Antimicrobial Animal Drug Distribution
Reports and Recordkeeping

OMB Control No. 0910-0659
RIN 0910-AG45
SUPPORTING STATEMENT

Terms of Clearance: None

A. Justification

1. Circumstances Making the Information Collection Necessary

Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA 105) (P.L. 110-316) amended section 512 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b) to require that sponsors of applications for new animal drugs containing an antimicrobial active ingredient submit an annual report to the Food and Drug Administration (FDA or "we") on the amount of each such ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product. The legislation was enacted to address the problem of antimicrobial resistance and to help ensure that FDA has the necessary information to examine safety concerns related to the use of antibiotics in food-producing animals.

Each report required must specify (1) the amount of each antimicrobial active ingredient by container size, strength, and dosage form; (2) quantities distributed domestically and quantities exported; (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.

FDA has promulgated regulations at 21 CFR section 514 to support the information collection requirements associated with ADUFA 105. The rulemaking revises the existing collection to incorporate the sales and distribution data reporting requirements specific to antimicrobial new animal drugs that were added to the FD&C Act by ADUFA 105. The rulemaking also requires species-specific information to be included on Form FDA 3744. Finally, the recordkeeping provision under the rulemaking remains unchanged.

We therefore request approval of the revised reporting requirements under 21 CFR 514.87, Form FDA 3744 entitled, "*Antimicrobial Animal Drug Distribution Report*," and the existing recordkeeping provision regarding monthly distribution data.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

We believe the revised reporting provisions under ADUFA 105 will improve our understanding of antimicrobial animal drug sales intended for use in specific food-producing animal species, and assist us in assessing antimicrobial sales trends in the major food-producing animal species and examining how such trends may relate to antimicrobial resistance. Collection of information on the amount of animal antimicrobials being distributed, including species-specific information, is necessary to support ongoing efforts to encourage the judicious use of antimicrobials in food-producing animals and helps ensure the continued availability of safe and effective antimicrobials for animals and humans.

3. Use of Information Technology and Burden Reduction

FDA believes that respondents to the collection already possess the computers, software, and equipment necessary to collect the required data and make reports. To facilitate reporting, we have developed and instituted Form FDA 3744, which may be submitted both in paper format and electronically.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Together with data collected under the National Animal Health Monitoring System (NAHMS) and the National Antimicrobial Resistance Monitoring System (NARMS) programs administered by the United States Department of Agriculture and the Centers for Disease Control respectively, the information collection provides a comprehensive and science-based assessment of antimicrobial drug use and resistance in animal agriculture.

5. Impact on Small Business or Other Small Entities

Although new animal drug development is typically an activity completed by larger drug firms, the information collection provisions apply to small firms as well. FDA provides for small business contacts in the Center for Veterinary Medicine (CVM), as well as other agency components.

6. Consequences of Collecting the Information Less Frequently

Information collection is consistent with statutory requirements.

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 Agency

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(B)), FDA solicited public comment on the information collection provisions in its proposed rule of May 20, 2015 (80 FR 28863). While some comments were received supporting our effort to eliminate duplicative reporting, suggesting specific modifications and different approaches, questioning or supporting the utility of the information, suggesting we wait for resolution of the current legal disputes over disclosure of confidential commercial information, and suggesting we provide a specific methodology for making species-specific sales estimates, no comments suggested that we modify burden estimates.

All comments received in response to the proposed rulemaking may be found in the agency docket, FDA-2012-N-0447, and are addressed in the agency's final rule that published May 11, 2016 (81 FR 29129). As finalized, we believe the regulations under 21 CFR part 514.87 reflect minimal reporting burden and satisfy the statutory requirements under ADUFA. We believe the existing recordkeeping burden under 21 U.S.C. 360b(l)(3)(C) also reflects minimal burden to respondents.

9. Explanation of Any Payment or Gifts to Respondents

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondent

Confidentiality of information submitted under the reporting requirements is protected under 21 CFR 514.11 where data access is restricted to FDA and physical security measures are employed. Records that may be reviewed during FDA inspections are subject to FDA regulations in 21 CFR Part 20. Confidential commercial information is protected from disclosure under FOIA in accordance with section 552(a) and (b) (5 U.S.C. 552(a) and (b)) and by part 20. To the extent that § 20.64 applies, we will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12a. Estimates of Hour Burden Including Annualized Hourly Costs

FDA estimates the burden associated with the information below. Our estimates are based on review of agency data and in consideration of feedback during rulemaking. More detailed information regarding our calculations may be found within the agency's Final Regulatory Impact Analysis (FRIA) under docket FDA-2012-N-0447.

Description of Respondents: Respondents to the information collection are animal drug manufacturers (Sponsors).

Table 1 – Estimated One-Time Reporting Burden[1]

21 CFR 514.87	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Administrative Review of the Rule: Sponsors With Active Applications	20	1	20	24	480
Administrative Review of the Rule: Sponsors With Inactive Applications	7	1	7	1	7
Report Species: Specific Estimate of Percent of Products Distributed Domestically	20	7.50	150	2	300
Total					787

[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 recent experience with the existing antimicrobial animal drug distribution reports program. We base our estimate of the number of respondents reported in tables 1 and 2 on a review of our records of sponsors with active and inactive applications, which shows that in the past 3 years the number of sponsors has increased from 26 to 27.

