Records And Reports Concerning Experience With Approved New Animal Drugs

OMB Control Number 0910-0284
Supporting Statement

A. JUSTIFICATION

1. Circumstances Making the Information Collection Necessary

Implementation of Section 512(l) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 514.80 requires applicants of approved new animal drug applications and abbreviated new animal drug applications to submit product/manufacturing defects, initial and follow-up reports for adverse drug experiences and lack of effectiveness of new animal drugs, increased frequency 15-day alert reports, periodic drug experience reports (annually or semi-annually in a specific format), and other reports (special drug experience reports, advertisement and promotional material submissions, and distributor statements).

This continuous monitoring of approved NADAs affords the primary means by which FDA obtains information regarding potential problems in safety and effectiveness of marketed animal drugs and potential manufacturing problems. Current data on file with FDA is not adequate because animal drug effects can change over time, and less apparent effects may take years to manifest themselves.

Adverse event reports are required to be submitted by the drug manufacturer on FDA Form 1932 following complaints from animal owners or veterinarians. Also, product defects and lack of effectiveness complaints are submitted to FDA by the drug manufacturer using FDA Form 1932 following their own detection of a problem or complaints from product users or their veterinarians. FDA Form1932a (the voluntary reporting form) is used by veterinarians and the general public to submit adverse event reports, product defects, and lack of effectiveness complaints directly to FDA. Form FDA 2301 is used to submit the required transmittal of periodic reports and promotional material for new animal drugs.

The specific citations within 21 CFR 500 regarding information collection requirements for which we request OMB approval are:

514.80(e) Recordkeeping.

Cites requirements that an applicant and nonapplicant establish and maintain records and files containing full records of information pertinent to the safety or effectiveness of a new animal drug for a period of 5 years after the date of submission.

21 CFR 514.80(b)(1) Reporting.

Specifies information pertaining to product defect/manufacturing defects that may result in serious adverse drug events is to be reported within 3 working days of first becoming aware that a defect may exist.

21 CFR 514.80(b)(2)(i) Reporting.

Specifies requirement that initial reports of serious adverse drug events and unexpected adverse drug events are to be submitted within 15 working days of first receiving the information.

21 CFR 514.80(b)(2)(ii) Reporting.

Specifies requirements for submitting follow-up reports to the initial report of serious adverse drug events and unexpected adverse drug events.

21 CFR 514.80(b)(3) Reporting.

Specifies requirements by nonapplicants to forward reports of adverse drug events to the applicant within 3 working days of first receiving the information. Nonapplicants may also elect to submit reports directly to FDA within 15 working days of first receiving the information.

21 CFR 514.80(b)(4)(i)-(iv) Reporting.

Specifies requirements for submitting 6 month periodic drug experience reports for the first two years following approval and then yearly thereafter. Specifies for yearly drug experience reports that applicants may petition FDA to change the date of reporting and(or) the frequency of reporting. Specifies requirements for submitting distribution data for each new animal drug product for quantities distributed domestically and quantities exported; applicant and distributor current package labeling; nonclinical laboratory studies and clinical data not previously submitted; and adverse drug experiences not previously submitted.

21 CFR 514.80(b)(5)(i) Reporting.

Specifies requirements for submitting special drug experience reports at different times or more frequently from those stated in 21 CFR 514.80.

21 CFR 514.80(b)(5)(ii) Reporting.

Specifies requirements for submitting advertisements and promotional labeling.

21 CFR 514.80(b)(5)(iii) Reporting.

Specifies requirements for submitting distributor statements.

We are also requesting OMB approval of the following forms:

Form FDA 1932, Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report

Form FDA 1932a, Veterinary Adverse Reaction, Lack of Effectiveness, or Product Defect Report (For VOLUNTARY Reporting)

Form FDA-2301, Transmittal of Periodic Reports and Promotional Material for New Animal Drugs

This information collection does not relate to the American Recovery and Reinvestment Act of 2009.

2. Purpose and Use of the Information.

Form FDA 1932a allows for voluntary reporting of adverse drug experiences or product/manufacturing defects.

Under §514.80, an applicant must report adverse drug experiences and product/manufacturing defects on Form FDA 1932. Periodic drug experience reports and special drug experience reports must be accompanied by a completed Form FDA 2301.

In 2010, the electronic version of Form FDA 1932 was incorporated into the FDA Safety Reporting Portal; incorporation of the electronic version of From FDA 1932a into the FDA Safety Reporting Portal is pending. This electronic system is used for collecting, submitting, and processing adverse event reports and other safety information for all FDA-regulated products. Burden for the electronic version of Forms FDA 1932 and 1932a is accounted for under OMB control number 0910-0645.

This approval request accounts for the collection of information using existing paper Forms FDA 1932, 1932a, and 2301 and is currently approved under OMB control number 0910-0284. We have found that the number of paper submissions of Form FDA 1932 has begun to decline and we expect that this trend will continue during the next 3-year approval cycle as use of the Electronic Submissions Gateway and the Safety Reporting Portal continues to grow.

