Reporting Associated with New Animal Drug Applications

0910-0032

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Under section 512(b)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(b)(1)), any person may file a new animal drug application (NADA) seeking our approval to legally market a new animal drug. Section 512(b)(1) sets forth the information required to be submitted in a NADA. Sections 514.1, 514.4, 514.6, 514.8, and 514.11 of our regulations (21 CFR 514.1, 514.4, 514.6, 514.8, and 514.11) further specify the information that the NADA must contain. The application must include safety and effectiveness data, proposed labeling, product manufacturing information, and where necessary, complete information on food safety (including microbial food safety) and any methods used to determine residues of drug chemicals in edible tissue from food producing animals. FDA Guidance #152 outlines a risk assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs. We request that applicants utilize Form FDA 356V, as appropriate, to ensure efficient and accurate processing of information to support new animal drug approval.

Under section 512(b)(3) of the FD&C Act, any person intending to file a NADA or supplemental NADA or a request for an investigational exemption under section 512(j) of the FD&C Act is entitled to one or more conferences with us prior to making a submission. Section 514.5 of our regulations (21 CFR 514.5) describes the procedures for requesting, conducting, and documenting pre-submission conferences. We have found that these meetings have increased the efficiency of the drug development and drug review processes. We encourage sponsors to submit data for review at the most appropriate and productive times in the drug development process. Rather than submitting all data for review as part of a complete application, we have found that the submission of data supporting discrete technical sections during the investigational phase of the new animal drug is the most appropriate and productive. This “phased review” of data submissions has created efficiencies for both us and the animal pharmaceutical industry.

Finally, § 558.5(i) of our regulations (21 CFR 558.5(i)) describes the procedure for requesting a waiver of the labeling requirements of § 558.5(h) in the event that there is evidence to indicate that it is unlikely a new animal drug would be used in the manufacture of a liquid medicated feed.

We request extension of OMB approval of the information collection requirements in the following citations; in Form FDA 356V, New Animal Drug Application; and in Guidance #152.

21 CFR 514.1 and 514.6 - Reporting

This section specifies content and format of the New Animal Drug Application and amendment of a pending application.

21 CFR 514.1(b)(8) and 514.8(c)(1) and Guidance #152 – Reporting

This section specifies information for NADAs and supplements for antimicrobial animal drugs. Guidance #152 provides sponsors with a recommended approach to assessing antimicrobial concerns as part of the overall pre-approval safety evaluation.

21 CFR 514.4 – Reporting

This section specifies definition of substantial evidence of effectiveness. (No burden hours associated with this definition).

21 CFR 514.5(b), (d) and (f) – Reporting

This section specifies paperwork needed to request a presubmission conference, provide the advanced materials, and comment on the memorandum of conference.

21 CFR 514.8(b) – Reporting

This section specifies required information for supplements requesting approval of changes to manufacturing for an approved new animal drug.

21 CFR 514.8(c)(1) – Reporting

This section specifies the information that must be provided to FDA to support a supplemental application, which describes each change in each condition established in an approved application.

21 CFR 514.8(c)(2) and (c)(3) – Reporting

This section specifies paperwork an applicant submits to support supplemental applications seeking changes to approved labeling.

21 CFR 514.11 – Reporting

This section specifies requirements for freedom of information summaries of information and data for an NADA. FDA generally takes responsibility for preparing the FOI Summary.

21 CFR 558.5(i) – Reporting

This section specifies requirements for obtaining a waiver (filing a petition) from labeling requirements for certain drugs intended for use in animal feed or drinking water.

2. <u>Purpose and Use of the Information Collection</u>

The reporting associated with NADAs and related submissions is necessary to ensure that new animal drugs are in compliance with section 512(b)(1) of the FD&C Act. We use the information

collected to review the data, labeling and manufacturing controls and procedures to evaluate the safety and effectiveness of the proposed new animal drug.

3. Use of Improved Information Technology and Burden Reduction

Submissions related to the new animal drug approval process contain summaries of data and narrative text. The animal health industry may use the free FDA eSubmitter software to prepare all submissions related to the new animal drug approval process. We currently accept this information electronically via the Electronic Submission Gateway (ESG). We estimate that 55% of the submissions will be submitted electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

The information provided in an application for approval of a new animal drug is unique to the particular product covered by the application. There are no other regulations that require the submission of this same information. The information is generally not available from any recognized scientific sources, unless the information has been made public by the NADA applicant.

