Supporting Statement for
Abbreviated New Animal Drug Applications and Form FDA 356V
OMB #0910-XXXX

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

On November 16, 1988, the President signed into law the Generic Animal Drug and Patent Restoration Act (GADPTRA)(P.L. 100-670). Among its provisions, GADPTRA extends eligibility for submission of Abbreviated New Animal Drug Applications (ANADAs) to all animal drug products approved for safety and effectiveness under the Federal Food, Drug, and Cosmetic Act (the Act).

GADPTRA provides 5 years of exclusivity for the first-time approval of a drug in animals (section 512(c)(2)(F) of the act) (21 U.S.C. 360b(c)(2)(F)). In enacting GADPTRA, Congress indicated that it viewed this term of exclusivity as a sufficient return on investment prior to generic competition to provide an incentive for the pioneer sponsor to develop a drug. This statute resulted in the need for a new information collection as described below.

FDA Form 356V- Application for Approval of a New Animal Drug – Data collection instrument that must be filled out to ensure efficient and accurate processing of information to support the approval of a generic new animal drug.

2. Purpose and Use of the Information Collection

Required information to support an ANADA or supplemental ANADA is accompanied by an FDA Form 356V – Application for Approval of a New Animal Drug. 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 an ANADA can be approved. In order to get approval of an ANADA, the applicant must, among other things, demonstrate that the proposed ANADA is bioequivalent to its referenced listed drug.

3. Use of Improved Information Technology and Burden Reduction

FDA accepts the submission of some data to support ANADAs and supplements electronically.

4. Effort to Identify Duplication and Use of Similar Information

The information as provided in an ANADA 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 ANADA applicant.

5. Impact on Small Businesses or Other Small Entities

FDA does assist small businesses to meet the application 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 submitting an application or supplement. 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 parts 514, 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 November 2, 2009 a 60-day notice published in the *Federal Register*. (74 FR56643 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. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under section 310(j) of the act.

11. Justification of Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12A. Estimates of Annualized Burden Hours and Costs

Table 1 – Estimated Annual Reporting Burden[1]

Section 512(n)(1) of the FD&C Act	Form FDA	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
ANADA	356v	17	1	17	159	2703
Phased Review With Administrative ANADA	356v	5	5	25	31.8	795
TOTAL						3498

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

***ANADA paperwork burden Section 512 (n)(1)of the act(21 U.S.C. 360b(b)(2))*.** Over the past 5 fiscal years, from October 2003 through September 2008, FDA has received an average of 17 ANADAs per year. FDA estimates that preparation an ANADA required under section 512(n)(1) of the act, to take approximately 159 hours. Thus the total annual reporting burden is estimated to be 2,703 hours, (17 x 159 = 2703 hours.). For the applicant who submits information for Phased Review followed by an Administrative ANADA which references that information, and FDA has determined that all the applicable technical sections are complete, FDA estimates that it takes 31.8 hours for preparing the paperwork under section 512 (n)(1) of the act. FDA is estimating that each ANADA that uses the phased review process, will have approximately 5 phased reviews per application. Therefore, assuming that 5 respondents will take advantage of the phased review option per year and an average of 5 phased review are submitted per application , the total annual reporting burden is estimated to be 795 hours per Administrative ANADA, (25 x 31.8 = 795 hours). Thus, the total annual reporting burden hours for the submission of an ANADA / Phased Review with Administrative ANADA is estimated to be 3,498 hours,, (2,703 hrs + 795 hrs = 3,498 hrs)

FDA believes that with time, more sponsors will take advantage of the phase review option, as it provides greater flexibility. Eventually, phased review will increase to the point of being the majority of ANADAs submitted during the course of the year. FDA also estimates it takes sponsors of ANADAs approximately 25% less time to put together the information to support an ANADA than an NADA because they only need to provide evidence of bioequivalence and not the data required in an NADA to support full demonstration of safety and effectiveness.

***Form FDA 356v*.** FDA requests that an applicant fill out and send in with an ANADA and Requests for Phased Review of data to support an ANADAs, a Form FDA 356v to ensure efficient and accurate processing of information to support the approval of a generic new animal drug.

This document also refers to previously approved collections of information found in FDA regulations. The collections of information under 21 CFR 514.80, which describes records and reports that are required post approval, have been approved under OMB control No. 0910-0284.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Animal Drug Sponsor	3,498	$38.00	$132,924.00

13. Estimates of Other Total Annual Costs to Respondents and Record Keepers

There are no capital costs or operating and maintenance costs associated with this collection. There are no other annual costs to respondents than those addressed in item 12 above.

14, Annualized Cost to the Federal Government

For calendar year 2008, we expended approximately 26,208 staff hours in reviewing ANADA applications and 3,000 hours of supervisory support of this review. We estimate a compensation cost of $44.43 for reviewers (2009 Washington Metro Area pay scale), which is the salary of a GS13/3, the average grade among the personnel involved in the review. Multiplying this figure by 26,208 = $1,164,121.44 as the cost for one year of review work.

The cost of supervisory review is 3,000 hours times $49.22 per hour for a GS-14/1 = $147,660. Total annual cost to the federal government for this information collection is $1,312,081.44.

15. Explanation for Program Changes or Adjustments

Passage of GADPTRA resulted in a program change requiring this new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for tabulation or project time schedule.

17. Reason Display of OMB Expiration Date is Inappropriate

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to Item 19 of OMB Form 83-I.

B. Statistical Methods

Information is not to be published for statistical use.