

Done at Washington, DC, on: August 2, 2013.

Alfred V. Almanza,
Administrator.

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FARM CREDIT ADMINISTRATION

12 CFR Parts 602, 618 and 621

RIN 3052-AC76

Releasing Information; General Provisions; Accounting and Reporting Requirements; Reports of Accounts and Exposures

AGENCY: Farm Credit Administration.

ACTION: Proposed rule.

SUMMARY: The Farm Credit Administration (FCA, we, or our) is proposing to establish a regulatory framework for the reliable, timely, accurate, and complete reporting of Farm Credit System (System) accounts and exposures for examination activities and risk evaluation. The proposed regulation specifies the reporting requirement(s) and performance responsibilities, including, but not limited to, establishing uniform and standard data fields to be collected from all System institutions and a disciplined and secure delivery of information. The proposed regulation would authorize a Reporting Entity (defined as the Federal Farm Credit Banks Funding Corporation (Funding Corporation) or an entity approved by FCA), to collect data from all banks and associations and serve as the central data repository manager. Additionally, the proposed regulation would require all banks and associations to provide data to the Reporting Entity to facilitate the collection, enhancement, and reporting of data to FCA.

DATES: Comments on this proposed rule must be submitted on or before September 9, 2013.

ADDRESSES: We offer a variety of methods for you to submit your comments. For accuracy and efficiency reasons, commenters are encouraged to submit comments by email or through the FCA's Web site. As facsimiles (fax) are difficult for us to process and achieve compliance with section 508 of the Rehabilitation Act, we do not accept comments submitted by fax. Regardless of the method you use, please do not submit your comment multiple times via different methods. You may submit comments by any of the following methods:

- *Email:* Send us an email at reg-comm@fca.gov.

- *FCA Web site:* <http://www.fca.gov>. Select "Public Commenters," then "Public Comments," and follow the directions for "Submitting a Comment."
- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* Barry F. Mardock, Deputy Director, Office of Regulatory Policy, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102-5090.

You may review copies of all comments we receive at our office in McLean, Virginia, or from our Web site at <http://www.fca.gov>. Once you are in the Web site, select "Public Commenters," then "Public Comments," and follow the directions for "Reading Submitted Public Comments." We will show your comments as submitted, but for technical reasons we may omit items such as logos and special characters. Identifying information you provide, such as phone numbers and addresses, will be publicly available. However, we will attempt to remove email addresses to help reduce Internet spam.

FOR FURTHER INFORMATION CONTACT:

Susan Coleman, Senior Policy Analyst, Office of Regulatory Policy, Farm Credit Administration, McLean, VA 22102-5090, (703) 883-4491, TTY (703) 883-4056, or Jane Virga, Senior Counsel, Office of General Counsel, Farm Credit Administration, McLean, VA 22102-5090, (703) 883-4020, TTY (703) 883-4056.

SUPPLEMENTARY INFORMATION:

I. Objectives

The objectives of this proposed rule are to:

- Reaffirm the authority for the FCA to collect data on System institution accounts and exposures for examination activities and risk evaluation;
- Require all banks and associations to provide data on accounts and exposures to the Reporting Entity, for the purposes of reporting to the FCA; and
- Establish the authority for and responsibilities of the Reporting Entity to collect, store, manage, and extrapolate data on accounts and exposures for reporting to the FCA.

II. Background

The Farm Credit Act of 1971, as amended (Act),¹ authorizes the FCA to issue regulations implementing the Act's provisions.² Our regulations are intended to ensure the safe and sound operations of System institutions. In

order to meet FCA's responsibility to ensure the safety and soundness of System institutions, we must have reliable, timely, accurate, and complete information about each banks' and associations' assets and liabilities.