Table 1 shows an estimated one-time burden associated with the new reporting provisions of the final rule. We expect current sponsors of approved or conditionally approved applications for antimicrobial new animal drugs sold or distributed for use in food-producing animals will need to review the provisions of the final rule and develop a compliance plan. As previously stated, based on a review of our records, we estimate a total of 27 sponsors, where 20 sponsors hold active (i.e., currently marketed) applications and 7 sponsors hold inactive applications, as reflected in rows 1 and 2. We estimate that the 20 sponsors with active applications will take 24 hours to complete the review and develop a compliance plan. We expect that the seven sponsors with inactive applications will take 1 hour to complete the review and will not need to develop a compliance plan.

Further, we estimate that the 20 sponsors with 150 applications will each spend approximately 2 hours to consider and decide upon a method to calculate the species-specific information required under § 514.87(c). This estimate is reflected in row 3.

Table 2 – Estimated Annual Reporting Burden[1]

Annual Reports Under 21 CFR 514.87	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Sponsors with active applications; paper submission	3744	10	7.5	75	62	4,650
Sponsors with active applications; electronic submission	3744	10	7.5	75	52	3,900

Annual Reports Under 21 CFR 514.87	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Sponsors with inactive applications; paper submission	3744	4	26.5	106	2	212
Sponsors with inactive applications; electronic submission	3744	3	35	105	2	210
Total						8,972

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

Table 2 shows the estimated annual reporting burden associated with the information collection. While we expect new § 514.87(c) will require 3 burden hours resulting from including species-specific estimates, we believe 1 hour will be saved by eliminating the requirement for sponsors to calculate the amount of antimicrobial active ingredients associated with their monthly product sales and distribution data (§ 514.80(b)(4)(i)(A)). Consequently, we estimate that the 20 sponsors with active applications will each expend approximately 2 additional reporting hours annually for new § 514.87. Under the final rule, we will continue to accept both paper and electronic submissions and estimate half of the respondents will report electronically and the other half by paper, as shown in rows 1 and 2.

While we estimate no increase in burden for the seven sponsors of inactive applications, we similarly will accept both paper and electronic submissions. Accordingly we retain the currently approved estimate under OMB Control No. 0910-0659 for these reporting burdens, as shown in rows 3 and 4.

Table 3—Estimated Annual Recordkeeping Burden

21 U.S.C. 360b(l)(3)(C)	No. of Respondents	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
All Applicants	27	1	27	2	54

Table 3 shows the estimated recordkeeping associated with the information collection. While specific recordkeeping requirements associated with new animal drugs are included under OMB Control Nos. 0910-0284 (periodic drug reports) and 0910-0139 (dosage form and distribution date), here we include burden associated with distribution data as required under 21 U.S.C. 360b(l)(3)(C) (monthly data regarding antimicrobial active ingredient). We believe the recordkeeping burden associated with this particular data element to be no more than 2 hours as shown in table 3. Although we have not changed our burden estimate associated with this recordkeeping, we have increased the number of respondents by one.

12b. Annualized Cost Burden

The total annualized cost burden is estimated to be $419,709 as calculated below.

Table 4 – Annualized Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Animal Drug Manufacturer /Sponsor (Reporting)	8,972	$46.50 / hr[2]	$417,198
Animal Drug Manufacturer/ Sponsor (Recordkeeping)	54	$46.50 / hr[2]	$2,511
Total			$419,709

[2] Buraeu of Labor Statistics Occupation employment and wages, May 2011, by occupation, for all industries (http://www.bls.gov). Wage ($46.50) includes mean hourly wage of $33.22 for Standard Occupational Classification 15-0000, computer and mathematics occupations, all industries; we add 40% to account for benefits.

13. Estimate of Other Total Cost Burden to Respondents and Recordkeepers

We estimate no other cost burden to respondents.

14. Annualized Cost to the Federal Government

There will be a total of four FDA personnel working on this project; three FTEs at the GS-12 level (average annual salary $84,855 x 3 = $254,565) and one FTE at the GS-13 level (average annual salary $100,904). We therefore calculate the annualized cost to the Federal government to be $355,469 ($254,565 + $100,904).

15. Explanation of Program Changes or Adjustments

The information collection includes a one-time burden of **787 hours** and **177 responses** to reflect current rulemaking. Upon its next request for renewal of the information collection the agency expects this burden to have been realized. Meanwhile, the annual reporting burden reflects a nominal adjustment of **330 fewer hours** with **37 additional responses**. Finally, the agency has adjusted the recordkeeping burden to include **one additional recordkeeper**, consistent with the number of respondents submitting reports and resulting in an additional **2 hours** of burden.

16. Plans for Tabulation and Publication and Project Time Schedule

Information is not to be published for statistical use.

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

Display is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.