UNITED STATES FOOD & DRUG ADMINISTRATION

Antimicrobial Animal Drug Distribution Reports and Recordkeeping

OMB Control No. 0910-0659

SUPPORTING STATEMENT

Terms of Clearance: None.

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations.

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 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

Many of the applicants have automated systems for reports of adverse drug experiences related to new animal drugs. Therefore, FDA believes that manufacturers of animal drugs already possess the computers, software, and equipment necessary to collect the required data and submit antimicrobial animal drug sales and distribution reports to us. 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 78% of the respondents will use electronic means to submit their antimicrobial animal drug sales and distribution reports, based on the submissions reported in table 1.

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

This collection carries the same burden for small or large firms. The FD&C Act and our regulations require all respondents to submit the same information. There is no exemption from the requirements of the regulation for small businesses. We estimate that approximately 35% of the respondents are small businesses. FDA aids small businesses in complying with its requirements through the Agency's Regional Small Business Representatives and through the scientific and administrative staffs within the Agency. FDA also provides a Small Business Guide on the Agency's website at http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm.

6. Consequences of Collecting the Information Less Frequently

Data collection and recordkeeping occurs occasionally. 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

FDA published a 60-day notice for public comment in the *Federal Register* of November 9, 2021 (86 FR 62178). No comments were received.

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

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This information collection request (ICR) is not collecting personally identifiable information (PII) or other data of a personal nature. This ICR involves the reporting to FDA of antimicrobial animal drug sales and distribution information. The FD&C Act and FDA's regulations specify the information that must be submitted to FDA by an animal drug manufacturer. Information collected from FDA Form 3744 (Antimicrobial Animal Drug Distribution Report) is not PII or other data of a personal nature. FDA determined that PII is not collected and the Privacy Act of 1974 does not apply.

Confidentiality of the information submitted under these reporting requirements is protected under 21 CFR 514.11. Confidentiality of information also will be safeguarded within the provisions of our public information regulations in 21 CFR part 20. Only information that is releasable under our regulations in part 20 would be released to the public. Finally, trade secret and confidential commercial information is also safeguarded by section 301(j) of the FD&C Act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

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[1]

21 CFR Section 514.87; FDA Form 3744	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
514.87(a) through (e)--Annual Reports for Sponsors With Active Applications--Paper Submission	4	1.5	6	62	372

21 CFR Section 514.87; FDA Form 3744	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
514.87(a) through (e)--Annual Reports for Sponsors With Active Applications--Electronic Submission	16	9.1	146	52	7,592
514.87(a) through (e)--Annual Reports for Sponsors With Inactive Applications--Paper Submission	5	3	15	2	30
514.87(a) through (e)--Annual Reports for Sponsors With Inactive Applications--Electronic Submission	16	12.6	201	2	402
TOTAL			0		0

[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 that 20 sponsors will have active applications and we assume that 75 percent of the respondents will report electronically while the other 25 percent will report on paper. We estimate that 4 sponsors with active applications 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 16 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 21 sponsors will have inactive applications and we assume that 93 percent of these respondents will report electronically while the other 7 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[1]

Activity	No. of Respondents	No. of Records per Respondent	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Recordkeeping required by section 512(*l*)(3) of the FD&C Act	21	1	21	2	42

[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 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 42 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)	8,396	$67.57	$567,317.72
Animal Drug Manufacturer/ Sponsor (Recordkeeping)	42	$67.57	$2,837.94
Total			$570,155.66

[1] May 2020 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics and including 30% for benefits (https://www.bls.gov/oes/2020/may/oes113010.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

There are five FDA personnel working on this project. One is GS-12 (average annual salary $98,827) and four GS-13s (average annual salary $117,516). We therefore calculate the annualized cost to the Federal Government to be $568,891 ($98,827 + $470,064).

15. Explanation for Program Changes or Adjustments*

We have adjusted our burden estimate downward by which has resulted in a decrease to the currently approved burden. We attribute this to respondents who submitted by paper in previous years are now reporting electronically. We also note a decrease in recordkeeping respondents. We attribute this to the mergers of sponsors over the years.

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 as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.