



4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2018-N-1857]**

**Agency Information Collection Activities; Proposed Collection; Comment Request;  
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive  
Controls for Food for Animals**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 the information collection requirements associated with current good manufacturing practice, hazard analysis, and risk-based preventive controls for animal food.

**DATES:** Submit either electronic or written comments on the collection of information by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before

**[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2018-N-1857 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made

publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential."

Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**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](mailto: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, 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.

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls

for Food for Animals--21 CFR Part 507

OMB Control Number 0910-0789--Extension

The information collection supports FDA regulations. As amended by the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), the Federal Food, Drug, and Cosmetic Act (the FD&C Act) enables the Agency to better protect the 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. Specifically, section 418 (21 U.S.C. 350g) of the FD&C Act sets forth requirements for hazard analysis and risk-based preventive controls for facilities that produce food for animals. To implement these provisions, regulations were codified under 21 CFR Part 507--*Current Good Manufacturing*

*Practice, Hazard Analysis, And Risk-Based Preventive Controls For Food For Animals.* The regulations establish requirements for a written food safety plan; hazard analysis preventive controls; monitoring; corrective actions and corrections; verification; supply-chain program; recall plan; and associated records and became effective November 16, 2015. Currently, we continue to evaluate burden associated with the information collection requirements however, for purposes of extending the information collection we retain the currently approved figures as shown below.

We estimate our burden of the information collection as follows:

Table 1.--Estimated Annual Reporting Burden for OMB Control No. 0910-0789<sup>1</sup>

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
507.7 exemption: submit attestation of preventive controls or compliance with State and local laws (non-federal)	1,120	0.5	560	0.5 (30 minutes)	280
507.67, 507.69, and 507.71; submission of an appeal, including submission of a request for an informal hearing	1	1	1	4	4
507.85(b); requests for reinstatement of exemption	1	1	1	2	2
Total					286

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

Table 2.--Estimated Annual Recordkeeping Burden<sup>1</sup>

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Subpart A--General Provisions					
507.7(e); records attesting that the facility is a "qualified" facility	1,120	0.5	560	0.1 (6 minutes)	56
507.4(d); documentation of animal food safety and hygiene training	7,469	0.75	5,579	0.05 (3 minutes)	279
Subpart C--Hazard Analysis and Risk-Based Preventive Controls					
507.31 through 507.55; food safety plan--including hazard analysis, preventive controls, monitoring, corrective actions, verification, validation reanalysis, modifications, and implementation records.	7,469	519	3,876,411	0.1 (6 minutes)	387,641

21 CFR Section; Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Subpart E--Supply-Chain Program					
507.105 through 507.175; written supply-chain program--including records documenting program	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Subpart F--Requirements Applying to Records					
507.200 through 507.215; general requirements, additional requirements applying to food safety plan, requirements for record retention, use of existing records, and special requirements applicable to written assurance.	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Totals			11,635,372		1,163,258

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

Table 3.--Estimated Annual Third-Party Disclosure Burden<sup>1</sup>

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
507.27(b); labeling for the animal food product contains the specific information and instructions needed so the food can be safely used for the intended animal species	330	10	3,300	0.25 (15 minutes)	825
507.7(e)(1); change labels on products with labels	1,526	4	6,104	1	6,104
507.7(e)(2); change address on labeling (sales documents) for qualified facilities	1,329	1	1,329	1	1,329
507.25(a)(2); animal food, including raw materials, other ingredients, and rework, is accurately identified	330	312	102,960	0.01 (36 seconds)	1,030
507.28(b); holding and distribution of human food byproducts for use as animal food	40,798	2	81,596	0.25 (15 minutes)	20,399
Total					29,687

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

These figures are based on our regulatory impact analysis in support of the final rule on Preventive Controls for Food for Animals, which published in the *Federal Register* of September 17, 2015 (80 FR 56170). Using Agency data we estimated the number of animal food facilities that we believe are subject to the regulations. We base our estimate of the time necessary for the individual reporting, recordkeeping, and third-party disclosure activities on our experience with similar information collections.

Dated: May 18, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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