5. Impact on Small Businesses or Other Small Entities

Because of the critical nature of the products, their uses and the impact on the consumer or user, any submission of an application for approval of a new animal drug from a small business concern is treated with the same rigorous scientific and technical review as that submitted by a large pharmaceutical firm. However, we assist small businesses to meet the part 514 requirements through FDA's Regional Small Business Representatives and through the scientific and administrative staff within the Center.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. There are no specific regulatory time frames imposed on an applicant for the collection or recording of information. After the initial submission of an application, the applicant can submit any required information as he/she sees fit or as may be imposed by the regulations under 21 CFR 514, 558, 211, 225, or 226.

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

There are no special circumstances associated with this collection of information.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of March 2, 2016 (81 FR 10871). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

We do not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

We expect that an application for approval of a new animal drug will contain trade secret and commercial confidential information. As a result, all files are maintained in a secured area. Confidentiality of the information submitted under these reporting requirements is protected under 21 CFR 514.11. Only information that is releasable under the agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by section 301(j) of the FD&C Act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

Table 1--Estimated Annual Reporting Burden

21 CFR Section; Activity	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Avg. Burden Per Response	Total hours
514.1 & 514.6; applications and amended applications	182	.05	9	212	1,908
514.1(b)(8) and 514.8(c)(1)[1] evidence to establish safety and effectiveness	182	.10	19	90	1,620
514.5(b), (d), (f); requesting presubmission conferences	182	.49	89	50	4,450
514.8(b); manufacturing changes to an approved application	182	1.40	255	35	8,925
514.8(c)(1); labeling and other changes to an approved application	182	.05	10	71	710
514.8(c)(2) & (3); labeling and other changes to an approved application	182	.43	79	20	1,580
514.11; submission of data, studies and other information	182	.09	16	1	16
558.5(i); requirements for liquid medicated feed	182	.01	1	5	5
Form FDA 356V	182	2.92	531	5	2,655
TOTAL			1009		21,959

[1]NADAs and supplements regarding antimicrobial animal drugs that use a recommended approach to assessing antimicrobial concerns as part of the overall pre-approval safety evaluation.

Based on the number of sponsors subject to animal drug user fees, we estimate an average of 182 annual respondents during the 5 fiscal years, from October 1, 2010 through September 30, 2014, on which these estimates were made. We use this estimate consistently throughout the table and calculate the number of responses per respondent by dividing the total annual responses by the total

number of respondents. We base our estimates of the average burden per response on our experience with NADAs and related submissions.

12b. Annualized Cost Burden Estimate

We estimate that the average hourly wage for respondents is equivalent to a GS-11-7 level in the locality pay area of Washington-Baltimore in 2016, approximately $37.17/hour. Increasing this wage by 30% to account for overhead costs ($11.15), FDA estimates the average hourly cost to respondents to be $48.32/hour. The overall estimated cost incurred by the respondents is $1,061,059 (21,959 burden hours x $48.32/hr = $1,061,058.88).

13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

We estimate the annualized cost to the Federal government for the review and evaluation of submissions to be $9,584,960. These figures are only an analysis of pioneer animal drug review work (NADAs) and do not include review hours and FTEs for generic animal drug review work (ANADA). We estimate that we expend approximately 176,000 person hours annually in review, support and supervisory support of the review of submissions. We estimate the average hourly wage for personnel to review and evaluate a submission to be at the GS-13-8 level in the locality pay area of Washington-Baltimore in 2016, approximately $54.46/hour. The estimated annualized cost to the Federal government is $9,584,960 (176,000 hours x $54.46/hr = $9,584,960).

15. Explanation for Program Changes or Adjustments

Although the number of respondents has increased (an adjustment from 169 to182 due to natural increases in the animal drug industry) the overall burden has reduced from 28,218 to 21,959 because we have determined that the number of responses per respondent has decreased.

The previously approved ICR submitted to OMB in 2013 included nine ICs entered into ROCIS. Upon this submission we are consolidating the ICs, thereby, reducing the number of ICs in ROCIS to one. The information collection activities, however, remain broken down in this supporting statement document.

16. Plans for Tabulation and Publication and Project Time Schedule

We have no plans to tabulate and publish information from this information collection.

17. Reasons Display of OMB Expiration Date is Inappropriate

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.