Abbreviated New Animal Drug Applications
OMB Control No. 0910-0669

SUPPORTING STATEMENT Part A

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 new animal drug (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 new animal drug. This statute resulted in the need for a new information collection as described below.

Form FDA 356v – Application for Approval of a New Animal Drug

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

The information submitted is used, among other things, to demonstrate bioequivalence to the pioneer or originally approved drug and thus, the safety and effectiveness of the generic new animal drug.

3. Use of Improved Information Technology and Burden Reduction

As a part of the reauthorization of the Animal Drug User Fee Act (ADUFA) in 2008, the Center for Veterinary Medicine (CVM) committed to developing an electronic submission tool for industry submissions within 24 months of appropriated ADUFA funds for FY 2009. The tool was made available by CVM's Office of New Animal Drug Evaluation (ONADE), for voluntary use by sponsors and manufacturers of both pioneer and generic animal drug products, on March 11, 2011.

Sponsors and manufacturers of generic animal drug products may use the eSubmitter, a secure online submission tool, for all submissions related to the abbreviated new animal drug approval process. Currently, 14% of submissions related to ANADAs are submitted electronically.

4. Efforts 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 assists small businesses to meet the application requirements through the Office of Small Manufacturers Association through the scientific and administrative staff with CVM. Approximately 50% of sponsors are small businesses.

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 special circumstances for 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 April 30, 2013 (78 FR 25,279). FDA received one comment, but it did not pertain to the information collection.

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 for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

Table 1. – ANADAs - Estimated Annual Reporting Burden

FD&C Act Section 512 (b)(2)	FDA Form	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
ANADA	356v	18	1	18	159	2862
Phased Review with Administrative ANADA	356v	3	5	15	31.8	477
Total						3339

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

ANADA paperwork burden (Section 512(b)(2) of the act) (21 U.S.C. 360b(b)(2)). Over the past 5 fiscal years, from October 2007 through September 2012, FDA has received an average of 21 ANADAs per year. FDA estimates that preparing the paperwork required under 21 USC 360b(n)(1) to be contained in an ANADA, whether all of the information is submitted with the ANADA or the applicant submits information for phased review followed by an Administrative ANADA that references that information, will take approximately 159 hours. (FDA is estimating that each ANADA that uses the phased-review process will have approximately 5 phased reviews per application. Therefore, assuming that 3 respondents will take advantage of the phased-review option per year and an average of 5 phased reviews are submitted per application, times 31.8 hours per phased review, equals 477 total hours per year or 159 hours per application.)

Although over the last 5 fiscal years all sponsors chose to submit traditional ANADAs, some sponsors did indicate an interest in using the phased-review option in the future. FDA believes that with time, more and more sponsors will take advantage of the phased-review option, as it provides greater flexibility, and it estimates that there will be 3 respondents for the phased-review option. FDA also estimates that 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 a full demonstration of safety and effectiveness.

Form FDA 356v. To ensure efficient and accurate processing of information to support an ANADA and request for phased review of data to support an ANADA, FDA requests applicants complete and submit Form FDA 356v, already approved under OMB Control No. 0910-0032.

21 CFR 514.80 describes records and reports that are required post-approval; these information collections are approved under OMB Control No. 0910-0284.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry Compliance Officer	3339	$39.00[1]	$130,221
Total			$130,221

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

For calendar year 2012, we expended approximately 37,419 staff hours in reviewing ANADA applications and approximately 9,996 hours of supervisory support for these reviews. We estimate a compensation cost of $44.08 for reviewers (2012 Washington Metro Area pay scale), which is the salary of a GS 13/2, the average grade among the personnel involved in the review. Multiplying this figure by 37,419 equals $1,649,429 as the cost for one year of review work. Likewise, supervisory costs at $55.45 per hour for a GS 14/4 multiplied by 9,996 hours equals $554,278. Thus, the total annual cost to the government is $2,203,707.

15. Explanation for Program Changes or Adjustments

There is an increase of 1 in the number of ANADA respondents, but a decrease of 2 in the number of respondents utilizing the phased in review process. This results in an overall decrease in burden hours of 159. This is a result of flucuations in the number of sponsors submitting applications to the agency.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for tabulation or project time schedule.

17. Reason(s) 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 the certification.

[1] May 2012 National Industry-Specific Occupational Employment and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics, 13-1041, $29.82 plus 30% adjusted for benefits equals approximately $39.00 per hour wage.