OMB CONTROL # 0910-0575
SUPPORTING STATEMENT

Waivers of *In Vivo* Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles

Part A. Justification

1. Circumstances Which Make This Information Collection Necessary

The Center for Veterinary Medicine has written this guidance to address a perceived need for agency guidance in its work with the animal health industry. This guidance describes the procedures that the agency recommends for the review of requests for waiver of *in vivo* demonstration of bioequivalence for generic soluble powder oral dosage form products and Type A medicated articles.

The Generic Animal Drug and Patent Term Registration Act (GADPTRA) of 1988 permitted the generic drug manufacturers to copy those pioneer drug products that were no longer subject to patent or other marketing exclusivity protection. The approval for marketing these generic products is based, in part, upon a demonstration of bioequivalence between the generic product and the pioneer product. This guidance clarifies circumstances under which FDA believes the demonstration of bioequivalence required by the statute does not need to be established on the basis of *in vivo* studies for soluble powder oral dosage form products and Type A medicated articles. The data submitted in support of the waiver request are necessary to validate the waiver decision.

2. How, by Whom, and the Purpose for Collecting This Information

The respondents for this collection of information are pharmaceutical companies manufacturing animal drugs. The requirement to establish bioequivalence through *in vivo* studies may be waived for soluble powder oral dosage form products or Type A medicated articles in either of two ways. A biowaiver may be granted if it can be shown that the generic product contains the same active and inactive ingredient(s) and is produced using the same manufacturing processes as the approved comparator product or article. Alternatively, a biowaiver may be granted without direct comparison to the pioneer product's formulation and manufacturing process if it can be shown that the active pharmaceutical ingredients(s) (API) is the same as the pioneer product, is soluble, and that there are no ingredients in the formulation likely to cause adverse pharmacologic effects. For the purpose of evaluating soluble powder oral dosage form products and Type A medicated articles, solubility can be demonstrated in one of two ways: "USP definition" approach and "Dosage adjusted" approach.

The purpose of collecting information is to prove that *in vivo* studies are not necessary to establish the bioequivalence of the generic product. This is desirable because the pharmaceutical companies would save the funds otherwise expended on *in vivo* studies by providing the data requested.

3. Use of Technology to Reduce the Burden on the Public

CVM is planning to accept electronic new animal drug applications and also requests for bioequivalence waivers in the near future.

4. Identification and Use of Duplicate Information

This information is not collected by any other agency in the Government. The information collection required by 21 CFR 514.1(b)(7) and (8) does not duplicate any other information collection.

5. FDA's Efforts to Reduce Burden on Small Business

Some of the comments to the draft guidance indicated that this bioequivalence waiver process would reduce the regulatory burden on the animal drug industry. A large number of these drug companies are classified as small businesses.

6. Impact of Not Collecting or Collecting Information Less Frequently

This information is collected only once in the generic animal drug approval process. If this data is not provided, the animal drug industry, which is largely composed of small businesses, would need to conduct costly *in vivo* animal drug testing to prove bioequivalence of the generic animal drug.

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

The information collection is consistent with 5 CFR 1320.5 and 5 CFR 1320.6.

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

On October 29, 2008 (73 FR 64338), FDA published a 60-day notice in the Federal Register, asking for comments on the information collection. 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 Respondent

During working hours, only FDA employees have access to the computer files and databases on a need to know basis. 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.

11. Use of Sensitive Questions

This information collection does not contain questions pertaining to any matter commonly considered private or of a sensitive nature.

12. Burden Hours and Cost Associated with this Burden

Table 1. Estimated Annual Reporting Burden for Water Soluble Powders[1]

	No. of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
Same formulation/ manufacturing process approach	1	1	1	5	5
Same API/ solubility approach	5	5	5	10	50
Total Burden Hours					55

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

Table 2. Estimated Annual Reporting Burden for Type A Medicated Articles[1]

	No. of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
Same formulation/ manufacturing process approach	2	2	2	5	10
Same API/ solubility approach	10	10	10	20	200
Total Burden Hours					210

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

13. Estimate of Other Total Cost Burden to Respondents and Recordkeepers

The estimates of cost burden have been addressed in item 12. No other cost burdens are associated with the collection of this information.

14. Annual Cost Estimate to FDA

The hourly review burden is probably about 4 hours per submission or 72 hours overall. Adding overhead in the Document Control Unit for logging, delivering, tracking, etc. brings the total to about 5 hours per submission or 90 hours overall. Ninety hours is about .04 full time employee (FTE) and an FTE costs CVM about $100,000 per year, so the annual cost in dollars to FDA is on the order of $4000 to process the projected 18 submissions.

15. Changes from Previous Approval

This is a new collection of information.

16. Publishing the Results of this Information Collection

The results of this information collection are not to be published.

17. Reason for Not Displaying the OMB approval date.

FDA will display the OMB approval date.

18. Exceptions to Section 19, "Certification for Paperwork Reduction Act Submissions"

There are no exceptions.

Part B. Collections of Information Using Statistical Methods

Not applicable.