Supporting Statement for
Presubmission Conferences, New Animal Drug Applications (NADA) and Supporting Regulations, and Guidance 152 and Form FDA 356V
OMB #0910-0032

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Abstract

Under section 512(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act), any person may file a New Animal Drug Application (NADA) seeking approval to legally market a new animal drug. Section 512(b)(1) sets forth the information required to be submitted in an NADA. FDA allows applicants to submit a complete NADA or to submit information in support of an NADA for phased review followed by submission of an administrative NADA when FDA finds all the applicable technical sections are complete.

Under section 512(b)(3) of the act, any person intending to file an NADA or supplemental NADA or a request for an investigational exemption under section 512(j) of the act is entitled to one or more conferences with FDA to reach an agreement acceptable to FDA establishing a submission or investigational requirement. FDA and industry have found that these meetings increased the efficiency of the drug development and drug review processes.

21 CFR 514.1 interprets section 512(b)(1) of the act and further describes the information that must be submitted as part of the NADA and the manner and form in which the NADA must be assembled and submitted. 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. Guidance #152 outlines a risk assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs. FDA requests that an applicant accompany NADAs, supplemental NADAs, and requests for phased review of data to support NADAs with the Form FDA 356V to ensure efficient and accurate processing of information to support new animal drug approval.

The Animal Drug Availability Act of 1996 required FDA to further define “substantial evidence” of effectiveness, and FDA further defined the term at 21 CFR 514.4.

21 CFR 514.8 describes the information that must be submitted as part of a supplemental application to support proposed changes to an approved NADA. An applicant may reference existing information from the NADA in the supplemental NADA, but must submit some subset of information required in §514.1 to support the proposed changes.

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 514.8(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 514.1(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

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)

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

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.

FDA is also requesting approval of FDA Form 356V- New Animal Drug Application

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

2. Purpose and Use of the Information Collection

Required information to support an NADA or supplemental NADA is accompanied by an FDA Form 356V – New Animal Drug Application. The information submitted is reviewed by professional personnel in the Center for Veterinary Medicine, in the FDA, including veterinarians, chemists, microbiologists, toxicologists, physiologists, pharmacologists, nutritionists, statisticians, consumer safety officers, and paid FDA consultants, as necessary, to determine if a new animal drug can be approved. In order to get approval of a new animal drug, the applicant must, among other things, demonstrate that the new animal drug is safe and effective for its intended uses.

Respondents are private sector animal drug manufacturing firms that operate for profit.

3. Use of Improved Information Technology and Burden Reduction

The Center for Veterinary Medicine (CVM, the Center) is accepting electronic new animal drug applications in the near future. Currently 0% of new animal drug applications are submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

The information as 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, FDA does assist small businesses to meet the part 514 requirements through the Office of Small Manufacturers Association through the scientific and administrative staff within the Center.

6. Consequences of Collecting the Information Less Frequently

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 reports required to be submitted which are inconsistent with 5 CFR 1320.5.

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

In accordance with 5 CFR 1320.8(d), on February 8, 2011, in Volume 76, No. 26, page 6798, a 60-day notice for public comment was published in the ***Federal Register*****.** No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Only FDA employees and contractors have access to the administrative files on a need-to-know basis during working hours. 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 or consistent with relevant disclosure laws. Confidentiality of the information submitted under these reporting requirements is protected under 21 CFR 514.11. 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 collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The total annual estimated burden imposed by this collection of information is 33,146 hours.

12a. Annualized Hour Burden Estimate

Table 1 – NADAs - Estimated Annual Reporting Burden[1]

21 CFR Part and/or FDA FORM #	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in Hours)	Total Hours
514.5(b), (d), (f)	154	.6	92	50	4600
514.1 & 514.6	154	.1	15	212	3180
514.4[2]	154	0	0	0	0
514.8(b)	154	2.84	437	35	15295
514.8(c)(1)	154	.1	15	71	1065

514.8(c)(2) & (3)	154	.7	108	20	2160
514.11	154	.2	31	1	31
558.5(i)	154	.01	2	5	10
514.1(b)(8) and 514.8(c)(1)[3]	154	.21	32	90	2880
FDA FORM 356V	154	5.1	785	5	3925
TOTAL HOURS					33,146

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Substantial Evidence--Because 21 CFR 514.4 only defines substantial evidence it should not be viewed as creating additional collection burden.
[3] These are New Animal Drug Applications and supplements regarding antimicrobial animal drugs that use a recommended approach to assessing antimicrobial concerns as part of the overall pre-approval safety evaluation.
[4] Based on the number of sponsors subject to animal drug user fees, FDA estimates that there was an average of 154 annual respondents during the 5 fiscal years, from October 1, 2005, through September 30, 2010, on which these estimates were made. We use this estimate consistently throughout the table and calculate the "annual frequency per respondent" by dividing the total annual responses by number of respondents.

12b. Annualized Cost Burden to Respondents

The estimated annual cost to respondents is $1,325,840

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Compliance Officer[1]	33,146	$40	$1,325,840

13. Estimates of Other Total Annual Costs to Respondents and/or Record-keepers/Capital Costs

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

14. Cost to Federal Government

For calendar year 2010, we expended approximately 174,000 person hours in review, support, and supervisory support of the review of submissions. We estimate about 1650 hours of work is performed per FTE. So, about 105.5 FTEs are used for application review work. We estimate a compensation cost of $106,839 per FTE (Washington Metro Area pay scale), which is the salary of a GS13/7, the average grade among the personnel involved in the review. Multiplying this figure by 105.5 FTEs = $11,271,514 as the cost for one year of review work. 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).

15. Explanation for Program Changes or Adjustments

[1] May 2009 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400, Pharmaceutical and Medicine Manufacturing, 13-1041, Compliance Officer, $31 per hour plus 30% for benefits. U.S. Bureau of Labor Statistics.

The number of respondents has changed from 134 to 154 due to natural increases in the animal drug industry.

16. Plans for Tabulation and Publication and Project Time Schedule

Information is not to be published for statistical use.

17. Reasons Display of OMB Approval Date is Inappropriate

FDA is not seeking approval of an exemption from displaying the expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.