Section 5.22A of the Act and § 621.12(a) of FCA regulations require each System institution to prepare and file such reports of condition and performance as may be required by FCA. Further clarification is provided in § 621.12(b), which states that these reports of condition and performance must be filed four times a year and may include such additional reports as may be necessary to ensure timely, complete, and accurate monitoring and evaluation of the affairs, condition, and performance of System institutions as determined by the Chief Examiner. In addition, § 621.12(c) requires all reports of condition and performance to be submitted electronically in accordance with the instructions prescribed by FCA. Also, section 5.9(4) of the Act provides FCA the power to require such reports as it deems necessary from System institutions.³

For over a decade, the FCA has collected detailed asset reports through loan data extracts from System institutions to facilitate examination activities and risk evaluation, and shared the data with the Farm Credit System Insurance Corporation (FCSIC) on a confidential basis. The need for consistent, comprehensive, and comparable data across all System institutions has evolved, as the complexity and volume of assets has increased. The availability of quality and timely data on accounts and exposures, including any loan, lease, letter of credit, derivative, or, any other asset, liability, other balance sheet account, or off-balance sheet exposure, has become critical to efficient and effective examination activities and risk evaluation. Accordingly, we continue to work with the System to collect more comprehensive data submissions and enhance the reporting to facilitate the evaluation of changing lending risks and conditions.

An integral component of the FCA's and FCSIC's ability to quickly and accurately identify and respond to risk is the collection of data on, and identification of, shared assets. Shared assets are any account or exposure where two or more System institutions have assumed a portion of the asset's benefits or risks. On October 3, 2012,

¹ Public Law 92-181, 85 Stat. 583 (1971), 12 U.S.C. 2001 *et seq.*

² 12 U.S.C. 2252(a)(8), (9), and (10).

³ Further, under section 5.17(a)(11) of the Act, the FCA may "[e]xercise such incidental powers as may be necessary or appropriate to fulfill its duties and carry out the purposes of {the} Act."

the FCA Board approved Bookletter BL-065, which describes FCA's expectations for each System institution and its board of directors to establish and implement an automated mechanism to consistently identify shared asset exposures.

In addition to other objectives, and in order to facilitate the identification of shared asset exposures and enable System risk assessment, the System has proposed the Funding Corporation create a central data repository to collect and store data from all System banks and associations, establish an automated mechanism to timely and accurately identify the System's shared asset exposures, and report Systemwide accounts and exposures on behalf of the System banks and associations to the FCA. The Funding Corporation, in coordination with the banks and associations, has begun planning and developing the central data repository and has prepared to assume the role of the Reporting Entity for the banks' and associations' reports of accounts and exposures. The Reporting Entity may also be any other entity approved by the FCA.

The proposed regulation reaffirms the FCA's authority to collect data from the System and communicates the authority for, and responsibilities of, the Reporting Entity to collect data on behalf of the System banks and associations for delivery to the FCA. The proposed rule also confirms FCA's authority to share examination reports or other information on System institutions prepared or held by the FCA with FCSIC. The proposed regulation would require the banks, associations, and Reporting Entity to establish a system of internal controls over the data. Additionally, the banks and associations will need to establish a data governance structure with the Reporting Entity to document the responsibilities and accountabilities for the conveyance, storage and uses of the information stored in the central data repository. This data governance structure should establish consensus among the banks, associations, and Reporting Entity and should be in place prior to the first transfer of data to the Reporting Entity.

During the System's data repository development phase, the banks and associations will continue to prepare and submit the reports of accounts and exposures to the FCA in accordance with the instructions prescribed by the FCA. Upon satisfactory demonstration by the Reporting Entity of the ability to prepare reliable, timely, complete and accurate reporting of accounts and exposures, FCA will accept report(s) of all banks' and associations' accounts

and exposures from the Reporting Entity, acting on behalf of the banks and associations.

The proposed regulation would require that the Reporting Entity notify the FCA immediately in writing in the event of any breach of data confidentiality or if there is a request for data from the reports of accounts and exposures. Additionally, in the event of a breach of information, the Reporting Entity would have to provide written notice of the breach to each bank and association concerned so that it may determine whether any notice of the breach to any of its borrowers is required under applicable laws and regulations.

The Reporting Entity may request that the banks and associations appoint a replacement Reporting Entity to assume the authorities and reporting obligations of the Reporting Entity described in the proposed regulation with 60 days prior notice to the FCA. Additionally, at their discretion, and with the approval of the FCA, the banks and associations may elect to select a replacement Reporting Entity to assume the authorities and reporting obligations of the Reporting Entity.

III. Section-by-Section Analysis

We request and encourage any interested person to submit comments on this proposed rule and ask that you support your comments with relevant data or examples.

