writing on the standards enumerated in the HOLA (12 U.S.C. 1467(a)). 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 April 13, 2015.

A. Federal Reserve Bank of Cleveland (Nadine Wallman, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101–2566:

1. CF Mutual Holding Company and CF Bancorp, Inc., both in Cincinnati, Ohio; to become a savings and loan holding company upon the conversion of Cincinnati Federal Savings Loan Association, Cincinnati, Ohio, which is converting from mutual to stock form.


B. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 500 Reunion Plaza, Dallas, Texas 75201–2272:

1. Beartooth Financial Corporation, Roseburg, Oregon; to become a savings and loan holding company; to acquire voting shares of Commercial Bancorp, and thereby indirectly acquire voting shares of Farmers State Bank, both in Pine Bluffs, Wyoming.


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 April 13, 2025.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunneier, Assistant Vice President) 9 Hennepin Avenue, Minneapolis, Minnesota 55440–0291:

1. Beartooth Financial Corporation, Billings, Montana; to become a bank holding company by acquiring 100 percent of the voting shares of Beartooth Bank, Billings, Montana.

B. Federal Reserve Bank of Dallas (Robert L. Tripplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:
1. FNBK Holdings, Inc., Dallas, Texas; to become a bank holding company by acquiring 100 percent of the voting shares of The First National Bank of Kemp, Kemp, Texas.


Michael J. Lewandowski, Associate Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0044]

Agency Information Collection Activities: Proposed Collection; Comment Request; Recommended Recordkeeping for Exempt Infant Formula Production

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on our proposed collection of certain information. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice invites comments on the information collection provisions of the draft guidance entitled “Draft Guidance for Industry: Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports.”

DATES: Submit either electronic or written comments on the collection of information by May 18, 2015.

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Recommended Recordkeeping for Exempt Infant Formula Production—OMB Control Number 0910—NEW

I. Background

Section 412(h)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350a(h)(1)) exempts an infant formula which is represented and labeled for use by an infant with an inborn error of metabolism, low birth weight, or who otherwise has an unusual medical or dietary problem from the requirements of section 412(a), (b), and (c) of the FD&C Act. These formulas are customarily referred to as “exempt infant formulas.” In the Federal Register of June 10, 2014 (79 FR 33057), we published a final rule that adopted, with some modifications, an interim final rule published on February 10, 2014 (79 FR 3033), that established requirements for quality factors for infant formulas and current good manufacturing practices (CGMPs), including quality control procedures, under section 412 of the FD&C Act. The final rule will help prevent the manufacture of adulterated infant formula, ensure the safety of infant formula, and ensure that the nutrients in infant formula are present in a form that is bioavailable.

In the Federal Register of February 10, 2014 (79 FR 7610), we published a notice of availability of the draft guidance document entitled “Guidance for Industry: Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports” (the draft guidance). The draft guidance, when finalized, will describe our current thinking on the manufacturing of exempt infant formula in relation to the requirements in part 106 (21 CFR part 106) for CGMPs, quality control procedures, conduct of audits, and records and reports that apply to nonexempt infant formulas. Persons with access to the Internet may obtain the draft guidance at http://www.fda.gov/FoodGuidances.

II. Analysis of the Proposed Information Collection

The proposed information collection seeks OMB approval of the recordkeeping recommendations of the draft guidance. Our estimate of the burden of the recordkeeping recommendations includes the one-time burden of developing production and in-process control systems and the annual burdens of developing and maintaining production aggregate production and control records, records pertaining to the distribution of infant formula, and records pertaining to regularly scheduled audits. Included in the burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Description of Respondents: The respondent recordkeepers are manufacturers of exempt infant formula.

Description: The records recommended, to the extent practicable, in the draft guidance include records required by part 106, subparts A, B, C, D, and F for non-exempt infant formulas. Because the records and reporting requirements related to part 106 subparts E and G are not generally applicable to exempt infant formula manufacturers, FDA is not recommending in the draft guidance that exempt infant formula manufacturers follow these