SUPPORTING STATEMENT ------ OMB 0910-0356
SUBSTANTIAL EVIDENCE OF EFFECTIVENESS OF NEW ANIMAL DRUGS

A. JUSTIFICATION

1. Circumstances Making the Information Collection Necessary.

Sections 512(a)(1) and (2) of the Federal Food, Drug, and Cosmetic Act (the act) state that a new animal drug, or an animal feed bearing or containing a new animal drug, is unsafe unless it is the subject of an approved new animal drug application (NADA). Approval of an NADA requires, among other things, a demonstration of the effectiveness of a new animal drug by "substantial evidence" derived from adequate and well controlled studies.

On October 9, 1996, Congress enacted the Animal Drug Availability Act (ADAA) (Pub. L. 104-250). One of the purposes of the ADAA was to facilitate the approval and marketing of new animal drugs and medicated feeds. Section 2(a) of the ADAA amended section 512(d)(3) of the act to revise the definition of "substantial evidence." Section 2(e) of the ADAA directed FDA to issue proposed regulations to further define the term " substantial evidence" in a manner that encourages the submission of NADA's and supplemental NADA's. Section 2(e) also directed FDA to issue regulations to encourage dose range labeling**.** A final rule accomplishing this was published in the July 28, 1999, **Federal Register** (64 FR 40746).

We are requesting OMB approval for the following collection of information requirements

21 CFR 514.4(a), Reporting -- Specifies requirements for submitting adequate and well-controlled studies to provide substantial evidence of effectiveness for a new animal drug.

2. Purpose and Use of the Information

Section 512(d)(1)(E) of the act requires us to issue an order refusing to approve a New Animal Drug Application (NADA), if there is a lack of substantial evidence that a new animal drug will have the effect it is purported or represented to have under the conditions of use prescribed in the proposed labeling. Therefore, substantial evidence must be submitted to the us as part of the NADA to establish effectiveness of a drug.

3. Use of Information Technology and Burden Reduction
We are continuously seeking ways through advances in information technology to reduce the burden on the government and sponsors. We are continuing to look at what information can be submitted electronically and will permit electronic submission of data to INAD files and NADAs as technology and resources permit.

4. Efforts to Identify Duplication and Use of Similar Information

There are no other regulations or Federal Agencies that require the submission of the same type information. There are no similar data/information that could be substituted for that required by these regulations.

5. Impact on Small Businesses or Other Small Entities

Our charge to approve only those new animal drugs that have been demonstrated to be effective applies whether small and large businesses apply for approval of a new animal drug. The law and corresponding regulations must be applied consistently and equally to all enterprises to ensure that only safe and effective new animal drugs are approved. While we cannot establish different standards with respect to statutory requirements, we do provide special help to small businesses. A small business coordinator has been established on the Commissioner's staff to ensure that small businesses have an adequate opportunity to express their concerns and to keep our management apprised of how its regulatory decisions may impact the small business community. Furthermore, we encourage sponsors, whether small or large businesses, to meet with us to discuss the development of evidence of safety and effectiveness to support approval of an NADA.

6. Consequences of Collecting the Information Less Frequently

There are no specific regulatory time frames imposed on a sponsor for conducting adequate and well-controlled studies to support a demonstration of effectiveness of a new animal drug. However, if at the time a sponsor submits a new animal drug application it does not contain substantial evidence of effectiveness, FDA is required by law to refuse to approve the application under section 512(d)(1)(E) of the act.

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

None of the information collection requirements are inconsistent with 5 CFR 1320.5.

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

In a **Federal Register** of November 2, 2006 (71 FR 64535), the FDA published a 60 day notice in the Federal register soliciting public comment on the proposed collection of information collection requirements. In response to that notice, no comments were received.

9. Explanation of Any Payment or Gift to Respondent

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondent

Information will be kept confidential in accordance with 18 USC 1905 and 21 USC 331(j), as well as Section 301(j) of the Act.

11. Justification for Sensitive Questions

There are no questions or references pertaining to sex behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimates of Hour Burden Including Annualized Hourly Costs

From consultation with several of the largest research and development (R&D), firms in 1997 and review of our data bases, we estimate that the 10 largest R&D firms are responsible for 90% of all "substantial evidence" expenditures. Data supplied by these firms, indicates an annual average of 86 studies by each firm with an average of 632.6 hours expended for each study, at an average cost of $140 per hour. This results in an annual hourly burden of 544,036 hours (10 firms X 86 studies X 632.6 hours). Cost is estimated at $76,165,040 (544,036 hours X $140/hour). This figure includes time spent from inception to completion of a study and submission to us. To project this figure to a total burden on industry, we would need to include the additional estimated 10% of studies submitted annually by the remainder of firms conducting studies to demonstrate substantial evidence. However, since we estimate that under the proposed definition of "substantial evidence" the number of adequate and well-controlled studies necessary to demonstrate efficacy will be reduced by approximately 10%, the two adjustments would essentially offset each other, leaving the total at $76,165,040.

Respondents, not all of whom submit studies in any given year, total 190. This number was derived by looking at the number of sponsors of approved applications listed in 21 CFR 510.600.
This burden estimate includes submission of new animal drug applications and supplemental new animal drug applications for single ingredient and combination new animal drugs. It also includes estimates for dose range labeling studies.

Estimated Annual Reporting Burden1

21 CFR	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
21 CFR 514.4a	190	4.546	860	632.6	544,036

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

13. Estimate of Other Total Annual Cost Burden To Respondents

Total annual cost burden is included in the preceding paragraph. There are no additional costs to respondents.

14. Annualized Cost to the Federal Government

Based on historical data and an estimated workload under the proposed definition of substantial evidence, we estimate that approximately 30.8 FTEs will be expended annually in discussion with sponsors and premarket review of effectiveness data. Number of FTEs per grade and grade salary were weighted to calculate an average FTE salary of $103,000. At a rate of $103,000 per each of the 30.8 FTEs, total government cost would be $3,172,400 annually ($103,000 X 30.8)

15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments. Burden remains similar to that reported in the final rule for this regulation published on July 28, 1999.

16. Plans for Tabulation and Publication and Project Time Schedules

There are no plans for tabulation and publication.

17. Displaying of OMB Expiration Date

We will display the expiration date for OMB approval of the information collection.

18. Exception to the Certification Statement - Item 19

There are no exceptions to the certification statement identified in Item 19. “Certification for Paperwork Reduction Act Submission,” of OMB Form 83-I.