A. Disclosing Reports of Examination and Other Non-Public Information [§ 602.2]

We propose adding a new paragraph (c) to § 620.2 that we may disclose, without waiving any privilege or limiting any of the requirements of section 5.59 the Act, reports of examination and other examination and non-public information,⁴ including data from reports of System accounts and exposures received pursuant to § 621.15 of this chapter, to the FCSIC pursuant to confidentiality and data security

⁴ Section 5.59(a)(5) of the Act provides that FCSIC, to the extent practicable, shall use the personnel and resources of the FCA to minimize duplication of effort and to reduce costs. Under section 5.59(b), if the FCSIC Board considers it necessary to examine an insured System bank or a System association or any System institution in receivership, it may use FCA examiners to conduct the examination using reports and other information on the System institution prepared or held by the FCA. If the FCSIC Board determines that such reports or information are not adequate to enable FCSIC to carry out the duties of FCSIC under section 5.59(b), it may request the FCA to examine or to obtain other information from or about the System institution and provide FCSIC the resulting examination report or such other information. See also section 5.19(d) of the Act.

agreements executed between the agencies.

B. Releasing Information—General Regulation [§ 618.8300]

The proposed regulation would delete “as authorized in the following paragraphs” and substitute “as authorized by Farm Credit Administration regulations” to clarify that banks and associations can provide information not contained in published reports or press releases to the Reporting Entity, as provided in the proposed regulation.

C. Lists of Borrowers and Stockholders [§ 618.8310]

We propose adding a new paragraph (c) to allow System institutions to provide information from its lists of borrowers and stockholders to the Reporting Entity, as provided in the proposed regulation.

D. Data Regarding Borrowers and Loan Applicants [§ 618.8320]

We propose adding a new paragraph (b)(10) to allow System institutions to release information not contained in published reports or press releases to the Reporting Entity, as provided in the proposed regulation.

E. Definitions [§ 621.2]

The proposed regulation would amend § 621.2 by adding new definitions for the terms “accounts and exposures,” “banks and associations,” “central data depository,” “reporting entity” and “shared asset”.

F. Applicability and General Instructions [§ 621.12]

The proposed regulation would amend the title of existing § 621.12 by removing “Applicability and general instructions” and inserting “Reports of condition and performance”.

G. Reports of Accounts and Exposures [§ 621.15]

The proposed regulation would establish a new § 621.15, which provides that banks and associations must submit accurate and complete reports of accounts and exposures in accordance with the instructions prescribed by the FCA or as may be required by the FCA. The Reporting Entity would collect, store, and manage the information submitted to it by each bank and association under the requirements of this section in a central data repository. The Reporting Entity would prepare and submit electronic report(s) of accounts and exposures to the FCA from all banks and associations in accordance with FCA regulations and

prescribed instructions. The Reporting Entity would be required to establish, implement, and maintain an automated mechanism to ensure the reliable, timely, accurate and consistent identification of the banks' and associations' shared asset exposures, and report these exposures and the shared asset identifiers in the electronic quarterly report on accounts and exposures to the FCA.

The proposed regulation would require each bank and association to provide written certification to the FCA and the Reporting Entity that the information provided in the report of accounts and exposures is a true and accurate record of the data maintained in the bank's or association's database, to the best of its knowledge and belief. Additionally, the Reporting Entity would be required to provide written certification to the FCA that the information provided in the report of all banks' and associations' accounts and exposures has been prepared in accordance with all applicable regulations and instructions and accurately represents the information provided to it by the banks and associations. The proposed regulation would require the banks, associations, and Reporting Entity to establish an effective system of internal controls over the data included in the report(s) of accounts and exposures, including controls for maintaining the confidentiality of borrower information.

The proposed regulation would require the Reporting Entity to notify FCA immediately in writing of the following events: (1) If there is a breach of information; (2) if there is a request for data from the reports of accounts and exposures from non-System entities; or, (3) if it is unable to prepare and submit the report(s) of accounts and exposures in compliance with the requirements of this section. Additionally, in the event of a breach of information, the Reporting Entity would have to provide written notice of the breach to each bank and association concerned so that it may determine whether any notice of the breach to any of its borrowers is required under applicable laws and regulations.

