provisions. We are taking this action in response to requests for an extension to allow interested persons more time to comment given that in addition to the proposed preventive control requirements, the proposed current good manufacturing practice (CGMP) requirements are also new to the animal food industry, unlike the human food industry.

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: FDA is extending the comment period on the proposed rule and its information collection provisions. Submit either electronic or written comments on the proposed rule and the information collection by March 31, 2014.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0922 and/or Regulatory Information Number (RIN) 0910–AG10, 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 of this document).

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 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, Docket No. FDA–2011–N–0922, and RIN 0910–AG10 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:* Kim Young, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–2207.

With regard to the information collection: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, *Domini.Bean@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 29, 2013, we published a proposed rule entitled ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals'' with a 120-day comment period on the provisions of the proposed rule and on the information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501–3520).

FDA has received requests for an extension of the comment period on the proposed rule. The requests conveyed concern that the current 120-day comment period does not allow time to develop a meaningful response to the proposed rule because, unlike the human food industry, in addition to the proposed preventive controls, the proposed CGMPs are new to the animal food industry. The requests also stated an extended comment period would allow interested persons an opportunity to consider the interrelationship between this proposed rule and the proposed rules entitled ''Foreign Supplier Verification Programs for Importers of Food for Humans and Animals'' (78 FR 45729, July 29, 2013) and ''Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications'' (78 FR 45782, July 29, 2013). FDA has considered the requests and is granting an extension of the comment period to March 31, 2014, for the ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals'' proposed rule to allow interested persons additional time to submit comments. We also are extending the comment period for the information collection provisions to March 31, 2014, to make the comment period for the information collection provisions the same as the comment period for the provisions of the proposed rule. To clarify, FDA is requesting comment on all issues raised by the proposed rule.

II. Paperwork Reduction Act of 1995

Interested persons may either submit electronic comments regarding the information collection to *oira_submission@omb.eop.gov* or fax written comments to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285. All comments should be identified with the title ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.''

III. Request for Comments

Interested persons may submit either electronic comments regarding the proposed rule to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: January 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02111 Filed 1–31–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 17

[Docket No. FDA–2014–N–0113]

Maximum Civil Money Penalty Amounts; Civil Money Penalty Complaints

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing this companion proposed rule to the direct final rule, issuing a new regulation to adjust for inflation the maximum civil money penalty (CMP) amounts for the various CMP authorities within our jurisdiction and to amend the process for initiating certain CMP administrative actions. We are taking these actions to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990

(FCPIAA), as amended, and to streamline our internal processes. The last CMP adjustment was published in the **Federal Register** of November 12, 2008, and the FCPIAA requires Federal Agencies to adjust their CMPs at least once every 4 years. We are using direct final rulemaking for these actions because the Agency expects that there will be no significant adverse comment on the rule.

DATES: Submit either electronic or written comments on the proposed rule by April 21, 2014. If FDA receives any significant adverse comments, the Agency will publish a document in the **Federal Register** withdrawing the direct final rule within 30 days after the comment period ends. FDA will then proceed to respond to comments under this proposed rule using the usual notice and comment procedures.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2014–N–0113, by any of the following methods.

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 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–2014–N–0113 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 ''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: Jarilyn Dupont, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301–796–4830.

SUPPLEMENTARY INFORMATION: The last CMP adjustment was published in the **Federal Register** of November 12, 2008 (73 FR 66750).

I. Background

A. CMP Amounts

FDA is amending § 17.2 (21 CFR 17.2) to update the maximum CMP amounts. In general, FCPIAA requires Federal Agencies to issue regulations to adjust for inflation each CMP provided by law within their jurisdiction. (28 U.S.C. 2461 note, as amended by the Debt Collection Improvement Act of 1996 (31 U.S.C. 3701)). FCPIAA directs Agencies to adjust the CMP provided by law by October 23, 1996, and to make additional adjustments at least once every 4 years thereafter. The adjustments are based on changes in the cost of living, and the FCPIAA defines the cost of living adjustment as the percentage (if any) for each civil monetary penalty by which the Consumer Price Index for the month of June of the calendar year preceding the adjustment, exceeds the Consumer Price Index for the month of June of the calendar year in which the amount of such civil monetary penalty was last set or adjusted pursuant to law (28 U.S.C. 2461 note, section 5(b)).

