



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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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

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 Burden¹

21 CFR Section	No. of Respondents	No. 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
514.87(a)-(e)--Annual Reports for Sponsors With Inactive Applications--Electronic Submission	10	17.9	179	2	358
Total					8,338

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

We base our estimate of the average burden per response on our recent experience with the existing antimicrobial animal drug distribution reports program. We base our estimate of the number of affected respondents reported in tables 1 and 2 and the average number of responses per respondent in table 1 on a review of our records of sponsors with active and inactive applications. We estimate sponsors with active applications, who submit an annual antimicrobial animal drug sales and distribution report on paper, will spend 62 hours to assemble the necessary information, prepare, and submit to FDA. We estimate sponsors with active applications, who submit an annual antimicrobial animal drug sales and distribution report electronically, will spend 52 hours to assemble the necessary information, prepare, and submit to FDA. We estimate that sponsors with inactive applications will spend 2 hours preparing their annual antimicrobial animal drug sales and distribution reports, whether electronically or on paper.

Table 2--Estimated Annual Recordkeeping Burden¹

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Recordkeeping required by section 512(l)(3) of the FD&C Act	23	1	23	2	46

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

Animal drug manufacturers are already required to maintain distribution records for their animal drug products to comply with FDA’s current good manufacturing regulations for periodic drug reports under § 514.80(b)(4)(i) (21 CFR 514.80(b)(4)(i)), approved under OMB control number 0910-0284. Section 512(l)(3) of the FD&C Act differs from § 514.80(b)(4)(i) in that it requires that records include separate information for each month of the calendar year. In addition, under 21 CFR 211.196 (approved under OMB control number 0910-0139), manufacturers currently are required to maintain distribution records that include dosage form, and date drug is distributed. Based on these requirements, FDA believes that manufacturers already keep detailed records of the dates when antimicrobial drugs are distributed for marketing and recall purposes from which monthly reports can be prepared as part of usual and customary business practices. However, FDA estimates an additional recordkeeping burden of 46 hours for further compliance with section 512(l)(3), as detailed in table 2.

After a review of the information collection since our last request for OMB approval, we have adjusted our estimates based on our experience with the antimicrobial animal drug distribution reports program. Our estimated burden for the information collection reflects a decrease of 54 burden hours and a corresponding decrease of 27 total annual responses. We attribute this to respondents who submitted by paper in previous years and are now reporting electronically.

Dated: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

