UNITED STATES FOOD & DRUG ADMINISTRATION

Antimicrobial Animal Drug Sales and Distribution

OMB Control No. 0910-0659 – EXTENSION

SUPPORTING STATEMENT

Terms of Clearance: None.

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection helps supports implementation of 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.

We therefore request OMB extension of the reporting and recordkeeping requirements as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Collection of information on the amount of animal antimicrobials being distributed, including species-specific information, is necessary to support our ongoing efforts to encourage the judicious use of antimicrobials in food-producing animals to help ensure the continued availability

of safe and effective antimicrobials for animals and humans. We intend to use these data to supplement existing information, including data collected under the National Animal Health Monitoring System (NAHMS) and the National Antimicrobial Resistance Monitoring System (NARMS) programs. Data from multiple sources are needed to provide a comprehensive and science-based picture of antimicrobial drug use and resistance in animal agriculture.

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

3. Use of Improved Information Technology and Burden Reduction

To facilitate reporting, we have developed and instituted **Form FDA 3744**, which may be submitted both in paper format and electronically via the CVM eSubmitter tool. The CVM eSubmitter tool is an electronic, question-based submission tool for creating information to be transmitted electronically to FDA through its secure Electronic Submission Gateway (ESG). FDA estimates that 100% of the respondents will use electronic means to submit their antimicrobial animal drug sales. Information collection associated with electronic records is currently approved under OMB control number 0910-0303.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We estimate that approximately 35% of the respondents are small businesses. Although the regulation provides for no exemption from the requirements for small businesses, FDA aids small businesses in complying with its requirements through its Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provides a Small Business Guide on our website at http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm.

6. Consequences of Collecting the Information Less Frequently

Data collection and recordkeeping is consistent with statutory and regulatory requirements. Reporting of antimicrobial animal drug sales and distribution data occurs annually, as required by section 512(*l*)(3) of the FD&C Act. Original antimicrobial animal drug sales and distribution reports are submitted only once and therefore cannot be collected less frequently.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

We published a 60-day notice for public comment in the *Federal Register* of October 24, 2024 (89 FR 84887). Although one comment was received, it was not responsive to the four information

collection topics solicited under 5 CFR 1320.8(d) and was therefore not addressed in our 30-day notice of May 1, 2025.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. This information collection request (ICR) does not collect personally identifiable information (PII) or information of a personal nature. This information collection supports the reporting of antimicrobial animal drug sales and distribution information to FDA. The FD&C Act and FDA's regulations specify the information that must be submitted to FDA by an animal drug manufacturer. Information collected using FDA **Form 3744** (*Antimicrobial Animal Drug Distribution Report*) is not PII or other data of a personal nature. Because neither FDA nor any party acting on behalf of the agency collects PII, the ICR is not subject to the Privacy Act of 1974 and the requirements of the Privacy Act such as displaying a Privacy Act Statement on a collection form do not apply.

The Freedom of Information Act

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1--Estimated Annual Reporting Burden

21 CFR Section; FDA Form 3744	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

21 CFR Section; FDA Form 3744	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 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

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 that 15 sponsors will have active applications and we assume that 100 percent of the respondents will report electronically. While we did not receive any paper submissions from Sponsors with active applications since our last review, we retain our current estimate of 1 respondent to permit such applications by respondents and also to permit related responses to FDA. We estimate that a sponsor will spend 62 hours annually to assemble the necessary information, prepare, and submit an annual antimicrobial animal drug sales and distribution report on paper and 15 sponsors with active applications will spend 52 hours annually to assemble the necessary information, prepare, and electronically submit an annual antimicrobial animal drug sales and distribution report.

We estimate that 10 sponsors will have inactive applications and we assume that 96 percent of these respondents will report electronically while the other 4 percent will report on paper.

We estimate that sponsors with inactive applications will spend 2 hours to prepare their annual antimicrobial animal drug sales and distribution reports, whether electronically or on paper.

Table 2--Estimated Annual Recordkeeping Burden

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

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 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.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Animal Drug Manufacturer /Sponsor (Reporting)	8,338	$75.75	$ 631,603.50
Animal Drug Manufacturer/ Sponsor (Recordkeeping)	46	$75.75	$ 3,484.50
Total			$635,088

[1] May 2023 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics and including 30% for benefits (https://www.bls.gov/oes/current/oes113012.htm)

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We estimate the annualized cost to the government to be $647,193. There are currently 5 FDA personnel supporting this project. The average annual salary of personnel in the Washington-Baltimore-Arlington, DC-MD-VA-WV-PA pay area is $129,438.60 ($129,438.60 x 5 = $647,193).

15. Explanation for Program Changes or Adjustments

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.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date and inform respondents of its significance as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.