FCPIAA also prescribes a rounding method based on the size of the penalty after the calculated increase, but states that the adjustment of a CMP may not exceed 10 percent of the penalty. FCPIAA defines a CMP as any penalty, fine, or other sanction that is for a specific monetary amount as provided by Federal law, or has a maximum amount provided for by Federal law, and is assessed or enforced by an agency pursuant to Federal law, and is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal Courts (28 U.S.C. 2461 note, section 3(2)).

B. CMP Complaints

Currently, under § 17.5(a) (21 CFR 17.5(a)), CMP complaints against retailers of tobacco products may only be signed by attorneys in FDA's Office of the Chief Counsel (OCC). Given the routine nature of many of these CMPs, FDA is amending this regulation to permit the Chief Counsel to designate other FDA staff, such as those in FDA's Center for Tobacco Products, to sign a tobacco retailer CMP complaint.

Based on FDA's experience, the large majority of the tobacco retailer complaints to date have involved alleged violations of the requirement to not sell cigarettes and smokeless tobacco to any person younger than 18 years of age or to verify age in accordance with 21 CFR 1140.14(b). These complaints have almost always been straightforward, they involve simple fact patterns, and they do not require a complex legal analysis. Over time, such CMP complaints have increased in volume, and we anticipate that the volume will continue to be relatively high.

We have determined that, with certain limitations and controls, non-attorney staff outside OCC can carry out the function of reviewing the evidence and signing the tobacco retailer CMP complaints in appropriate circumstances. The proposed amendment to § 17.5(a) would give this decisionmaking authority to the Chief Counsel, who could ensure the authority to sign complaints is only given to appropriate staff and under appropriate circumstances. Under the proposal, the Chief Counsel would have the authority to set and revise limitations and controls, and to broaden, limit, or rescind any authorizations to sign tobacco retailer CMP complaints.

The limitations could include, for example, limiting the delegation to situations where the CMP amount is below a certain dollar value; the CMP involves specified tobacco retailer charges that OCC has determined are routine and predictable and do not require a complex legal analysis; and involve charges for which FDA has developed OCC-approved templates, parameters, and procedures. The controls could include, for example, an audit or other quality review.

This proposed rule incorporates requirements specifically set forth in the FCPIAA requiring FDA to issue a regulation implementing inflation adjustments for all its CMP provisions. These technical changes, required by law, do not substantively alter the existing regulatory framework, nor do they in any way affect the terms under which CMPs are assessed by FDA. The formula for the amount of the penalty adjustment is prescribed by Congress in the FCPIAA, and these changes are not subject to the exercise of discretion by FDA. The amendment to § 17.5(a) changes an internal process.

This proposed rule is a companion to the direct final rule published elsewhere in this issue of the **Federal Register**. This companion proposed rule and the direct final rule are identical in substance. This companion proposed rule will provide the procedural framework to proceed with standard notice-and-comment rulemaking in the event the direct final rule receives significant adverse comment and is

withdrawn. The comment period for the companion proposed rule runs concurrently with the comment period of the direct final rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule and vice versa.

A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment unless the comment states why this rule would be ineffective without the additional change.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to the companion proposed rule. Instead, we will publish a confirmation notice in the **Federal Register** within 30 days after the comment period ends. We intend the direct final rule to become effective 30 days after publication of the confirmation notice.

If we receive significant adverse comments, we will withdraw the direct final rule. We will proceed to respond to all the comments received regarding the direct final rule, treating those comments as comments to this proposed rule. The Agency will address the comments in the subsequent final rule. We will not provide additional opportunity for comment. If we receive a significant adverse comment that applies to part of the rule and that part may be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of significant adverse comment.

For additional background information, see the corresponding direct final rule published elsewhere in this issue of the **Federal Register**.

