NW, Washington, DC 20551–0001, not later than May 16, 2025.

A. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Community Bankshares, Inc., through its wholly-owned subsidiary, Phoenix Lender Services, LLC, both of LaGrange, Georgia;* to engage de novo in extending credit and servicing loans, pursuant to section 225.28(b)(1) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2025–07545 Filed 4–30–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5581]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Additives Intended for Use in Animal Food, Food Additive Petitions, Investigational Food Additive Files Exemptions, and Declaration on Animal Food Labels

AGENCY: Food and Drug Administration, 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 June 2, 2025.

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 0910–0546. Also include the FDA docket number found in brackets in the heading of this document.

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.*

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.

Food Additives Intended for Use in Animal Food, Food Additive Petitions, Investigational Food Additive Files Exemptions, and Declarations on Animal Food Labels

OMB Control Number 0910–0546—Revision

This information collection helps support implementation of FDA's authority over food additives intended for use in animal food. Misbranded foods are prohibited under section 403 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343); food additives are covered in section 409 of the FD&C Act (21 U.S.C. 348), which provides, at section 409(a) of the FD&C Act, that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation that prescribes the condition(s) under which it may safely be used, or unless it is exempted by regulation for investigational use. Section 409(b) of the FD&C Act provides for petitions to establish safety of food additives and specifies information that must be submitted to FDA before a regulation permitting its use may be issued. Agency regulation in 21 CFR part 570 sets forth general provisions applicable to food additives intended for use in animal food, provides relevant definitions, establishes principles for determining safety, and explains prescribed elements to be included in a Generally Recognized as Safe (GRAS) notice. The regulation also provides for certain exemptions for investigational use and discusses related procedures. Agency regulation in 21 CFR part 571 establishes procedural requirements applicable to the submission of petitions filed under section 409(b) of the FD&C Act, including content and format elements to facilitate FDA processing of a food additive petition. Finally, Agency regulation in 21 CFR part 501 establishes disclosure requirements for animal food labeling, including the disclosure of the presence of certified and noncertified color additives (21 CFR 501.22(k)). Additional disclosure requirements are found in 21 CFR parts 573 (food additives permitted in feed and drinking water of animals) and 579 (irradiation in the production, processing, and handling of animal food), and are included in the scope of coverage for the information collection.

We are revising the information collection to include related authority established through enactment of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (2018 Amendments) (Pub. L. 115–234). Intending to help ensure the safety of pet food, section 306(c) of the 2018 Amendments provides for the issuance of guidance on pre-petition consultations for animal food additives. We have issued the following guidance documents to assist respondents in this regard:

Guidance for Industry (GFI) #262, ''Pre-Submission Consultation Process for Animal Food Additive Petitions or Generally Recognized as Safe (GRAS) Notices'' (December 2020), is available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-262-pre-submission-consultation-process-animal-food-additive-petitions-or-generally.* The guidance document describes the types of information our Center for Veterinary Medicine recommends be included in:

1. pre-petition consultations prior to submission of food additive petitions (FAP) for food additives intended for use in animal food;

2. pre-submission consultations regarding an animal food substance for which an entity plans to provide notice of its conclusion that the intended use of the substance is GRAS under FDA's animal food GRAS Notification program; or

3. a Food Use Authorization request to permit the use, in human or animal foods, of animal products derived from animals that have been administered an investigational substance intended for use in animal food.

Additionally, GFI #294, ''Animal Food Ingredient Consultation (AFIC)'' (January 2025), available for download at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-294-animal-food-ingredient-consultation-afic,* describes the AFIC process, which provides for a way, within the regulatory framework, for firms that are developing animal food ingredients to consult with FDA, and for FDA to review information from developers and the public regarding the ingredients and any relevant safety concerns. The AFIC process includes opportunities for public awareness of, and input on, the ingredients for which FDA is providing consultation. The guidance document also explains that FDA generally would not intend to take

enforcement action against an ingredient for being an unapproved animal food additive if FDA has sent an AFIC ''consultation complete'' letter, provided the ingredient is used in accordance with the terms described in the letter and there continues to be no questions or concerns about the safety of the ingredient.

Description of Respondents: Respondents to this collection of information are animal food manufacturers or animal food additive manufactures. With regard to submission activities, we assume 2,508 respondents based on the number of registrants who identify as animal food additive manufacturers. With regard to labeling activities under 21 CFR 501.22(k), we assume 3,120 respondents based on information found in previous Agency rulemaking (RIN–0910AG02) regarding declarations for animal food product labels.

In the **Federal Register** of December 19, 2024 (89 FR 103838), we published a 60-day notice soliciting public comment on the proposed collection of information. One comment was received offering general support for the utility of the information collection.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Regulatory authority; submission of information	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Food Additive Petitions					
21 CFR 571.1(c); Moderate Category	3	1	3	3,000	9,000
21 CFR 571.1(c); Complex Category	3	1	3	10,000	30,000
21 CFR 571.6; Amendment of Petition	5	1	5	1,300	6,500
Investigational Food Additive Files					
21 CFR 570.17; Moderate Category	8	1	8	1,500	12,000
21 CFR 570.17; Complex Category	10	1	10	5,000	50,000
Animal Food Ingredient Consultation					
Consultation Category	12	1	12	3,000	36,000
Amendment of Consultation	12	1	12	1,300	15,600
Color Additives					
21 CFR 501.22(k); labeling of color additive or lake of color additive; labeling of color additives not subject to certification.	3,120	0.8292	2,587	0.25 (15 minutes)	647
Total Hours					159,747

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

We have determined that food additive petitions and investigational food additive files that are submitted, fall into one of two categories of complexity. Fluctuations in the number and types of food and color additive petitions received in any given year are governed by market forces.