IV. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the FCA hereby certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities. Each of the banks in the Farm Credit System, considered together with its affiliated associations, has assets and annual income in excess of the amounts

that would qualify them as small entities. Therefore, Farm Credit System institutions are not "small entities" as defined in the Regulatory Flexibility Act.

List of Subjects

12 CFR Part 602

Courts, Freedom of information, Government employees.

12 CFR Part 618

Agriculture, Archives and records, Banks, banking, Insurance, Reporting and recordkeeping requirements, Rural areas, Technical assistance.

12 CFR Part 621

Accounting, Agriculture, Banks, banking, Penalties, Reporting and recordkeeping requirements, Rural areas.

For the reasons stated in the preamble, parts 602, 618 and 621 of chapter VI, title 12 of the Code of Federal Regulations, are proposed to be amended as follows:

PART 602—RELEASING INFORMATION

■ 1. The authority citation for part 602 is revised to read as follows:

Authority: Secs. 5.9, 5.17, 5.59 of the Farm Credit Act (12 U.S.C. 2243, 2252, 2277a–8); 5 U.S.C 301, 552; 12 U.S.C. 1821(t); 52 FR 10012; E.O. 12600; 52 FR 23781, 3 CFR 1987, p. 235.

■ 2. Section 602.2 is amended by:

- a. Revising the heading;
- b. Redesignating existing paragraph (c) as newly designated paragraph (d); and
- c. Adding new paragraph (c) to read as follows:

§ 602.2 Disclosing reports of examination and other non-public information.

* * * * *

(c) *Disclosure to the Farm Credit System Insurance Corporation.* Without waiving any privilege or limiting any of the requirements of section 5.59 of the Farm Credit Act of 1971, as amended, we may disclose reports of examination and other examination and non-public information, including data from reports of System accounts and exposures received pursuant to § 621.15 of this chapter, to the Farm Credit System Insurance Corporation pursuant to confidentiality and data security agreements executed between the agencies.

* * * * *

PART 618—GENERAL PROVISIONS

■ 3. The authority citation for part 618 continues to read as follows:

Authority: Secs. 1.5, 1.11, 1.12, 2.2, 2.4, 2.5, 2.12, 3.1, 3.7, 4.12, 4.13A, 4.25, 4.29, 5.9, 5.10, 5.17, of the Farm Credit Act (12 U.S.C. 2013, 2019, 2020, 2073, 2075, 2076, 2093, 2122, 2128, 2183, 2200, 2211, 2218, 2243, 2244, 2252).

■ 4. Section 618.8300 is amended by removing the words "as authorized in the following paragraphs" and adding in their place, the words "as authorized by Farm Credit Administration regulations".

■ 5. Section 618.8310 is amended by adding a new paragraph (c) to read as follows:

§ 618.8310 Lists of borrowers and stockholders.

* * * * *

(c) In connection with preparing and submitting an electronic report of all System accounts and exposures to the Farm Credit Administration in accordance with the requirements of § 621.15 of this chapter, each bank and association may provide information from its lists of borrowers and stockholders to the Reporting Entity as defined in § 621.2 of this chapter.

■ 6. Section 618.8320 is amended by adding a new paragraph (b)(10) to read as follows:

§ 618.8320 Data regarding borrowers and loan applicants.

* * * * *

(b) * * *

(10) * * * In connection with preparing and submitting an electronic report of all System accounts and exposures to the Farm Credit Administration in accordance with the requirements of § 621.15 of this chapter, each bank and association may provide data on its accounts and exposures to the Reporting Entity as defined in § 621.2 of this chapter.

* * * * *

PART 621—ACCOUNTING AND REPORTING REQUIREMENTS

■ 7. The authority citation for part 621 continues to read as follows:

Authority: Secs. 5.17, 8.11 of the Farm Credit Act (12 U.S.C. 2252, 2279aa–11); sec. 514 of Pub. L. 102–552.

■ 8. Section 621.2 is amended by:

- a. Redesignating paragraph (a) as paragraph (b), paragraph (b) as paragraph (d), and paragraphs (c) through (i) as paragraphs (f) through (l), respectively; and
- b. Adding new paragraphs (a), (c), (e), (m) and (n) to read as follows:

§ 621.2 Definitions.

