OMB Control Number 0910- NEW
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) (110 P.L. 316; 122 Stat. 3509) 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. 154 Cong Rec H 7534.

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 first report must be submitted not later than March 31, 2010. 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 approval of " Form FDA 3744."

2. Purpose and Use of the Information

This legislation contains 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`s intent is to develop a system that supports the submission of Form FDA 3744 in electronic format.

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. However, under the Regulatory Flexibility Act, CVM analyzes regulatory options that would minimize any significant impact on small entities. CVM will assist small businesses in complying with regulatory requirements. FDA will provide help to small firms through the Office of Small Manufacturers Assistance, if requested. This regulation is not expected to have a significant economic impact on these small entities since the final rule is intended to simplify and clarify current recordkeeping and reporting requirements.

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 § 211.96) (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 October 26, 2009 (74 FR 55046), that requested comment on the proposed information collection and received comments from two organizations. Both commenters supported the information collection and stated that the data to be collected would be useful in addressing the problem of antimicrobial resistance. However, both comments suggested that more extensive measures are necessary to address this problem. For example, one of the comments stated that the practical utility of the data would be broadened in conjunction with a larger federal monitoring effort requiring manufacturers to report uses of their products in all food animal products, which would involve collecting data from end users such as veterinarians and animal owners. The other comment stated that the information collection would not be sufficient to show how much of each class of antimicrobial is sold for use in different types of food animals, and recommended that FDA collect distribution data on medicated feeds for this purpose because feeds are specific to animal species and class. The comment also recommended that FDA require all data to be submitted through a web based application directly into a form created by FDA, and that FDA create a publically accessible database that allows searches by drug class, dose form, and marketing status.

FDA has considered the comments, but at this time we have decided to only require the submission of information 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, during which time we will assess any additional data requirements.

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. Further, under the terms of the Freedom of Information Act, the veterinarian's name, address, and phone number, and the owner's name, etc., reported on Form FDA 3744 cannot be made available to a public request.

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[1]

21 U.S. Code 360(b)(l)(3)/Form FDA 3744	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Annual Reports for Sponsors with Active Applications	29	6.7	194	80	15,520
Annual Reports for Inactive Applications	23	4.0	92	1	92
Total					15,612

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

Table II—Estimated Annual Recordkeeping Burden[1]

21 U.S. Code 360(b)(l)(3)	No. of Respondents	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
All Applicants	34	1	34	2	68
Total					68

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

The reporting burden estimates including the total number of annual responses are based on the number of sponsors and approved applications for antimicrobial drug products in food producing animals. The annual frequency of responses was calculated as the total annual responses divided by the number of respondents. Thus, the agency derived the estimated annual reporting burden as follows: There are 34 sponsors with approved applications for antimicrobial drugs for food-producing animals. There are 29 animal drug manufactures with 194 approved applications for antimicrobial drugs for food – producing animals for which the drugs are being actively marketed. In addition, there are 92 approved applications for antimicrobial drugs for food-producing animals for which drugs are not being marketed (inactive applications), owned by 23 animal drug manufacturers. FDA believes the large majority of the burden will be incurred by industry in the first year in which reporting is required to design a report that meets the statutory requirements. The agency has estimated this burden at 80 hours per applicant. The total estimated reporting burden for animal drug manufacturers with active applications is 15,520 hours ((194 x 80 = 15,520 hrs). The agency has estimated the hours / response for sponsors with inactive applications at 1 hour, since the sponsors would only have to submit a report stating that the drug is not being marketed. The total estimated annual reporting burden for animal drug manufacturers with inactive applications is 92 hours (91 x 1 = 92)

FDA has developed the Form FDA 3744 for animal drug manufacturers to report their information in paper format. Use of Form FDA 3744 is entirely voluntary. In addition, animal drug manufacturers can exercise the option of designing their own form in paper format or design their own electronic form whose results could be submitted to the agency on a compact disc or own paper. For subsequent years, FDA believes the reports will be automated and that the process for producing reports will take less time i.e. estimated at 3 hours.

For recordkeeping requirements , animal drug manufacturers are already required to maintain distribution records for their drug products to comply with FDAs 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 (I)(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 68 hours for further compliance with section 512(I)(3) as detailed in Table II

12b. Annualized Cost Burden

The total annualized cost burden has been estimated to be $548,800. (See Table III below)

Table III

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Animal Drug Manufacturer /Sponsor (Reporting)	15,612	$35 / hr²	$546,420
Animal Drug Manufacturer /Sponsor (Recordkeeping)	68	$35 / hr²	$2,380
Total			$548, 800

13. <u>Estimate of Other Total Cost Burden to Respondents and Recordkeepers</u>

As previously discussed, animal drug manufacturers can submit their annual reports in paper format using either the FDA – provided form (Form FDA 3744), or one of their own design or by designing their own electronic form whose results could be submitted to the agency on a compact disc or own paper. The cost to animal drug sponsors for gathering the necessary information for report design and preparation for completing Form FDA 3744 in

the first year of reporting is $107,880 (29 active sponsors x 80 hours x $46.50/hour[2] = $107,880) This is a one time cost for a computer or mathematic employee to design and prepare a report that satisfies the statutory requirements of section 512 (I)(3)of the act. For subsequent years, the preparation of the report should take approximately 3 hours. The cost in subsequent years would be $139.50. Thus the 3 year annualized cost burden for this collection of information is estimated to be $36,053, ($107,880 + $279 [2x$139.50] = $108,159 / 3 = $36,053).

14. Annualized Cost to the Federal Government

There will be a total of 1360 FDA personnel hours per year. 1360/2080 annual hours per FTE = .65 FTE per year allocated for post marketing surveillance activities. If each FTE equals approximately $89,033 (GS-13/Step 1)(Washington Area Pay Scale), the total FTE burden to the Federal Government would be $57,871 (.65 x $89,033). For contract data entry personnel, there will be 1888 hours/yr for data techs at $25.49 per hour ($48,125) plus 236 hours at $28.28 per hour ($6,682) for a quality control tech.
The total cost burden to the Federal Government would be $112,678.

15. Explanation of Program Changes or Adjustments

This is a program change resulting from a new statutory mandate under ADUFA 2008.

16. Plans for Tabulation and Publication and Project Time Schedule

Information is not to be published for statistical use.

[2]BLS Occupation employment and wages, May 2006, 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.