

views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than June 22, 2011.

A. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) P.O. Box 442, St. Louis, Missouri 63166-2034:

1. Thomas R. Garrison, individually, and in concert with, and as trustee of the Thomas R. Garrison Trust U/W Sheridan Garrison, the Thomas R. Garrison 2005 Retained Annuity Trust, and the Estate of F. S. Garrison, all of Fayetteville, Arkansas; to gain control of Pinnacle Bancshares, Inc., and thereby indirectly gain control of Pinnacle Bank, both in Rogers, Arkansas.

Board of Governors of the Federal Reserve System, June 2, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011-13948 Filed 6-6-11; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0425]

Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements related to the recall of infant formula.

DATES: Submit either electronic or written comments on the collection of information by August 8, 2011.

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:

Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

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, including each proposed extension of an existing 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.

Infant Formula Recall Regulations—21 CFR 107.230, 107.240, 107.250, 107.260, and 107.280 (OMB Control Number 0910-0188)—Extension

Section 412(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350a(e)) provides that if the manufacturer of an infant formula has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer has left its control and may not provide the

nutrients required in Section 412(i) of the FD&C Act or is otherwise adulterated or misbranded, the manufacturer must promptly notify the Secretary of Health and Human Services (the Secretary). If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary. Section 412(f)(2) of the FD&C Act states that the Secretary shall by regulation prescribe the scope and extent of recalls of infant formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall. FDA's infant formula recall regulations in part 107 (21 CFR part 107) implement these statutory provisions.

Section 107.230 requires each recalling firm to conduct an infant formula recall with the following elements: (1) Evaluate the hazard to human health, (2) devise a written recall strategy, (3) promptly notify each affected direct account (customer) about the recall, and (4) furnish the appropriate FDA district office with copies of these documents. If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with a copy of the notice. Section 107.240 requires the recalling firm to conduct an infant formula recall with the following elements: (1) Notify the appropriate FDA district office of the recall by telephone within 24 hours, (2) submit a written report to that office within 14 days, and (3) submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for written FDA concurrence (§ 107.250). Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (§ 107.260). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§ 107.280).

The reporting and recordkeeping requirements described previously are designed to enable FDA to monitor the

effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination or nutritional inadequacy

or otherwise adulterated or misbranded. FDA uses the information collected under these regulations to help ensure

that such products are quickly and efficiently removed from the market. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section ²	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
107.230	2	1	2	4,500	9,000
107.240	2	1	2	1,482	2,964
107.250	2	1	2	120	240
107.260	1	1	1	650	650
Total					12,854

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

² No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

The reporting burden estimate is based on Agency records, which show that there are five manufacturers of infant formula and that there have been, on average, two infant formula recalls per year for the past 3 years. Based on this information, we estimate that there will be, on average, approximately two infant formula recalls per year over the next 3 years.

Thus, FDA estimates that two respondents will conduct recalls annually pursuant to §§ 107.230, 107.240, and 107.250. The estimated number of respondents for § 107.260 is minimal because this section is seldom used by FDA; therefore, the Agency estimates that there will be one or fewer respondents annually for § 107.260. The estimated number of hours per response is an average based on the Agency's experience and information from firms that have conducted recalls. We estimate that two respondents will conduct infant formula recalls under § 107.230 and that it will take a respondent 4,500 hours to comply with the requirements of that section, for a total of 9,000 hours. We estimate that two respondents will conduct infant formula recalls under § 107.240 and that it will take a respondent 1,482 hours to comply with the requirements of that section, for a total of 2,964 hours. We estimate that two respondents will submit recommendations for termination of infant formula recalls under § 107.250 and that it will take a respondent 120 hours to comply with the requirements of that section, for a total of 240 hours. Finally, we estimate that one respondent will need to carry out additional effectiveness checks and issue additional notifications under § 107.260, for a total of 650 hours.

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

Dated: June 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-13941 Filed 6-6-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel, Aging and Economics.

Date: June 24, 2011.

Time: 10 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Rebecca J. Ferrell, PhD, Scientific Review Officer, National Institute on Aging, Gateway Building Rm. 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-402-7703, ferrellrj@mail.nih.gov.

Name of Committee: National Institute on Aging Special Emphasis Panel, Non-Communicable Diseases.

Date: June 29, 2011.

Time: 12 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C218, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Alfonso R. Latoni, PhD, Deputy Chief and Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Suite 2C218, Bethesda, MD 20892, 301-402-7702, Alfonso.Latoni@nih.gov.

Name of Committee: National Institute on Aging Special Emphasis Panel, Statistical Methods in Aging Research.

Date: July 18, 2011.

Time: 10 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Rebecca J. Ferrell, PhD, Scientific Review Officer, National Institute on Aging, Gateway Building Rm. 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-402-7703, ferrellrj@mail.nih.gov.