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. The CVM has provided under 21 CFR 514.80(d) that applicants may computer generate Form FDA 1932 or Form FDA 2301. CVM works domestically with the animal pharmaceutical industry and internationally under VICH to develop methods and standards for electronic submissions. FDA anticipates over time that adverse event reporting for small businesses will shift more and more to the electronic FDA Safety Reporting Portal.

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 21 CFR 514.80 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 under 21 CFR 514.80 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 assists small businesses in complying with regulatory requirements. FDA will provide help to small firms through the Office of Small Manufacturers Assistance, if requested.

6. Consequences of Collecting the Information Less Frequently.

Part 514.80 establishes a reporting frequency that is dictated by the need to focus on potential problems concerning the safety and effectiveness of new animal drugs. Less frequent data collection would hinder early detection of such threats to the public health. New, unusual, and serious adverse experiences can suddenly begin to appear due to many reasons and under many circumstances. Also, when a new drug is approved, adverse events can appear at any time due to the large distribution of the drug as compared to its use during the preapproval clinical trials.

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

The reporting requirements under 21 CFR 514.80(b)(1), (b)(2)(i)-(ii), (b)(3), and (e) are inconsistent with 5 CFR 1320.5. This section requires justification for requesting respondents to report more often than quarterly. Pursuant to 21 CFR 514.80(b)(1), the applicant is required to submit product and manufacturing defects that may result in serious adverse drug events within 3 working days of first becoming aware that a defect may exist. Pursuant to 21 CFR 514.80(b)(2)(i)-(ii), the applicant is required to submit initial and follow-up reports within 15 working days. Pursuant to 21 CFR 514.80(b)(3), the non-applicant required to report adverse drug experiences to the applicant within 3 working days of first receiving the information or if reported to FDA within 15 working days. This short time for reporting is necessary so that FDA is informed as soon as possible of any serious problems with a drug product, so that the agency can take appropriate action.

The maintenance period for keeping records is also inconsistent with 5 CFR 1320.6. Pursuant to 21 CFR 514.80(e), the applicant and non-applicant must maintain records and reports of all information for a period of 5 years after the date of submission. This extended period is due to the potential for litigation, delayed recognition of adverse drug experiences, long expiration dates, and needed for studies of delayed effects such as carcinogenicity.

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

In the FEDERAL REGISTER of September 29, 2014, (2014-23059). FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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 1932 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.

12. Estimates of Annualized Burden Hours and Costs.

12a. Estimates of Hour Burden Including Annualized Hourly Costs

The reporting and recordkeeping burden estimates, including the total number of annual responses, are based on the submission of reports to the Division of Veterinary Product Safety and the Division of Surveillance, Center for Veterinary Medicine. The annual frequency of responses was calculated as the total annual responses divided by the number of respondents.

FDA estimates the burden of this collection of information as follows:

Table 1—Estimated Annual Reporting Burden[1]

21 CFR Section or section of the act	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
514.80(b)(1), 514.80(b)(2)(i) and (ii), 514.80(b)(3)	1932	22	81.05	1,783	1	1,783
Voluntary reporting FDA Form 1932a for the public	1932a	197	1	197	1	197
514.80(b)(4)	2301	200	8.11	1,622	16	25,952
514.80(b)(5)(i)	2301	200	0.57	114	2	228
514.80(b)(5)(ii)	2301	200	20.12	4,024	2	8,048
514.80(b)(5)(iii)	2301	190	0.1	19	2	38
Total Hours						36,246

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

Table 2 – Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
514.80(e)2	646	7.20	4,651	14	65,117

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

[2] Section 514.80(e) covers all recordkeeping hours for all adverse event reporting.

12b. Annualized Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage rate	Total Respondent Cost
Animal Drug Manufacturers	101,363	$35.00	$3,547,705

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

There is no additional cost burden to the respondents.

14. Annualized Cost to the Federal Government.

CVM currently has a contract for manual data entry of reports submitted on paper, costing $700,000 for FY15. CVM no longer contracts document processing and so does not directly track this cost which is incorporated in the overall budget for management of records information. However, the personnel payroll cost has decreased by $31,503.

15. Explanation of Program Changes or Adjustments.

This collection is being revised to reflect submissions received over the past 3 years of reporting and recordkeeping. While no changes have been made to the recordkeeping provisions, the reporting provisions have been revised. Overall, we estimate a decrease in the number of responses by **14,559**, and a decrease in the hourly burden by **10,416**. Changes to the individual information collection elements are detailed below.

IC No.	Change in responses	Change in burden
1	-16,098	-16,098
2	+115	+115
3	+194	+3,104
4	+88	+176
5	+1,175	+2,350
6	-33	-60
TOTAL	-14,559	-10,416

The agency attributes these adjustments to increased use of electronic reporting through the FDA Safety Reporting Portal, which is accounted for under OMB control no. 0910-0645.

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.

FDA will display OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions.

There are no exceptions to the certification.