UNITED STATES FOOD & DRUG ADMINISTRATION

Adverse Events Associated With New Animal Drugs

OMB Control No. 0910-0284

SUPPORTING STATEMENT

Terms of Clearance: None.

**Part A: Justification**:

1. Circumstances Making the Collection of Information Necessary

This information collection supports statutory and regulatory requirements governing reporting associated with certain animal drug products. With regard to adverse events and product/manufacturing defects associated with approved new animal drugs, section 512(l) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(l)) requires applicants with approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to establish and maintain records and reports of data relating to experience with uses of such drug, or with respect to animal feeds bearing or containing such drug, to facilitate a determination under section 512(e) as to whether there may be grounds for suspending or withdrawing approval of the NADA or ANADA under section 512(e) or 512(m)(4). Regulations in § 514.80 (21 CFR 514.80) require the electronic submission of postmarketing safety reports for approved new animal drugs but provide a procedure for requesting a temporary waiver from the requirement. We, therefore, retain use of certain paper-based forms. Section 514.80 requires applicants and nonapplicants to keep records of and report to us data, studies, and other information concerning experience with new animal drugs for each approved NADA and ANADA.

Following complaints from animal owners or veterinarians, or following their own detection of a problem, applicants or nonapplicants are required to submit adverse event reports and product/manufacturing defect reports under § 514.80(b)(1), (b)(2)(i) and (ii), (b)(3), and (b)(4)(iv)(A) and (C) on **Form FDA 1932** (to include FDA 1932 and 1932a (e-form). The information collection also includes **Form FDA 2301**; Transmittal of Periodic Reports and Promotional Material for New Animal Drugs.

The information collection also includes submissions under § 514.80(d)(2), by an applicant or nonapplicant requesting, in writing, a temporary waiver of the electronic submission requirements. The initial request may be by telephone or email to CVM’s Division of Pharmacovigilance and Surveillance, with prompt written follow-up submitted as a letter to the application(s). FDA will grant waivers on a limited basis for good cause shown. If FDA grants a waiver, the applicant or nonapplicant must comply with the conditions for reporting specified by FDA upon granting the waiver.

We therefore request OMB extension of OMB approval of the reporting requirements found in 21 CFR 514.80 and the associated forms, as discussed in this supporting statement.

1. Purpose and Use of the Information Collection

Respondents to the collection of information are applicants and nonapplicants as defined in 21 CFR 514.3. Respondents include individuals and the private sector (for-profit businesses). The information collection allows FDA to implement specified public health protection provisions under the FD&C Act regarding approved new animal drugs.

1. Use of Improved Information Technology and Burden Reduction

We estimate 95% of the respondents will use electronic means to fulfill the information collection. As communicated on our website at <https://www.fda.gov/animal-veterinary/report-problem/veterinary-adverse-event-reporting-manufacturers>, we provide instruction on submission of the information:

**Electronic Reporting:**

CVM accepts electronic submission of adverse event information for veterinary drugs through the Electronic Submissions System (ESS) and the Rational Questionnaire (RQ) in the Safety Reporting Portal (SRP), a joint FDA-National Institutes of Health initiative.

The ESS integrates with the FDA Electronic Submissions Gateway (FDA ESG) to allow adverse drug experience reports, either individually or in batches, to be transmitted directly from industry to CVM via gateway-to-gateway submission.

The Rational Questionnaire in the SRP provides another option for animal drug manufacturers to submit adverse event reports electronically to CVM.  The Rational Questionnaire is a web-based questionnaire that displays a series of questions to be answered by the person submitting the report.  These questions are intended to ensure proper collection of the information that is needed by FDA to appropriately evaluate the reported incident. Since the SRP only supports transmission of individual reports via the Rational Questionnaire, companies wanting to send batches of multiple reports might prefer the gateway-to-gateway method.

**Three-day Field Alert Reports:**

Three-day NADA/ANADA Field Alert Reports must be submitted directly to the appropriate FDA District Field Office or local FDA resident post. The information initially may be provided by telephone or other telecommunication means, with prompt written follow up using Form FDA 1932. (See 21 CFR 514.80(b)(1)).

* If the Marketing Authorization Holder (MAH, also referred to as the applicant) elects to submit a three-day NADA/ANADA field alert report *electronically via gateway to gateway submission or the Safety Reporting Portal directly to FDA’s CVM*, a copy of the report will automatically be sent to the District Office identified in the report.
* If the MAH chooses to submit a paper copy of Form FDA 1932 to FDA’s CVM, this does not alleviate the MAH’s responsibility to submit this report (via paper form) to the FDA District Field Office or local FDA resident post.  If submitting a three-day NADA/ANADA field alert report using the paper form, we prefer that the revised Form FDA 1932 (OMB No. 0910-0284) be used.

1. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information. Reporting and recordkeeping associated with the index of legally marketed unapproved new animal drugs for minor species (21 CFR part 516) is approved under OMB control number 0910-0620.

1. Impact on Small Businesses or Other Small Entities

No undue burden is imposed on small entities. At the same time, FDA aids small businesses in complying with its requirements through Regional Small Business Representatives and scientific and administrative staffs within the agency. Also, a Small Business Guide is available on our website at: [www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm](https://fda.sharepoint.com/sites/OC-Intranet-OC-OO-OEMS-DIG-Paperwork-Reduction/Shared%20Documents/www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm).

We estimate that 10% of the respondents are small businesses.

1. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

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

The reporting requirements under 21 CFR 510.301(a) and (b), 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. Under 21 CFR 510.301(a) and (b), a licensed medicated feed manufacturer must submit certain information to us immediately and other information to us within 15 days. 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 shorter reporting time is necessary to inform FDA as soon as possible of serious problems associated with a regulated product so that appropriate action may be taken to offset threats to the public health.

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.

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

We published a 60-day notice for public comment in the *Federal Register* of December 22, 2022 (87 FR 78694). One comment was received, however it was not responsive to the four information collection topics solicited by FDA.

1. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

1. Assurance of Confidentiality Provided to Respondents

*The Privacy Act of 1974*

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals’ professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted via **Form FDA 1932** (Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report), **Form FDA 1932a** (Veterinary Adverse Drug Reaction, Lack of Effectiveness, or Product Defect Report (for Voluntary Reporting)), and **Form FDA 2301** (Transmittal of Periodic Reports and Promotional Material for New Animal Drugs) is point of contact name, work address, work telephone number, work fax number, and work email address. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

*Freedom of Information Act (FOIA)*

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). 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 of disclosure of the trade secrets required in applications is specifically prohibited under the 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.

1. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

1. Estimates of Annualized Burden Hours and Cost

*12a. Annualized Hour Burden Estimate*

Table 1.--Estimated Annual Reporting Burden1

| 21 CFR Section | Form No. | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
| --- | --- | --- | --- | --- | --- | --- |
| Medicated feed reports, 510.301(a) and (b) | N/A | 8 | 1 | 8 | .25  (15 minutes) | 2 |
| Submission of postmarketing safety reports under § 514.80(b)(1), (2)(i) and (ii), (3) , and (4)(iv)(A) and (C) | 1932 | 85 | 1249 | 98,639 | 1 | 98,639 |
| Voluntary reporting FDA Form 1932a for the public | 1932a | 106 | 1 | 106 | 1 | 106 |
| 514.80(b)(4) Periodic Drug Experience Reports | 2301 | 79 | 20 | 1,582 | 16 | 25,312 |
| 514.80(b)(5)(i) Special Drug Experience Reports | 2301 | 78 | 215 | 16,790 | 2 | 33,580 |
| 514.80(b(5)(ii) Advertisement and Promotional labeling | 2301 | 38 | 192 | 7,282 | 2 | 14,564 |
| 514.80(b)(5)(iii) Distributor’s Statements | 2301 | 22 | 2 | 36 | 2 | 72 |
| 514.80(d)(2) | N/A | 1 | 1 | 1 | 1 | 1 |
| Total |  | 417 |  | 124,444 |  | 172,276 |

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

Table 2.--Estimated Annual Recordkeeping Burden1

| 21 CFR Section | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
| --- | --- | --- | --- | --- | --- |
| Recordkeeping, 510.3012 | 8 | 1 | 8 | 4 | 32 |
| Recordkeeping, 21 U.S.C. 360b(1) and 514.80(e)3 | 79 | 1,575.14 | 124,436 | 14 | 1,742,104 |
| Total |  |  | 124,444 |  | 1,742,136 |

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

2 This estimate includes all recordkeeping by licensed medicated feed manufacturers under § 510.301.

3 This estimate includes all recordkeeping by applicants of approved NADAs, ANADAs, and conditional NADAs under § 514.80(e).

*12b. Annualized Cost Burden Estimate*

|  |  |  |  |
| --- | --- | --- | --- |
| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
| Industry Compliance Officer | 1,914,412 | $55.09 | $105,464,957.08 |

1 May 2021 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics and

including 30% for benefits (https://www.bls.gov/oes/current/naics3\_325000.htm).

1. 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.

1. Annualized Cost to the Federal Government

We estimate Federal government costs in the amount of $3,000,000 to reflect a percentage of the agency’s overall expenditures to maintain its adverse event information collection activities.

1. Explanation for Program Changes or Adjustments\*

Upon review of the information collection, we have adjusted our estimated burden to reflect an overall increase of 1,814,530 hours and 237,951 responses/records, annually to correspond with current submission data.

1. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

Display of the OMB Expiration Date is appropriate.

1. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.