responses. We calculate a reporting burden of 120 hours per response, for a total burden of 1,440 hours. We estimate 42 respondents will submit 2 Category D submissions annually, for a total of 84 responses. We calculate a reporting burden of 150 hours per response, for a total burden of 12,600 hours. We estimate 38 respondents will submit 1 Category E submission annually, for a total of 38 responses. We calculate a reporting burden of 150 hours per response, for a total burden of 5,700 hours.

In row 6, we estimate 190 respondents will submit information to a pre-notification consultation or a master file in support of FCN submission using Form FDA 3480. We calculate a reporting burden of 0.5 hours per response, for a total burden of 95 hours. In row 7 we estimate 100 respondents will submit an amendment (Form FDA 3480A) to a substantive or non-substantive request of additional information to an incomplete FCN submission, an amendment to a pre-notification consultation, or an amendment to a master file in support of an FCN. We calculate a reporting burden of 0.5 hours per response, for a total burden of 50 hours.

In row 8, we estimate one respondent will submit one indirect food additive petition under § 171.1, for a total of one response. We calculate a reporting burden of 10,995 hours per response, for a total burden of 10,995 hours.

In row 9, we estimate 10 respondents will utilize the recommendations in the guidance document entitled, ''Use of Recycled Plastics in Food Packaging: Chemistry Considerations,'' to develop the additional information for one such submission annually, for a total of 10 responses. We calculate a reporting burden of 25 hours per response, for a total burden of 250 hours.

Finally, in row 10, we estimate 2 respondents will utilize the recommendations in the draft guidance, once finalized, entitled, ''Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk,'' to develop the additional information for one such submission annually, for a total of 2 responses. We calculate a reporting burden of 5 hours per response, for a total burden of 10 hours.

Dated: September 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19898 Filed 9–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1857]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 15, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0789. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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 (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 in the following tables.

In the **Federal Register** of May 24, 2018 (83 FR 24124), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received three comments, however none pertained to the information collection or underlying regulations.

We estimate our burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number 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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
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

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of record-keepers	Number of records per record-keeper	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
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

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number 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

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

As previously stated, we retain the currently approved burden estimate for the information collection. 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: September 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19909 Filed 9–12–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3381]

Science Board to the Food and Drug Administration Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.