domestic and foreign food facilities that are required to register under the FD&C Act are required to identify and implement mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation.

In an effort to reduce burden and assist respondents, FDA offers tools and educational materials related to protecting food from intentional adulteration, including FDA's Food Defense Plan Builder, a user-friendly tool designed to help owners and operators of food facilities develop a personalized food defense plan, and the Mitigation Strategies Database, a database for the food industry providing a range of preventative measures that firms may choose to implement. These and other informational resources are available at *https://www.fda.gov/food/food-defense/food-defense-tools-educational-materials.* FDA also offers a small entity compliance guide entitled ''Mitigation Strategies to Protect Food Against Intentional Adulteration'' (August 2017) to inform domestic and foreign food facilities about compliance with regulations to protect against intentional adulteration. Further, FDA developed two draft guidance documents entitled ''Mitigation Strategies to Protect Food Against Intentional Adulteration: Draft Guidance for Industry'' (March 2019) and ''Supplemental Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration'' (February 2020). Once finalized, the draft guidance documents would assist the food industry in developing and implementing the elements of a food defense plan. These guidance documents are available at *https://www.fda.gov/food/food-defense.* All Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

Description of Respondents: The respondents to this information collection are manufacturers, processors, packers, and holders of retail food products marketed in the United States.

In the **Federal Register** of December 17, 2021 (86 FR 71646), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Exemption for food from very small businesses; § 121.5.	18,080	1	18,080	0.5 (30 minutes)	9,040

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

Certain facilities may qualify for an exemption under the regulations. Because these facilities must provide documentation upon request to verify their exempt status, we have characterized this as a reporting burden.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; 21 CFR Section	Number of record-keepers	No. of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Food Defense Plan; § 121.126	3,247	1	3,247	23	74,681
Actionable Process Steps; § 121.130 ..	9,759	1	9,759	20	195,180
Mitigation Strategies; § 121.135(b)	9,759	1	9,759	20	195,180
Monitoring Corrective Actions, Verification; §§ 121.140(a), 121.145(a)(1), and 121.150(c).	9,759	1	9,759	175	1,707,825
Training;§ 121.160	367,203	1	367,203	0.67 (40 minutes) ..	246,026
Records; §§ 121.305 and 121.310	9,759	1	9,759	10	97,590
Total	.....	.....	.....	.....	2,516,482

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments other than to increase the burden estimate by 1,224 hours due to a corrected calculation for the estimate related to training (§ 121.160).

Dated: June 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–12361 Filed 6–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0482]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drug Applications and Veterinary Master Files

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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: Submit written comments (including recommendations) on the collection of information by July 8, 2022.

ADDRESSES: To ensure that comments on the information collection are received,

OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0032. 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.

New Animal Drug Applications and Veterinary Master Files

OMB Control Number 0910–0032—Extension

This information collection supports implementation of section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b), which governs new animal drugs. Agency regulations in 21 CFR part 514 and associated regulations in 21 CFR part 558, establish format and content requirements regarding new animal drug application (NADA) submissions, as well as provide for preapplication submissions, amended applications, and application supplements. This information collection also supports implementation of section 571 of the FD&C Act (21 U.S.C. 360ccc) regarding application for conditional approval of new animal drug (CNADA) submissions. As set forth in the FD&C Act and Agency regulations, requisite elements include safety and effectiveness data, proposed labeling, product manufacturing information, and, where necessary, complete information on food safety (including microbial food safety) and any methods used to determine residues of drug chemicals in edible tissue from food producing animals. Applications must be prepared as appropriate to support the particular submission. Respondents to the information collection are persons developing, manufacturing, and/or researching new animal drugs.

We developed Form FDA 356v (Application for Approval of a New Animal Drug (or Submission to Support New Animal Drug Approval)) to provide a uniform format for submitting requisite information and to ensure efficient processing by the Agency. Form FDA 356v is available for download from our website at *https://www.fda.gov/about-fda/reports-manuals-forms/forms.* We also develop Agency guidance documents that may assist respondents with understanding NADA/CNADA requirements and related information collection activity. This includes FDA Guidance #152,[1] which outlines a risk assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs and includes Agency recommendations in this regard.

Under section 512(b)(3) of the FD&C Act, any person intending to file a NADA or supplemental NADA or a request for an investigational exemption under section 512(j) of the FD&C Act may request a conference prior to making a submission. Section 514.5 of our regulations (21 CFR 514.5) sets forth procedures for presubmission conferences and describes documentation associated with making requests, and preparing for and conducting meetings. We recommend submission of data supporting discrete technical sections during the investigational phase, rather than submitting all data for review as part of a complete application. This ''phased review'' of data submissions creates efficiencies in the review process for both FDA and the animal pharmaceutical industry.

