OMB Control Number 0910- 0659
SUPPORTING STATEMENT
Animal Drug User Fee Amendments of 2008 (ADUFA 2008)--21 U.S.C. 360b(l)

A. JUSTIFICATION

1. Circumstances Making the Information Collection Necessary

Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA 2008) (P.L. 110-316; 122 Stat. 3509) (154 Cong Rec H 7534) amended section 512 of the Federal Food, Drug, and Cosmetic Act (the 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 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 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.

The reports required under section 105 of ADUFA 2008 are required to be separate from periodic drug experience reports that are required under 21 CFR § 514.80(b)(4) (OMB Control No. 0910-0284).

FDA is requesting OMB renewal of Form FDA 3744 and approval of the new e-form FDA 3744a.

2. Purpose and Use of the Information Collection

This information collection responds to legislation that contained provisions that increase the availability and accessibility of data on the amount of animal antibiotics being distributed. Its purpose is to ensure that the FDA has the necessary information to examine safety concerns related to the use of antibiotics in food-producing animals. The statute requires that sponsors of applications for new animal drugs containing an antimicrobial active ingredient submit an annual report to the Food and Drug Administration 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.

3. Use of Information Technology and Burden Reduction

Many of the applicants have automated systems for reports of adverse drug experiences 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 make reports. FDA has developed a system that supports the submission of Form FDA 3744 in electronic format (called Form FDA 3744a).

4. Efforts to Identify Duplication and Use of Similar Information

This information is not collected by any other Agency in the Government. The information collection required as a result of the statute does not duplicate any other information collection.

5. Impact on Small Business or Other Small Entities

Although new animal drug development is typically an activity completed by large drug firms, the information collection required applies to small as well as large companies. FDA will provide help to small firms through the Office of Small Manufacturers Assistance, if requested.

6. Consequences of Collecting the Information Less Frequently

The annual report required under ADUFA 2008 is necessary to address potential problems concerning the safety and effectiveness of antimicrobial new animal drugs. Less frequent data collection would hinder this purpose.

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

The reporting requirements under ADUFA 2008 are consistent with 5 CFR 1320.5 because they require reporting annually of monthly quantities marketed during the calendar year preceding the report. The maintenance period for keeping records is also consistent with 5 CFR 1320.6 because ADUFA 2008 does not mandate the recordkeeping for any particular time period. Regarding the recordkeeping burden associated with this collection of information, FDA believes that most of the necessary information for the annual report required to be submitted under section 512(l)(3) of the act is already collected and maintained by animal drug manufacturers under existing requirements.

Animal drug manufacturers are already required to maintain distribution records for their drug products to comply with FDA's current good manufacturing practice regulations under § 211.196 (21 CFR § 211.196) (OMB Control No. 0910-0139), and to comply with regulations for periodic drug experience reports under § 514.80(b)(4)(i) (21 CFR § 514.80(b)(4)(i)) (OMB Control No. 0910-0284) of FDA regulations. Therefore, FDA believes that manufacturers of animal drugs already possess the computers, software, and other equipment necessary to collect and maintain the necessary records, and to make reports.

Section 512(l)(3) of the act differs from § 514.80(b)(4)(i) in that it requires that records include separate information for each month of the calendar year. Under § 211.196 (OMB Control No. 0910-0139), manufacturers currently are required to maintain distribution records that include the dosage form and date the drug is distributed. Additionally, 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 their usual and customary practice.

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

FDA published a 60-day notice in the **Federal Register** of January17, 2012 (FDA-2012-N-0032) (77FR2302), that requested comment on the proposed information collection and received three comments, two from organizations and one from a member of Congress. The commenters generally supported the collection of sales data, and stated that this information would be useful in assessing antimicrobial drugs used in food-producing animals to better address the problem of antimicrobial resistance. One commenter stated that the information supplied by drug companies should be submitted in a format that would allow it to be easily merged with data from other FDA databases.

Beyond the scope of this Federal Register Notice, all commenters recommended collection of antimicrobial use information in addition to the current requirements of ADUFA 2008 sales reporting. All commenters also recommended revisions to the public reporting of the data being collected. The commenters requested FDA report sales of antimicrobial drug classes by month, by route of administration, by indication, by over-the-counter or prescription status, or grouped by their importance in human medicine. It was recommended that FDA collect and publicly report distribution information down to the state or regional level. ADUFA 2008 requires that no class with fewer than 3 distinct sponsors of approved applications shall be independently reported; it was recommended that FDA seek additional authority from Congress to report sales figures for all antimicrobial classes regardless of the number of distinct drug sponsors. There was also a recommendation that all of the information collected be made publicly available in a searchable database.

