Designated New Animal Drugs for Minor Use and Minor Species

OMB No. 0910-0605

Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary--Abstract

The Minor Use and Minor Species (MUMS) Animal Health Act of 2004 authorized FDA to establish new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species as well as uncommon diseases in major animal species. This statute provides incentives designed to help pharmaceutical companies overcome the financial burdens they face in providing animal drugs for which there is limited demand. These incentives are only available to sponsors whose drugs are "MUMS-designated" by FDA. Minor use drugs are drugs for use in major species (cattle, horses, swine, chickens, turkeys, dogs and cats) that are needed for diseases that occur in only a small number of animals either because they occur infrequently or in limited geographic areas.

Minor species are all animals other than the major species, for example, zoo animals, ornamental fish, parrots, ferrets and guinea pigs. Some animals of agricultural importance are also minor species. These include animals such as sheep, goats, catfish, and honeybees.

2. Purpose and Use of the Information Collection

The purpose of the information collection under 21 CFR part 516 is to enable FDA to process requests for MUMS-drug designation, requests to amend MUMS-drug designation, changes in sponsorship, termination of MUMS-drug designation, requirements for annual reports from sponsors, and provisions for insufficient quantities of MUMS-designated drugs. (21 CFR parts 516.20, 516.26, 516.27, 516.29, 516.30, and 516.36, respectively). The likely respondents of this information collection are pharmaceutical companies, i.e. new animal drug sponsors.

3.Use of Improved Information Technology and Burden Reduction

We encourage the submission of data electronically, and will consider any such electronic submissions which will be more efficient for industry and facilitate review by the Agency.

4. Efforts to Identify Duplication and Use of Similar Information

The information provided is unique to the particular product or application cited. There are no other regulations that require the submission of this same information.

5. Impact on Small Business and Other Small Entities

Because many new animal drugs for minor uses and minor species traditionally come from smaller drug companies, we expect the MUMS incentive program to have a beneficial impact on small business. The collection of information is commensurate with what is required by the MUMS Act and should pose no greater burden to small businesses than it does to large pharmaceutical firms. 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 questions concerning submissions.

6. Consequences of Collecting the Information Less Frequently

FDA feels that annual progress reporting, as specified in section 516.30, is appropriate. Regular progress reports from MUMS designees are necessary to insure "due diligence" in their efforts to gain drug approval, as required by section 573(a)(3)(B) of the act. Since only one MUMS designation is granted for any given drug and indication, the consequence of an ineffectual effort will be for FDA to terminate the MUMS designation for that sponsor and reassign it to another competing sponsor. Annual reporting allows FDA to assess "due diligence" in a timely manner thereby insuring that drug development moves forward.

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

Required reports are consistent 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), FDA published a 60-day notice for public comment in the **Federal Register** on July 20, 2010 (75 FR 42094). One comment was received but it did not relate to the information collection proposed and did not respond to the four questions of the use and suitability of collecting the information.

9. Explanation of any Payment or Gift to Respondents

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Center for Veterinary Medicine and the FDA are required under 21 CFR Part 20 and sections 514.11 and 514.12 to maintain the confidentiality of all information received in conjunction with the submissions of NADAs and INADs. These requirements are specified in section 21 CFR 516.52.

In addition to the requirements of 21 CFR part 20 and sections 514.11 and 514.12, the Center exercises security precautions in the handling of documents. A security controlled document file room, locked files, drawers and doors are required for in-house protection. Unused documents are destroyed by shredding. This protection is continued after approval of the drug.

The Center has a Freedom of Information Officer who is responsible for administering the policies relative to the release of information.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Burden of Information Collection

TABLE 1. ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. Of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
516.20	15	5	75	16	1200
516.26	3	1	3	2	6
516.27	1	1	1	1	1
516.29	2	1	2	1	2
516.30	15	5	75	2	150
516.36	1	1	1	3	3
Total					1362

1 There is no capital or operating and maintenance cost associated with this collection of information.

The burden estimate for this reporting requirement was derived in our Office of Minor Use and Minor Species Animal Drug Development by extrapolating the current INAD/NADA reporting requirements for similar actions by this same segment of the

regulated industry and from previous interactions with the minor use/minor species community.

13. Costs to Respondents

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

14 Costs to the Federal Government

1.5 FTEs in OMUMS × 15% spent on paperwork × $135,000 per FTE = $30,375.

15. Explanation of Program Changes or Adjustments

There are no changes to the program.

16. Plans for Tabulation and Publication of Project Time Schedule

There is no intent on the part of the Federal Government to publish this data, nor is any general statistical analysis by the Federal Government anticipated.

17. Reasons Display of OMB Expiration Date is Inappropriate

Display is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.