§ 571.1(c) Moderate Category: For a food additive petition without complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per petition is approximately 3,000 hours. We estimate that, annually, 3 respondents will submit 1 such petition, for a total of 9,000 hours.

§ 571.1(c) Complex Category: For a food additive petition with complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per petition is approximately 10,000 hours. We estimate that, annually, 3 respondents will each submit 1 such petition, for a total of 30,000 hours.

§ 571.6 Amendment of Petition: For a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. We estimate that, annually, 5 respondents will each submit 1 such amendment, for a total of 6,500 hours.

§ 570.17 Moderate Category: For an investigational food additive file without complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per file is approximately 1,500 hours. We estimate that, annually, 8 respondents will each submit 1 such file, for a total of 12,000 hours.

§ 570.17 Complex Category: For an investigational food additive file with complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per file is approximately 5,000 hours. We estimate that, annually, 10 respondents will each submit 1 such file, for a total of 50,000 hours.

Consultation Category: We estimate developers of animal food ingredients will spend 3,000 hours consulting with FDA on an ingredient. We estimate that, annually, 12 respondents will consult with FDA, for a total of 36,000 hours.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the FD&C Act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements for a particular color additive or food additive involve information required as part of the safety review process, the burden hours for labeling are included in the estimate for 21 CFR 501.22(k) and 571.1.

We base our estimate of the total annual responses on submissions received over the last 3 years. We base

our estimate of the hours per response on our experience with the labeling, food additive petition, and filing processes.

Based on review of the information collection, there was a decrease of food additive petition (FAP) responses and a corresponding decrease in burden hours for FAPs. We attribute this adjustment to an increase in the number of GRAS notices (21 CFR part 570, subpart E) received, which tend to substitute for FAP submissions due to a similar quantity and quality of data and information requirement. These numbers can fluctuate year to year. We also note that investigational food additive file responses have increased due to more respondents providing information during the premarket process prior to providing a more formal regulatory response (*e.g.,* FAP or GRAS notice). We did not adjust the number of responses received for the declaration of color additives on animal food labels from the previous collection.

Our estimated burden for the information collection reflects an overall increase of 40,600 total hours and 24 responses. We attribute this to accounting for the consultation process for firms developing animal food ingredients.

Dated: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–07588 Filed 4–30–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4470]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Antimicrobial Animal Drug Sales and Distribution

AGENCY: Food and Drug Administration, 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 June 2, 2025.

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 0910–0659. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Antimicrobial Animal Drug Sales and Distribution—21 CFR 514.87

OMB Control Number 0910–0659—Extension

This information collection helps support implementation of Agency statutory and regulatory requirements regarding new animal drugs containing an antimicrobial active ingredient. Sponsors of approved or conditionally approved applications for new animal drugs containing an antimicrobial active ingredient are required by section 512 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b) to submit to FDA an annual report on the amount of each such ingredient in the drug that is sold or distributed for use in food-producing animals. Sponsors are also required to maintain distribution records for their animal drug products, including separate information for each month of the calendar year, under section 512(l)(3) of the FD&C Act. These provisions were enacted to assist FDA in our continuing analysis of the interactions (including drug resistance), efficacy, and safety of antimicrobials approved for use in both humans and food-producing animals for the purpose of mitigating the public health risk associated with antimicrobial resistance.

Section 514.87 of our regulations (21 CFR 514.87) codifies the reporting requirements established in the FD&C Act. Sponsors submit antimicrobial animal drug sales and distribution reports to us on Form FDA 3744. Each report must specify: (1) the amount of each antimicrobial active ingredient by container size, strength, and dosage form; (2) quantities distributed domestically and quantities exported; and (3) a listing of the target animals, indications, and production classes that are specified on the approved label of the product. The report must cover the period of the preceding calendar year and include separate information for each month of the calendar year. Each report must also provide a species-specific estimate of the percentage of each product that was sold or distributed domestically in the reporting year for use in cattle, swine, chickens, or turkeys for such species that appear on the approved label.

Description of Respondents: Animal drug manufacturers (sponsors). Respondents include individuals and the private sector (for-profit businesses).

In the **Federal Register** of October 24, 2024 (89 FR 84887), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
514.87(a)–(e)—Annual Reports for Sponsors With Active Applications—Paper Submission	1	1	1	62	62
514.87(a)–(e)—Annual Reports for Sponsors With Active Applications—Electronic Submission	15	10.1	152	52	7,904
514.87(a)–(e)—Annual Reports for Sponsors With Inactive Applications—Paper Submission	2	3.5	7	2	14