FDA has considered the comments, but at this time we can only require the submission of information on the new e-form FDA 3744a that is expressly required to be submitted by section 512(l)(3) of the act. We are pursuing notice and comment rulemaking to codify these requirements, and are currently assessing any additional data requirements. In this regard, FDA published an Advance Notice of Proposed Rulemaking (ANPRM) on July 17, 2012, in which FDA solicited comment on 1) whether FDA should require submission of an estimate of the amount of antimicrobial ingredient sold or distributed for use in each approved food animal species, 2) how FDA can best compile and present required summary information, and 3) alternative methods there may be for obtaining additional data and information about the extent of antimicrobial drug use in food-producing animals and are there alternative methods the Agency can employ within its existing authority.

FDA extended the comment period for the ANPRM until November 26, 2012.

9. Explanation of Any Payment or Gifts to Respondents

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondent

During working hours, only FDA employees have access to the computer files and database on a need-to-know basis. During duty and non-duty hours building security is provided through a contract with a private protection agency. None of these provisions bar the release of the confidential information if subpoenaed by a court of law. Confidentiality of the information submitted under these reporting requirements is protected under 21 CFR 514.11 and under 21 CFR part 20. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under Section 310(j) of the Act.

11. Justification for Sensitive Questions

This information does not contain questions pertaining to sex behavior, attitude, religious beliefs, or any other matter commonly considered private or of a sensitive nature.

12a. Estimates of Hour Burden Including Annualized Hourly Costs

Table 1—Estimated Annual Reporting Burden

21 U.S.C. 360b	Form FDA No.	Number of Re-spondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours	Capital Costs
Annual Reports for Sponsors With Active Applications—Paper Submission	3744	14	5.9	83	60	4,980	$6,975
Annual Reports for Sponsors with Active Applications—Electronic Submission	e-Form 3744a	12	6.7	80	50	4,000	0
Annual Reports for Sponsors with Inactive Applications—Paper Submission	3744	13	6.2	81	2	162	0
Annual Reports for Sponsors	e-Form 3744a	11	7.3	80	2	160	0

with Inactive Applications—Electronic Submission							
TOTAL						9,302	$6,975

The total annual responses were calculated by multiplying the number of respondents times the number of responses per respondent. Total burden hours were calculated by multiplying the total annual responses times the average burden per response. The initial one-time capital costs are for the design of the report. Here, e-form FDA 3744a and reporting via the Electronic Submission Gateway are provided by FDA. Thus, the remaining cost, as described in approved OMB control number 0910-0659 is $6,975 per year (3 hours x $46.50 wage rate x 50 sponsors = $6,975). FDA believes the sponsors already possess the computer equipment needed to prepare the report so that additional capital expenditures will not be necessary.

Table 2—Estimated Annual Recordkeeping Burden

21 U.S. C. 360(b)(l)(3)	No. of Respondents	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
All Applicants	26	1	26	2	52
Total					52

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 act differs from § 514.80(b)(4)(i) in that it requires that records include separate information for each month of the calendar year.

Under §211.196 (OMB Control no. 0910-0139), manufacturers currently are required to maintain distribution records that include dosage form, and date drug is distributed. In addition, 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 52 hours for further compliance with section 512(I)(3) as detailed in Table 2. ***Although the 60-day notice of January 17, 2012, reported the number of respondents in Table 2 as 34, upon further review FDA finds that the actual number is 26, and the total hours are adjusted to 52.

12b. Annualized Cost Burden

The total annualized cost burden has been estimated to be $435,705.

Table 3 – Annualized Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Animal Drug Manufacturer /Sponsor (Reporting)	9,302	$46.50 / hr[2]	$432,543
Animal Drug Manufacturer/ Sponsor (Recordkeeping)	68	$46.50 / hr[2]	$3,162
Total			$435,705

[2]BLS 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

There is no other cost burden to respondents and recordkeepers.

14. Annualized Cost to the Federal Government

There will be a total of four FDA personnel working on this project. Three will be GS-12s (average annual salary $84,855 x 3 = $254,565) and one GS-13 (average annual salary $100,904 + 254,565 = $355,469.)

15. Explanation of Program Changes or Adjustments

This ICR is characterized as a revision (agency discretion program change) to introduce an electronic form for use by sponsors of applications for new animal drugs containing an antimicrobial active ingredient.

While this ICR is a revision because the agency is introducing an electronic form, the burden does not increase as a result of this new form. There is actually a decrease but it is due to an adjustment as described below but not due to the introduction of the e-form.

The decrease in burden (an adjustment of -6,328 hours and $-100,905) reflects updated and current data obtained on the number of annual reports submitted by sponsors of applications.

The two hours designated as an increase in program change due to OPDIV discretion in ICRAS/ROCIS are “a marker” in the system for the e-form added to this ICR. The use of the e-form does not, in fact, increase burden on the respondents.

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.