actions. It should be noted that the 1997 policy statement was created at a time when electronic communication was much less common than it is today and no longer reflects the current practices of the federal banking agencies in coordinating formal enforcement actions. Importantly, the formal enforcement actions taken by the federal banking agencies are now published on the individual agencies' public websites, making it no longer necessary for the agencies to provide written notice of all such actions to each other. Moreover, the FRB, FDIC, and OCC have adopted a new policy that encourages notification to other interested federal banking agencies at the earliest practicable date and promotes coordination among the FBAs related to formal enforcement actions as appropriate. For the above reasons, the 1997 Policy Statement is being rescinded.

Dated at Washington, DC, this 22nd day of May 2018.

Federal Financial Institutions Examination Council.

Judith E. Dupre,

Executive Secretary.

[FR Doc. 2018–12557 Filed 6–11–18; 8:45 am]

BILLING CODE 7535–01– 6714–01– 6210–01–4810–33–4810–AM–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 July 5, 2018.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Midwest Banc Holding Co., Pierce, Nebraska;* to acquire up to 100 percent of the voting shares of Redstone Bank, Centennial, Colorado.

Board of Governors of the Federal Reserve System, June 6, 2018.

Ann Misback,

Secretary of the Board.

[FR Doc. 2018–12596 Filed 6–11–18; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Home Owners' Loan Act (12 U.S.C. 1461 *et seq.*) (HOLA), Regulation LL (12 CFR part 238), and Regulation MM (12 CFR part 239), and all other applicable statutes and regulations to become a savings and loan holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a savings association and nonbanking companies owned by the savings and loan 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 application also will 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 HOLA (12 U.S.C. 1467a(e)). 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 10(c)(4)(B) of the HOLA (12 U.S.C. 1467a(c)(4)(B)). 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 July 6, 2018.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23219. Comments can also be sent electronically to or *Comments.applications@rich.frb.org:*

1. *CBM Bancorp Inc., Parkville, Maryland;* to become a savings and loan holding company by merging with Banks of Chesapeake, M.H.C. Parkville, Maryland, and thereby indirectly acquire Chesapeake Bank of Maryland, Parkville, Maryland.

In connection with the proposal, Banks of Chesapeake M.H.C will convert from mutual to stock form.

Board of Governors of the Federal Reserve System, June 6, 2018.

Ann Misback,

Secretary of the Board.

[FR Doc. 2018–12537 Filed 6–11–18; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1164]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Qualified Facility Attestation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 12, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910—NEW and title ''Qualified Facility Attestation.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three

White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Qualified Facility Attestation

OMB Control Number 0910—NEW

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production.

Section 103 of FSMA amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 418 (21 U.S.C. 350g) with requirements for hazard analysis and risk-based preventive controls for facilities that produce food for humans or animals. We have established regulations to implement these requirements primarily within subparts C and G, with associated requirements in subparts A, D, E, and F, of the rule entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food'' (Preventive Controls for Human Food Rule) (21 CFR part 117) and primarily within subparts C and E, with associated requirements in subparts A, D, and F, of the rule entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals'' (Preventive Controls for Animal Food Rule) (21 CFR part 507). A business that meets the definition of a ''qualified facility'' (see 21 CFR 117.3 or 21 CFR 507.3) is subject to modified requirements in § 117.201 of the Preventive Controls for Human Food Rule or in § 507.7 of the Preventive Controls for Animal Food Rule. These modified requirements require the business to submit a form to FDA, attesting to its status as a qualified facility.

Section 418(*l*)(2)(B)(ii) of the FD&C Act directs FDA to issue guidance on the documents a business is required to submit to FDA to show its status as a qualified facility. FDA issued a draft guidance for industry entitled, ''Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food): Guidance for Industry.'' This draft guidance explains FDA's current thinking on how to determine whether a business is a qualified facility, and describes FDA procedures regarding the submission of attestations as established under both the Preventive Controls for Human Food Rule and the Preventive Controls for Animal Food Rule. FDA has developed proposed Forms FDA 3942a and FDA 3942b for use by a business in reporting its status as a ''qualified facility'' under the applicable regulations.

Description of Respondents: Respondents to the collection of information are owners, operators, or agents in charge of domestic or foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States, are required to register with FDA, and attest that a facility is a ''qualified facility'' under applicable FDA regulations.

In the **Federal Register** of May 16, 2016 (81 FR 30219), FDA published a 60-day notice requesting public comment on the proposed collection of information. One individual submitted several comments.

(Comment 1) One comment suggests that Forms FDA 3942a and FDA 3942b could be organized differently to help respondents. Specifically, the suggestion offered that the forms themselves should follow the submission type order as provided in section 2 of both forms so that the ''Status Change'' section is at the end of each form.

(Response) FDA agrees and will reorganize Forms FDA 3942a and FDA 3942b so that the ''Status Change'' section will now be section 6.