This proposed rule:

- Revises the table in § 17.2 to adjust the maximum CMP amounts for inflation as prescribed by FCPIAA.
- Revises § 17.5(a) to provide authority for the Chief Counsel to delegate the responsibility for initiating a CMP administrative action against a tobacco retailer.

II. Environmental Impact

The Agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act

This proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IV. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule simply adjusts the maximum amount of CMPs administered by FDA, the adjustment is required by the FCPIAA, and the proposed rule makes a change to FDA's internal processes, the Agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule, when finalized, to result in any 1-year expenditure that would meet or exceed this amount.

VI. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

List of Subjects in 21 CFR Part 17

Administrative practice and procedure, Penalties.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, FDA proposes that 21 CFR part 17 be amended as follows:

PART 17—CIVIL MONEY PENALTIES HEARINGS

■ 1. The authority citation for 21 CFR part 17 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa–28; 5 U.S.C. 554, 555, 556, 557.

■ 2. Section 17.2 is revised to read as follows:

§ 17.2 Maximum penalty amounts.

The following table shows maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary penalties under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS

U.S.C. section	Former maximum penalty amount (in dollars)	Assessment method	Date of last penalty figure or adjustment	Adjusted maximum penalty amount (in dollars)
		21 U.S.C.		
333(b)(2)(A)	60,000	For each of the first two violations in any 10-year period ...	2013	65,000
333(b)(2)(B)	1,200,000	For each violation after the second conviction in any 10-year period.	2013	1,275,000
333(b)(3)	120,000	Per violation	2013	130,000
333(f)(1)(A)	16,500	Per violation	2008	16,500
333(f)(1)(A)	1,200,000	For the aggregate of violations	2013	1,275,000
333(f)(2)(A)	55,000	Per individual	2013	60,000
333(f)(2)(A)	300,000	Per "any other person"	2013	325,000
333(f)(2)(A)	600,000	For all violations adjudicated in a single proceeding	2013	650,000
333(f)(3)(A)	10,000	For all violations adjudicated in a single proceeding	2013	11,000
333(f)(3)(B)	10,000	For each day the violation is not corrected after a 30-day period following notification until the violation is corrected.	2013	11,000
333(f)(4)(A)(i)	250,000	Per violation	2013	275,000
333(f)(4)(A)(i)	1,000,000	For all violations adjudicated in a single proceeding	2013	1,075,000
333(f)(4)(A)(ii)	250,000	For the first 30-day period (or any portion thereof) of continued violation following notification.	2013	275,000
333(f)(4)(A)(ii)	1,000,000	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day violation.	2013	1,075,000
333(f)(4)(A)(ii)	10,000,000	For all violations adjudicated in a single proceeding	2013	10,850,000
333(f)(9)(A)	15,000	Per violation	2009	15,000
333(f)(9)(A)	1,000,000	For all violations adjudicated in a single proceeding	2013	1,050,000
333(f)(9)(B)(i)(I)	250,000	Per violation	2013	275,000
333(f)(9)(B)(i)(I)	1,000,000	For all violations adjudicated in a single proceeding	2013	1,050,000
333(f)(9)(B)(i)(II)	250,000	For the first 30-day period (or any portion thereof) of continued violation following notification.	2013	275,000
333(f)(9)(B)(i)(II)	1,000,000	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day violation.	2013	1,050,000
333(f)(9)(B)(i)(II)	10,000,000	For all violations adjudicated in a single proceeding	2013	10,525,000
333(f)(9)(B)(ii)(I)	250,000	Per violation	2013	275,000
333(f)(9)(B)(ii)(I)	1,000,000	For all violations adjudicated in a single proceeding	2013	1,050,000
333(f)(9)(B)(ii)(II)	250,000	For the first 30-day period (or any portion thereof) of continued violation following notification.	2013	275,000
333(f)(9)(B)(ii)(II)	1,000,000	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day violation.	2013	1,050,000
333(f)(9)(B)(ii)(II)	10,000,000	For all violations adjudicated in a single proceeding	2013	10,525,000
333(g)(1)	250,000	For the first violation in any 3-year period	2013	275,000
333(g)(1)	500,000	For each subsequent violation in any 3-year period	2013	550,000
333 note	250	For the second violation (following a first violation with a warning) within a 12-month period by a retailer with an approved training program.	2009	250
333 note	500	For the third violation within a 24-month period by a retailer with an approved training program.	2009	500
333 note	2,000	For the fourth violation within a 24-month period by a retailer with an approved training program.	2009	2,000
333 note	5,000	For the fifth violation within a 36-month period by a retailer with an approved training program.	2009	5,000
333 note	10,000	For the sixth or subsequent violation within a 48-month period by a retailer with an approved training program.	2013	11,000
333 note	250	For the first violation by a retailer without an approved training program.	2009	250
333 note	500	For the second violation within a 12-month period by a retailer without an approved training program.	2009	500
333 note	1,000	For the third violation within a 24-month period by a retailer without an approved training program.	2013	1,100
333 note	2,000	For the fourth violation within a 24-month period by a retailer without an approved training program.	2009	2,000
333 note	5,000	For the fifth violation within a 36-month period by a retailer without an approved training program.	2009	5,000
333 note	10,000	For the sixth or subsequent violation within a 48-month period by a retailer without an approved training program.	2013	11,000
335b(a)	300,000	Per violation for an individual	2013	325,000
335b(a)	1,200,000	Per violation for "any other person"	2013	1,275,000
360pp(b)(1)	1,100	Per violation per person	2008	1,100