(a) *Accounts and exposures* means data related to any loan, lease, letter of credit, derivative, or, any other asset,

liability, other balance sheet account, or off-balance sheet exposure of a System institution.

* * * * *

(c) *Banks and associations* mean all Farm Credit banks, Agricultural credit banks, and associations.

* * * * *

(e) *Central data repository* means a central data warehouse that electronically collects and stores current and historical data and is created by integrating data from one or more disparate sources.

* * * * *

(m) *Reporting Entity* means the Federal Farm Credit Banks Funding Corporation, or other entity approved by the Farm Credit Administration.

(n) *Shared asset* means any account or exposure where two or more Farm Credit institutions have assumed a portion of the asset's benefits or risks. An institution's share in the asset may be established through means such as syndications, participation agreements, assignments, or other arrangements with System entities.

■ 9. Revise the heading of subpart D to read as follows.

Subpart D—Reports of Condition and Performance and Accounts and Exposures

■ 10. Section 621.12 is amended by revising the heading to read as follows:

§ 621.12 Reports of condition and performance.

■ 11. Subpart D is amended by adding a new § 621.15 to read as follows:

§ 621.15 Reports of accounts and exposures.

(a) *Responsibilities of banks and associations for preparing and submitting reports.* The banks and associations must prepare and submit an accurate and complete report of all bank and association accounts and exposures electronically to the Farm Credit Administration pursuant to the requirements of this part. In order to accomplish such submission, each bank and association must:

(1) Prepare and submit an accurate and complete report of its accounts and exposures electronically to the Reporting Entity;

(i) In accordance with the instructions prescribed by the Farm Credit Administration, or as may be required by the Farm Credit Administration; and

(ii) Within 20 calendar days after each quarter-end date, and at such other times as the Farm Credit Administration may require.

(2) Submit to the Farm Credit Administration and the Reporting Entity

a written certification that the information provided in the report of accounts and exposures has been prepared in accordance with all applicable regulations and instructions, and is a true and accurate record of the data maintained in the bank's or association's database, to the best of its knowledge and belief. The reports shall be certified by the officer of the reporting bank or association named for that purpose by action of the reporting bank's or association's board of directors. If the board of directors of the bank or association has not acted to name an officer to certify to the accuracy of its reports of accounts and exposures, then the reports shall be certified by the president or chief executive officer of the reporting bank or association. In the event the bank or association learns of a material error or misstatement in the information submitted to the Reporting Entity, it must notify the Reporting Entity and the Farm Credit Administration immediately of the error or misstatement and prepare and submit corrected information as soon as practicable.

(3) Respond promptly to any questions by the Reporting Entity related to information provided under this section in connection with the preparation of a report of accounts and exposures, including any data required to establish, implement and maintain consistent, accurate, and complete shared asset identification and reporting of shared asset exposures to the Farm Credit Administration.

(4) Develop, implement and maintain an effective system of internal controls over the data included in the report of accounts and exposures, including controls for maintaining the confidentiality of borrower information. The system of internal controls, at a minimum, must comply with the requirements of applicable Farm Credit Administration regulations, including § 618.8430 of this chapter.

(b) *Responsibilities of the Reporting Entity for preparing and submitting reports.* The Reporting Entity must:

(1) Collect, store, and manage the information submitted to it by each bank and association under the requirements of this section in a central data repository in accordance with Farm Credit Administration regulations and prescribed instructions.

(2) Prepare and submit an electronic quarterly report on the accounts and exposures of all banks and associations to the Farm Credit Administration in accordance with the instructions prescribed by the Farm Credit

Administration or as may be required by the Farm Credit Administration;

(3) Establish, implement, and maintain an automated mechanism to ensure the reliable, timely, accurate and consistent identification of the banks' and associations' shared asset exposures, and report these exposures and the shared asset identifiers in the electronic quarterly report on accounts and exposures to the Farm Credit Administration. In connection with establishing and implementing the automated shared asset identification mechanism, the Reporting Entity may provide the banks and associations information from the central data repository to identify and report shared asset exposures.