(Comment 2) One comment recommends changing the term ''Biennial Submission'' to ''Biennial (Renewal) Submission'' or in some way to indicate that biennial submission happens in the years after the ''Initial Submission.''

(Response) FDA agrees and will change ''Biennial Submission'' to ''Biennial (Renewal) Submission'' for both forms.

(Comment 3) One comment suggests that any revisions applied to either the forms or instructions should be consistent between all the documents.

(Response) FDA agrees and will make sure that revisions to the forms and instructions are consistent.

(Comment 4) One comment suggests that, for clarity, the instructions direct respondents to the guidance for additional reference.

(Response) FDA agrees and will include a reference to the guidance document in each section of the instruction document.

(Comment 5) One comment suggests that, for clarity, Question II.A.1 (and III.A. 1) of the guidance should advise respondents that the definition for ''very small business'' is forthcoming in the next question.

(Response) FDA agrees, and for clarity, will revise the final guidance to indicate that the definition for ''very small business'' is provided in the next question in the guidance.

(Comment 6) One comment suggests that Question II.A. 2 (and III.A.2) in the guidance should provide clarity as to the two options for meeting the qualified facility definition.

(Response) FDA agrees and will revise the final guidance to provide clarity as to the two options for meeting the qualified facility definition.

(Comment 7) One comment suggests that the guidance should provide more details about what other documentation FDA would accept as to support the first and second attestation options.

(Response) FDA agrees and will provide more details about the types of documentation FDA would accept to support the first attestation option. FDA will also include a list of examples of documents that FDA would accept to support the second attestation option consistent with the preamble discussions for §§ 117.201(a)(2)(ii) and 507.7(a)(2)(ii).

(Comment 8) One comment suggests that Question II.C.6 (and III.C.6) of the guidance oversimplifies the definition of farm and should clarify that farms that satisfy FDA's definition of ''farm'' need not submit Form FDA 3942a.

(Response) FDA agrees and will revise our responses to clarify that farms that satisfy FDA's definition of ''farm'' need not submit Form FDA 3942a or Form FDA 3942b.

(Comment 9) One comment suggests that Question II.C.7 (and III.C 7) of the guidance related to farm mixed-type facilities is missing certain information to assist farm mixed-type facilities to determine their level of coverage and compliance under regulations.

(Response) FDA agrees and will revise our response to provide greater clarity for farm mixed-type facilities to determine their level of coverage and compliance under the regulations.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance section	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Section II; Human Food	3942a	37,134	.5	18,567	.5 (30 minutes)	9,284
Section III; Animal Food	3942b	1,120	.5	560	.5 (30 minutes)	280
Total						9,564

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Consistent with the estimates found in our Preventive Controls for Human Food Rule, we estimate that approximately 37,134 human food facilities will each spend approximately 30 minutes (0.5 hour) reporting their status as a qualified facility to FDA every 2 years. Thus, dividing this figure by two to determine the annual burden, we estimate there will be 18,567 responses and 9,284 burden hours associated with this information collection element.

Similarly, and consistent with the estimates found in our Preventive Controls for Animal Food Rule, we estimate that approximately 1,120 animal food facilities will each spend approximately 30 minutes (0.5 hour) reporting their status as a qualified facility to FDA every 2 years. Thus, dividing this figure by two to determine the annual burden, we estimate there will be 560 responses and 280 burden hours associated with this information collection element.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 117 have been approved under OMB control number 0910–0751. The collections of information in 21 CFR part 507 have been approved under OMB control number 0910–0789.

Dated: June 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12615 Filed 6–11–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0073]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 12, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0186. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Irradiation in the Production, Processing, and Handling of Food

OMB Control Number 0910–0186—Extension

This information collection supports FDA regulations. Specifically, under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(s) and 348), food irradiation is subject to regulation under the food additive premarket approval provisions of the FD&C Act. The regulations providing for uses of irradiation in the production, processing, and handling of food are found in part 179 (21 CFR part 179). To ensure safe use of a radiation source, § 179.21(b)(1) requires that the label of sources bear appropriate and accurate information identifying the source of radiation and the maximum (or minimum and maximum) energy of the emitted radiation. Section 179.21(b)(2) requires that the label or accompanying labeling bear adequate directions for installation and use and a statement supplied by FDA that indicates maximum dose of radiation allowed. Section 179.26(c) requires that the label or accompanying labeling bear a logo and a radiation disclosure statement. Section 179.25(e) requires that food processors who treat food with radiation make and retain, for 1 year past the expected shelf life of the products up to a maximum of 3 years, specified records relating to the irradiation process (*e.g.,* the food treated, lot identification, scheduled process, etc.). The records required by § 179.25(e) are used by FDA inspectors to assess compliance with the regulation that establishes limits within which radiation may be safely used to treat food. We cannot ensure safe use without a method to assess compliance with the dose limits, and there are no practicable methods for analyzing most foods to determine whether they have been treated with ionizing radiation and are within the limitations set forth in part 179. Records inspection is the only way to determine whether firms are complying with the regulations for treatment of foods with ionizing radiation.