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]

BILLING CODE 6210–01–P

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.

• 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–0362 for ''A Risk-Based Approach to Monitoring of Clinical Investigations—Questions and Answers.'' 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, 240–402–7500.

• 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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Room 5431, Silver Spring, MD 20993–0002; or the Office of Clinical Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Mona Shing, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3355, Silver Spring, MD 20993–0002, 301–796–0910, *mona.shing@fda.hhs.gov;* Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; Martin Hamilton, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002, 301–796–5666, *CDRHClinicalEvidence@fda.hhs.gov;* Sheila Brown, Office of Clinical Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5109, Silver Spring, MD 20993, 301–796–6563, *Sheila.Brown@fda.hhs.gov;* or Hector Colon, Office of Regulatory Affairs/Office of Bioresearch Monitoring Operations, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–3899, *orabimoinspectionpoc@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''A Risk-Based Approach to Monitoring of Clinical Investigations—Questions and Answers.'' Sponsors of clinical investigations involving human drugs, biological products, medical devices, and combination products are required to provide oversight of the conduct of their clinical investigations. Such oversight helps to ensure adequate protection of the rights, welfare, and safety of human subjects and the integrity of the data submitted to FDA. Therefore, FDA recommends that sponsors implement a system to manage risks to human subjects and data integrity throughout all stages of the clinical investigation process.

This system to manage the quality of the investigation should help ensure data integrity while safeguarding the rights, safety, and welfare of trial participants by, for example, focusing on the design of efficient clinical trial protocols, tools for identifying and tracking potential risks, and procedures for data collection and processing. This system should include a risk-based approach to monitoring tailored to the potential risks for the specific clinical investigation. Clinical investigation monitoring is a quality control tool for determining whether investigation activities are being carried out as planned, so that, among other things, deficiencies can be identified and corrected. The types and intensity of monitoring activities should be proportionate to the risks to participants' rights, safety, and welfare and to data integrity inherent in the investigation. Effective implementation of risk-based monitoring of clinical investigations, including the prioritization of monitoring and other oversight activities directed at processes and procedures critical for human subject protection and maintaining data integrity, should help maximize the quality of a clinical investigation.

This guidance finalizes the draft guidance entitled ''A Risk-Based Approach to Monitoring of Clinical Investigations: Questions and Answers,'' issued on March 15, 2019 (84 FR 9531). FDA considered comments received on the draft guidance as the guidance was being finalized and revised the guidance as appropriate in response to the comments. Additionally, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''A Risk-Based Approach to Monitoring of Clinical Investigations—Questions and Answers.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the

requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 50 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303; and the collections of information in FDA's guidance for industry entitled ''Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring'' have been approved under OMB control number 0910–0733.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products,* or *https://www.regulations.gov.*

Dated: April 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07687 Filed 4–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0721]

Center for Devices and Radiological Health Radiation Sterilization Master File Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA, Agency, or we) Center for Devices and Radiological Health (CDRH or Center) is announcing its Radiation Sterilization Master File Pilot Program (''Radiation Pilot Program''). The Radiation Pilot Program is voluntary and intends to allow companies that terminally sterilize single-use medical devices (''sterilization providers'') using gamma radiation or ethylene oxide (EO) to submit Master File(s) when making certain changes to sterilization sites, methods, or processes under the specific conditions outlined in this notice. Under this voluntary pilot program, manufacturers of class III devices subject to premarket approval (''PMA holders'') who have been granted a right of reference by a sterilization provider may, upon notification from FDA that a manufacturer may do so, include references to Master File(s) accepted into the Radiation Pilot Program in postapproval reports describing the particular changes noted above affecting the sterilization sites, methods, or processes of their class III devices, in lieu of submitting premarket approval application (PMA) supplements for such changes. By helping industry advance alternatives for gamma radiation and EO sterilization of medical devices, the Radiation Pilot Program seeks to help ensure patient access to safe medical devices and, through evaluation of data from pilot participants, provide insights into future regulatory approaches that may help address potential device shortages related to sterilization site, method, or process shifts and facilitate supply chain resiliency.

DATES: FDA is seeking participation in the voluntary Radiation Pilot Program beginning April 12, 2023. See the ''Participation'' section for eligibility criteria for participation in the Radiation Pilot Program and the ''Procedures'' section for instructions on how to submit a Master File for consideration for inclusion into the Radiation Pilot Program. Up to nine eligible participants may be selected for the Radiation Pilot Program.

FOR FURTHER INFORMATION CONTACT: Clarence W. Murray, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4536, Silver Spring MD 20993, 301–796–0270, *Clarence.Murray@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Radiation-based sterilization is widely used to sterilize medical devices and thereby keep them safe for patient use. Established sources of radiation that may be used to generate radiation for medical device sterilization in accordance with FDA-recognized international consensus standards include gamma radiation, x-rays, and electron beams. Of these three types of radiation-based sterilization, gamma radiation is the most frequently used radiation source for medical device sterilization and, more broadly, is the second most frequently used sterilization method by sterilization providers,[1] accounting for approximately 40 to 45 percent of sterile medical devices (Ref. 1). The most frequently used sterilization method is ethylene oxide (EO), which is used to sterilize approximately 50 percent of sterile medical devices (Ref. 2).

Before sterile medical devices subject to PMA requirements are approved for marketing, FDA reviews the submitted PMA to determine if the sterility information is adequate (*e.g.,* in accordance with internationally agreed upon voluntary consensus standards that FDA recognizes). If a medical device manufacturer changes the sterilization method (*i.e.,* changes the type of sterilization modality used), process, or facility identified in its original PMA submission for sterilizing its devices, the manufacturer generally needs to submit a PMA supplement so the Agency can review these changes (Ref. 3).

However, FDA recognizes the need to facilitate more timely changes to alternative sterilization methods, processes, or sites among sterilization providers who use gamma radiation or EO to support sterilization supply chain resiliency.[2] In the case of gamma radiation, the radiation used for medical device sterilization is generated using radioactive cobalt (Co^{60}) as a source material, and there may be potential supply chain constraints for Co^{60} relative to the level of demand for radiation sterilization (Ref. 4). FDA also is aware of ongoing supply chain considerations for EO sterilization of medical devices as well as concerns about the effects of EO exposure and environmental emissions. In 2019, FDA

[1] In this notice, ''method'' or ''modality'' generally refers to the type of sterilization and ''processes'' generally refers to steps within that method to achieve a sterile device.

[2] Further, FDA more generally seeks to improve and strengthen the device supply chain through other broader initiatives, such as the planned Resilient Supply Chain and Shortages Prevention Program (RSCSPP). See FDA's Budget, Medical Device Supply Chain and Shortages Prevention Program, *https://www.fda.gov/news-events/fda-voices/fdas-budget-medical-device-supply-chain-and-shortages-prevention-program.*