Food and Drug Administration
Designated New Animal Drugs for Minor Use and Minor Species

OMB Control Number 0910-0605

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Minor Use and Minor Species (MUMS) Animal Health Act of 2004 (P.L. 108-282) 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. Some 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 annually either because they occur infrequently or in limited geographic areas.

Minor species are all animals other than humans that are not 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 honey bees.

21 CFR 516.20	Content and format of MUMS designation request	Reporting
21 CFR 516.26	Requirements for amending MUMS designation	Reporting
21 CFR 526.27	Changes in sponsorship	Reporting
21 CFR 516.29	Termination of MUMS designation	Reporting
21 CFR 516.30	Requirements for annual reports	Reporting
21 CFR 516.36	Insufficient quantities	Reporting

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 consider any such submissions to be more efficient for industry and to facilitate review by the Agency. In OMUMS, we are able to accept electronic submissions for our Designation and Indexing programs. We are receiving approximately 75% of all submissions electronically at this time, but the trend is for a continuing increase in the number made electronically over the next few years. Many sponsors and requestors are learning the approval process and will need time to develop the skills to use the electronic format.

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 Businesses or Other Small Entities

Because many new animal drugs for minor uses and minor species traditionally come from smaller drug companies (approximately 50% are small businesses), 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

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* on June 12, 2019 (84 FR 27333). 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 Respondents

This information collection request (ICR) is collecting personally identifiable information (PII). PII is collected in the context of the individuals' professional capacity. The PII submitted in a request for designation under 21 CFR 516.20 is name, address, telephone number, fax number, and email address. This ICR involves the submission to FDA of applications for a MUMS-designated drug. The FD&C Act and FDA's regulations specify the information that must be submitted to FDA by persons developing, manufacturing, and/or researching MUMS-designated drugs.

FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected. FDA also minimized the PII to be collected to protect the privacy of the individuals.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected.

We expect that regulatory information will contain trade secret and commercial confidential information. As a result, all files are maintained in a secured area. Confidentiality of the information submitted under these reporting requirements is protected under 21 CFR 514.11. Only information that is releasable under the agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by section 301(j) of the FD&C Act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Table 1. Estimated Annual Reporting Burden [1]

21 CFR Part	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
21 CFR 516.20	15	5	75	16	1200
21 CFR 516.26	3	1	3	2	6

21 CFR 516.27	1	1	1	1	1
21 CFR 516.29	2	1	2	1	2
21 CFR 516.30	15	5	75	2	150
21 CFR 516.36	1	1	1	3	3
Total					1,362

[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.

12 b. Annualized Cost Burden Estimate

Table 2. Annualized Cost Burden Estimate[1]

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Compliance Officer	1362	$51.82	$70,578.84

[1]Occupation Employment and Wages, Bureau of Labor Statistics, May 2018, Compliance Officers, 13-1041, $39.86 per hour plus 30% benefits. Department of Labor.

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

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

15. Explanation for Program Changes or Adjustments

There are no changes to the program

16. Plans for Tabulation and Publication and 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. Reason(s) 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.