SUPPORTING STATEMENT

DESIGNATION OF NEW ANIMAL DRUGS FOR MINOR USE OR MINOR SPECIES

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

This information collection approval request is for a Food and Drug Administration (FDA) final rule implementing section 573 of the Minor Use and Minor Species (MUMS) Animal Health Act of 2004. The MUMS Act establishes 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 legislation provides incentives designed to help pharmaceutical companies overcome the financial burdens they face in providing limited-demand animal drugs. These incentives are only available to sponsors whose drugs are "MUMS-designated" by the FDA. Participation in the MUMS program is completely optional for drug sponsors so the associated paperwork only applies to those sponsors who request and are subsequently granted MUMS designation. This final rule specifies the criteria and procedures for requesting MUMS designation as well as the annual reporting requirements for MUMS designees.

The specific citations within 21 CFR 500 regarding information collection requirements for which we request OMB approval are:

Section 516.20: Content and format of a request for designation for a minor use or minor species new animal drug designation.

Section 516.26: Amendment to minor use or minor species new animal drug designation.

Section 516.27: Change in ownership of minor use or minor species new animal drug designation.

Section 516.29: Termination of minor use or minor species new animal drug designation.

Section 516.30: Annual reports of holder of minor use or minor species new animal drug designation.

Section: 516.36: Insufficient quantities of designated minor use or minor species new animal drugs.

2. How, By Whom, Purpose of Collection

Requests for MUMS designation, as specified in section **516.20**, will be prepared by drug sponsors and submitted to the FDA/Center for Veterinary Medicine (CVM), Office of Minor Use and Minor Species Animal Drug Development (OMUMS). Based on the criteria

provided in the MUMS Act and in this final rule, OMUMS will grant or deny MUMS designation for each requesting sponsor and their specific drug and proposed indication. This collection of information occurs only once for each specific sponsor/drug/indication request.

MUMS designated sponsors may amend their designations (section **516.26**) or change designation ownership (section **516.27**) by notifying OMUMS in writing.

MUMS designated sponsors must notify OMUMS in writing if they plan to discontinue active pursuit of an approval or discontinue manufacturing an approved designated drug (section **516.29**). FDA will terminate the designation upon such notification.

Annual reports, as specified in section **516.30**, will be prepared by sponsors of unapproved MUMS-designated drugs and will be submitted to OMUMS. The reports will be used by OMUMS to insure "due diligence" by drug sponsors during the pre-approval process as required in section 573(a)(3)(B) of the MUMS ACT.

If FDA determines that insufficient quantities of an approved designated drug are being manufactured, the sponsor will provide OMUMS, orally or in writing, their proposal for increasing production or their permission, in writing, for OMUMS to grant another approval for the same drug and indication before the end of their exclusive approval period (section **516.36**).

All information collection specified in this final rule is new.

3. Consideration Given to Information Technology

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. Identification of 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. Small Business

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 outlined in this final rule 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. Less Frequent Information Collection

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. Information Collection Circumstances

Required reports are consistent with 5 CFR 1320.5.

8. Consultations with Persons Outside FDA

This rule making was subject to public comment under the Administrative Procedures Act, and public comments were addressed as part of the public rule making process. In the FEDERAL REGISTER of September 27, 2005, FDA published a proposed rule and invited comments for a 75-day period on the proposed collection of information. Also, in the FEDERAL REGISTER of December 28, 2005, FDA published a notice reopening the comment period for the proposed rule to allow interested persons 30 additional days to comment. In response to these FEDERAL REGISTER notices, FDA did not receive any comments regarding the information collection requirements contained in the final rule.

9. Payment or Gift

There are no payments or gifts to respondents at this time. However, the MUMS Act will eventually provide grant money to sponsors for drug development studies. This provision will not become active until all final implementing regulations are published.

10. Confidentiality Provisions

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 516.52 of this final rule.

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. Privacy

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. Reason for Changes

This is a new program.

16. Statistical Reporting

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.