on April 12, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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.