We also encourage, as appropriate, the submission of a veterinary master file (VMF). For more information on VMFs, we invite you to visit *https://www.fda.gov/animal-veterinary/development-approval-process/veterinary-master-files.* A VMF provides detailed information used in support of application submissions. Questions regarding VMF submissions may be directed to our Center for Veterinary Medicine at *cvmesubmitter@fda.hhs.gov.* We have found that utilizing VMFs has increased the efficiency of the animal drug development and animal drug review processes for FDA and the animal pharmaceutical industry, providing for the confidential exchange of information with FDA and a process for reporting information outside of a NADA/CNADA or an investigational new animal drug file, as well as an opportunity for increased communication with FDA during the early stages of product development. A holder of a VMF may also authorize other parties to reference information included in the VMF without disclosing information in the file to those parties. VMFs can be used as repositories for information that can be referenced in multiple submissions to the Agency.

Section 558.5(i) of FDA regulations (21 CFR 558.5(i)) describes the procedure for requesting a waiver of the labeling requirements in § 558.5(h) in the event that there is evidence to indicate that it is unlikely a new animal drug would be used in the manufacture of a liquid medicated feed.

Finally, section 571 of the FD&C Act establishes requirements for the conditional approval of certain drugs [2] and the procedures for submitting applications for conditional approval. Although FDA receives fewer than one application submission under section 571 of the FD&C Act annually when averaged over a 3-year period, we use a placeholder of one response and 1 hour annually to account for the burden associated with these submissions.

Information collection associated with NADAs/CNADAs and related submissions is necessary to ensure that new animal drugs are in compliance with sections 512(b)(1) and 571 of the FD&C Act. We review the information, including data, labeling, and manufacturing controls and procedures, to evaluate the safety and effectiveness of the proposed new animal drug.

In the **Federal Register** of March 2, 2022 (87 FR 11713), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but did not pertain to the information collection requirements.

FDA estimates the burden of this collection of information as follows:

[1] Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-152-evaluating-safety-antimicrobial-new-animal-drugs-regard-their-microbiological-effects.*

[2] Animal drugs intended for use in minor species, minor use in major species, or for serious or life-threatening conditions or unmet animal or human health needs where a demonstration of effectiveness would require a complex or particularly difficult study or studies.

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
§§ 514.1 and 514.6; applications and amended applications.	187	0.07	13	212	2,756
§§ 514.1(b)(8) and 514.8(c)(1); [2] evidence to establish safety and effectiveness.	187	0.44	82	90	7,380
§ 514.5(b), (d), and (f); requesting presubmission conferences.	187	0.67	125	50	6,250
§ 514.8(b); manufacturing changes to an approved application.	187	2	374	35	13,090
§ 514.8(c)(1); labeling and other changes to an approved application.	187	0.06	11	71	781
§ 514.8(c)(2) and (3); labeling and other changes to an approved application.	187	0.84	157	20	3,140
§ 514.11; submission of data studies and other information.	187	0.13	24	1	24
§ 558.5(i); requirements for liquid medicated feed	187	0.01	2	5	10
Applications for conditional approval submitted under section 571 of the FD&C Act.	1	1	1	1	1
Form FDA 356V	187	36.5	6,825	0.75 (45 minutes)	5,118
VMF submissions	15	1	15	20	300
Total			7,628		38,849

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] NADAs and supplements regarding antimicrobial animal drugs that use a recommended approach to assessing antimicrobial concerns as part of the overall preapproval safety evaluation.

Although we have characterized the information collection activity as a reporting burden, we include in our estimate time required for searching data sources, and preparing and maintaining necessary and applicable records. As stated above, although we receive fewer than one submission annually when averaged over a 3-year period, we attribute one response and 1 hour annually to account for CNADA submissions.

We have adjusted our estimate of the information collection to reflect a decrease in burden associated with application submissions in acknowledgement of respondents' preference in using FDA's ''eSubmitter'' system, which automatically generates Form FDA 356v and allows respondents to complete the form and submit applications and associated information electronically.

Dated: June 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–12355 Filed 6–7–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1192]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Generally Recognized as Safe: Notification Procedure

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: Submit written comments (including recommendations) on the collection of information by July 8, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0342. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Substances Generally Recognized as Safe: Notification Procedure—21 CFR Part 170, Subpart E and 21 CFR Part 570, Subpart E

OMB Control Number 0910–0342—Extension

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that all food additives (as defined by section 201(s) (21 U.S.C. 321(s)) be approved by FDA before they are marketed. Section 409 of the FD&C Act (21 U.S.C. 348) establishes a premarket approval requirement for ''food additives.'' Section 201(s) of the FD&C Act provides an exclusion to the definition of food additive and, thus, from the premarket approval requirement for uses of substances that are generally recognized as safe (GRAS) by qualified experts. The GRAS provision of section 201(s) of the FD&C Act is implemented in parts 170