(4) Submit to the Farm Credit Administration a written certification that the information provided in the report of each banks' and associations' accounts and exposures has been prepared in accordance with all applicable regulations and instructions and accurately represents the information provided to it by the banks and associations. The reports shall be certified by the president or chief executive officer of the Reporting Entity. In the event the Reporting Entity learns of a material error or misstatement in the information submitted to the Farm Credit Administration, it must notify the Farm Credit Administration immediately of the error or misstatement and prepare and submit corrected information as soon as practicable.

(5) Develop, implement and maintain an effective system of internal controls over the central data repository, including controls for maintaining the confidentiality of borrower information. The system of internal controls, at a minimum, must comply with the requirements of applicable Farm Credit Administration regulations, including § 618.8430 of this chapter and require that the Reporting Entity:

(i) Develop policies and procedures to ensure that the information submitted in the report on accounts and exposures to the Farm Credit Administration is complete and consistent with the information submitted to the Reporting Entity from the banks and associations under § 621.15(a); and

(ii) Specify procedures for monitoring any material corrections or adjustments, in a timely manner, and provide timely notification and resubmission of the report on accounts and exposures to the Farm Credit Administration.

(6) Notify the Farm Credit Administration if it is unable to prepare and submit the quarterly report of accounts and exposures in compliance

with the requirements of this section. The notification:

(i) Must be signed by the chief executive officer, or person in an equivalent position, and submitted to the Farm Credit Administration as soon as the Reporting Entity becomes aware of its inability to comply;

(ii) Must explain the reasons for its inability to prepare and submit the report; and

(iii) May include a request that the Farm Credit Administration extend the due date for the quarterly report of accounts and exposures.

(7) In the event there is a breach of information, immediately provide written notice of the breach to:

(j) The Farm Credit Administration; and

(ii) Each bank and association concerned so that it may determine whether any notice of the breach to any of its borrowers is required under applicable laws and regulations and, if so, each bank and association shall be responsible for providing such notification;

(iii) For the purposes of this section, "breach of information" means unauthorized acquisition of or access to the central data repository, any quarterly reports of accounts and exposures or any other information received pursuant to § 621.15(a)(1).

(8) Notify the Farm Credit Administration in writing of any request for data contained in the reports of accounts and exposures that are not explicitly allowed for in § 618.8320(b) of this chapter.

Dated: August 5, 2013.

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2013-19231 Filed 8-8-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211

[Docket No. FDA-2011-N-0920]

RIN 0910-AG36

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Extension of Comment Periods

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period for the proposed rule

and for its information collection provisions.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the proposed rule, and for the information collection related to the proposed rule, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food," that appeared in the **Federal Register** of January 16, 2013. We are taking this action to allow interested persons an opportunity to consider the interrelationships between this proposal and the two proposals announced in July 2013 on the Foreign Supplier Verification Program and on Accreditation of Third-Party Auditors/Certification Bodies. We also are taking this action to keep the comment period for the information collection provisions associated with the rule consistent with the comment period for the proposed rule.

DATES: The FDA is extending the comment period on the above proposed rule. Submit either electronic or written comments on the proposed rule by November 15, 2013. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by November 15, 2013 (see the "Paperwork Reduction Act of 1995" section).

ADDRESSES: You may submit comments, identified by Docket No. FDA-2011-N-0920 and/or Regulatory Information Number (RIN) 0910-AG36, by any of the following methods, except that comments on information collection issues under the PRA must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2011-N-0920, and RIN 0910-AG36 for this rulemaking. All

comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

With regard to the proposed rule: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2166. *With regard to the information collection:* Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Drive, PI50-400T, Rockville, MD 20850, domini.bean@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 16, 2013 (78 FR 3646), we published a proposed rule entitled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" with a 120-day comment period on the provisions of the proposed rule and a 30-day comment period on the information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501-3520).

OMB and FDA previously received requests for a 90-day extension of the comment period for the information collection provisions of the proposed rule. We considered the requests and extended the comment period for the information collection for 90 days to make the comment period for the information collection provisions the same as that for the proposed rule—i.e., until May 16, 2013 (**Federal Register** of February 19, 2013, 78 FR 11611). FDA continued to receive comments requesting an extension of the comment period on the proposed rule. Each request conveyed concern that the 120-day comment period did not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule. FDA considered the requests and granted a 120-day extension of the comment period for the proposed rule