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS—Continued

U.S.C. section	Former maximum penalty amount (in dollars)	Assessment method	Date of last penalty figure or adjustment	Adjusted maximum penalty amount (in dollars)
360pp(b)(1)	355,000	For any related series of violations	2013	375,000
42 U.S.C.				
263b(h)(3)	11,000	Per violation	2008	11,000
300aa–28(b)(1)	120,000	Per occurrence	2013	130,000

[1] Not adjusted.

■ 3. In § 17.5, revise paragraph (a) to read as follows:

§ 17.5 Complaint.

(a) The Center with principal jurisdiction over the matter involved shall begin all administrative civil money penalty actions by serving on the respondent(s) a complaint signed by the Office of the Chief Counsel attorney for the Center and by filing a copy of the complaint with the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. For a civil money penalty action against retailers of tobacco products, the complaint may be signed by any Agency employee designated by the Chief Counsel.

* * * * *

Dated: January 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02149 Filed 1–31–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 507

[Docket No. FDA–2013–N–1043]

Draft Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for a document we made available for public comment in the **Federal Register** of October 29, 2013 (78 FR 64428) (the draft RA). We are taking this action to make the comment period for the draft RA conform to the comment period for proposed rule entitled ''Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals'' (the proposed preventive controls rule for food for animals).

DATES: FDA is extending the comment period on the draft RA. Submit either electronic or written comments by March 31, 2014.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–1043 by any of the following methods:

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 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–2013–N–1043. 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**.

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: Kim Young, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–2207.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 29, 2013, we published a notification with a 120-day comment period announcing the availability of, and requesting comment on, a document entitled ''Draft Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm'' (the draft RA). The purpose of the draft RA is to provide a science-based risk analysis of those activity/animal food combinations that would be considered low risk.

We conducted this draft RA to satisfy requirements of the FDA Food Safety Modernization Act (FSMA) to conduct a science-based risk analysis and to consider the results of that analysis in rulemaking that is required by FSMA.

In the **Federal Register** of October 29, 2013, we announced that we had used the results of the draft RA to propose to exempt certain animal food facilities (i.e., those that are small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing, or holding activities identified in the draft RA as low-risk activity/animal food combinations) from the proposed requirements of the Federal Food, Drug, and Cosmetic Act for hazard analysis and risk-based preventive controls (the proposed preventive controls rule). Interested persons were originally given until February 26, 2014, to comment on the proposed preventive controls rule.

FDA has received requests for an extension of the comment period on the proposed preventive controls rule for