OMB Control No. 0910-0620
SUPPORTING STATEMENT Part A
INDEX OF LEGALLY MARKETED UNAPPROVED NEW ANIMAL DRUGSFOR MINOR SPECIES

A. JUSTIFICATION

1. Circumstances Making the Information Collection Necessary

This information collection approval request is for a Food and Drug Administration (FDA) regulation that implements section 572 of the Minor Use and Minor Species (MUMS) Animal Health Act of 2004. The MUMS Act is made up of three sections (571, 572, and 573) and it 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. Section 572 of the legislation provides for a public index listing of legally-marketed unapproved new animal drugs for minor species of animals. The drugs in this index are only indicated for use in non-food minor species or for use in early non-food life stages of food-producing minor species. This regulation, among other things, specifies the procedures for requesting eligibility and addition to the index as well as the annual reporting requirements for index holders.

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

Section 516.119: Permanent-resident U.S. agent for foreign requestor.

Section 516.121: Meetings.

Section 516.123: Informal conferences

Section 516.125: Investigational use of new animal drugs to support indexing.

Section 516.129: Content and format of a request for determination of eligibility for indexing.

Section 516.141: Qualified expert panels.

Section 516.143: Written report.

Section 516.145: Content and format of a request for addition to the index.

Section 516.161: Modifications to indexed drugs.

Section 516.163: Change in ownership of an indexed drug

Section 516.165: Records and Reports.

2. Purpose and Use of the Information Collection

Foreign drug companies provide the FDA with the name and address of a permanent U.S. resident agent to represent them at the time they establish their initial index file. Such information, or any changes in such information, are submitted in writing to the FDA/Center for Veterinary Medicine (CVM), Office of Minor Use and Minor Species Animal Drug Development (OMUMS), as specified in section **516.119**.

Drug companies may request, in writing, a meeting with FDA to discuss the requirements for indexing under section **516.121** as well as an informal conference to dispute an action taken by FDA in regards to a request for indexing, as specified in section **516.123**.

Section 516.125 provides for investigational use of new animal drugs intended for indexing.

Requests for determination of index eligibility and, if determined eligible, subsequent requests for addition to the index, including a written report, are prepared by drug companies and submitted to OMUMS, as specified in sections **516.129** and **516.145**. Based on the criteria provided in the MUMS Act and in this regulation, OMUMS will grant or deny such requests for each drug owner and their specific drug, dosage form, and intended use. These two collections of information from each drug owner are required only once for each specific drug/dosage form/intended use. A description of the written report required in section 516.145 can be found under section **516.143**.

Under section **516.141** are provisions for drug companies to nominate a qualified expert panel as well as the panel's recordkeeping requirements. This section also calls for the submission of a written conflict of interest statement to FDA by each proposed panel member.

Index holders may modify their index listing (section **516.161**) or change drug ownership (section **516.163**) by notifying OMUMS in writing.

Records and reports, as specified in section **516.165**, are prepared by holders of indexed drugs and are submitted to OMUMS. One of these requirements is an annual written drug experience report. These reports are used by OMUMS to monitor possible drug-related adverse events.

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. Currently 0% of submissions are electronic.

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 or Other Small Entities

Because many new animal drugs for minor uses and minor species traditionally come from smaller drug companies, we expect the MUMS Act to have a beneficial impact on small business. The collection of information outlined in this regulation is commensurate with what is required by the MUMS Act and poses 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

Periodic drug experience reports, as proposed in section 516.165, are submitted to OMUMS annually. This frequency is the same as is currently required for approved drugs under 21 CFR 514.80(b)(4). FDA reviews the records and reports required in this section to facilitate a determination under section 572(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ccc-1) as to whether there may be grounds for removing a drug from the index.

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

FDA provided for public comment in a 60-day notice that published in the Federal Regsiter April 7, 2014 (79 FR 19094). No comments were received.

9. Explanation of any Payment or Gift to Respondents

There are no provisions for payments or gifts to respondents under section 572 of the MUMS Act.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of data and information in an index file is provided for in section 516.171 of this regulation. In order to comply with the requirements of 21 CFR part 20 and sections 514.11 and 514.12, the Center exercises security precautions in the handling of documents. This same level of security is provided for index files. 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 a drug is added to the index.

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. Estimates of Annualized Burden Hours and Costs

12a. Annualized Burden Hour Estimate

FDA estimates the burden of this collection of information as follows:

TABLE 1.—Estimated Annual Reporting Burden [1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
516.119	2	1	2	1	2
516.121	30	2	60	4	240
516.123	3	1	3	8	24
516.125	2	3	6	20	120
516.129	30	2	60	20	1200
516.141	20	1	20	16	320
516.143	20	1	20	120	2400
516.145	20	1	20	20	400
516.161	1	1	1	4	4
516.163	1	1	1	2	2
516.165	10	2	20	8	160
Total					4,872

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

TABLE 2.—Estimated Annual Recordkeeping Burden [1]

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours
516.141	30	2	60	0.5	30
516.165	10	2	20	1	20
Total					50

[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 from agency experience with the MUMS Indexing program.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry compliance officer[1]	4872	$35	$170,520
Clerical worker[2]	50	$15	$750

13. Estimates of Other Total Annual Costs to Respondents and/or Record keepers/Capital Costs

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

14. Annualized Costs to the Federal Government

There is one half FTE at a GS-15 ($61,879) plus three quarters of an FTE at a GS-13 ($66,775) equals $128,654 annual cost to the Federal government.

15. Explanation of Program Change or Adjustment

The burden has not changed from the burden shown in the current inventory.

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. **Reasons Display of OMB Expiration Date is Inappropriate**

Display is appropriate.

18. **Exceptions to Certification of Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

[1, 2] May 2009 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics and including 30% for benefits.