FOOD AND DRUG ADMINISTRATION

Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

OMB Control No. 0910-0620

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Minor Use and Minor Species Animal Health Act of 2004 (the MUMS Act) (Pub. L. 108-282) added section 572 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360ccc-1), which authorizes 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 (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats). In enacting the MUMS Act, Congress sought to encourage the development of these new animal drugs. Congress recognized that the markets for drugs intended to treat these species, diseases, or conditions are so small that there are often insufficient economic incentives to motivate drug companies to develop data to support approvals. Further, Congress recognized that some minor species populations are too small or their management systems too diverse to make it practical to conduct traditional studies to demonstrate safety and effectiveness of animal drugs for such uses. As a result of these limitations, drug companies have generally not been willing or able to collect data to support legal marketing of drugs for these species, diseases, or conditions. Consequently, Congress enacted the MUMS Act to provide incentives to develop new animal drugs for minor species, while still ensuring appropriate safeguards for animal and human health.

Section 572 of the FD&C Act provides for a public index listing of legally marketed unapproved new animal drugs for minor species. FDA regulations in part 516 (21 CFR part 516) specify, among other things, the criteria and procedures for requesting eligibility for indexing and for requesting addition to the Index, as well as the annual reporting requirements for index holders. The administrative procedures and criteria for indexing a new animal drug for use in a minor species are set forth in 21 CFR 516.111 through 516.171. Section 516.165 sets forth the annual reporting requirements for index holders. FDA needs the information to determine: 1) the eligibility of a new animal drug for indexing; 2) that a qualified expert panel proposed to review certain information regarding the new animal drug meets the selection criteria listed in the regulations; 3) whether the agency agrees with the recommendation of a qualified expert panel that a drug be added to the Index; and, 4) whether there may be grounds for removing a drug from the Index.

We request extension of OMB approval of the reporting and recordkeeping requirements contained in the following citations:

21 CFR 516.119 – Reporting

Requires a foreign drug company to submit to FDA the name and address of a permanent U.S. resident agent, and provide notification of changes in such agents or changes of address of agents within 60 days of the effective date of such changes.

21 CFR 516.121 – Reporting

Specifies information to be contained in a written request for a meeting with FDA to discuss the requirements for indexing a new animal drug.

21 CFR 516.123 – Reporting

Specifies information to be contained in a written request for an informal conference and a requestor's written response to an FDA initial decision denying a request.

21 CFR 516.125 – Reporting

Specifies the requirements for correspondence and information associated with investigational use of new animal drugs intended for indexing.

21 CFR 516.129 – Reporting

Specifies the content and format of a request for determination of eligibility for indexing.

21 CFR 516.141 – Reporting

Specifies information to be submitted to FDA by a requestor seeking to establish a qualified expert panel.

21 CFR 516.143 – Reporting

Specifies the content and format of the written report of the qualified expert panel.

21 CFR 516.145 – Reporting

Specifies the content and format of a request for addition to the Index.

21 CFR 516.161 – Reporting

Specifies the content and format of a request for modification of an indexed drug.

21 CFR 516.163 – Reporting

Specifies information to be contained in a request to FDA to transfer ownership of a drug's index file to another person.

21 CFR 516.165 – Reporting

Requires drug experience reports and distributor statements to be submitted to FDA.

21 CFR 516.141 – Recordkeeping

Requires the qualified expert panel leader to maintain a copy of the written report and all notes or minutes relating to panel deliberations that are submitted to the requestor for 2 years after the report is submitted.

21 CFR 516.165 – Recordkeeping

Requires the holder of an indexed drug to maintain records of all information pertinent to the safety or effectiveness of the indexed drug, from foreign and domestic sources.

2. Purpose and Use of the Information Collection

The information collected in requests for determination of eligibility for indexing and in requests for addition to the Index, as well as the annual reporting requirements for index holders is submitted to the Office of Minor Use and Minor Species Animal Drug Development (OMUMS). The information is used by OMUMS to determine: the eligibility of a new animal drug for indexing; that a qualified expert panel proposed to review certain information regarding the new animal drug meets the selection criteria listed in the regulations; and, whether the agency agrees with the recommendation of a qualified expert panel that a drug be added to the Index. The information collected in annual written drug experience reports is used by OMUMS to monitor possible drug-related adverse events. OMUMS reviews the records and reports required in 21 CFR 516.165 to facilitate a determination under section 572(f) of the FD&C Act as to whether there may be grounds for removing a drug from the Index.

3. Use of Improved Information Technology and Burden Reduction

The regulations in part 516 do not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Companies are free to use whatever forms of information technology may best assist them in fulfilling the agency's submission requirements, retaining the appropriate records, and making them available to regulatory officials. We estimate that approximately 50% of requests for determination of eligibility for indexing and requests for addition to the Index will be submitted electronically in the next three years. We estimate that about 50% of respondents will keep some of the required records electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

The information collected in requests for eligibility for indexing and for addition to the Index, as well as the annual reporting requirements for index holders, is unique to each new animal drug requestor and their specific drug, dosage form, and intended use. Because FDA is the only Federal agency with the authority to maintain a public index listing of legally marketed unapproved new animal drugs for minor species, there is no likelihood of duplication by other Federal agencies.

5. Impact on Small Businesses or Other Small Entities

We estimate that approximately 5 of the affected firms are small businesses. Because many new animal drugs for minor uses and minor species traditionally come from smaller drug companies, we believe the MUMS Act and our regulations in part 516 have a beneficial impact on small business. The collection of information outlined in part 516 is commensurate with what is required by the MUMS Act and poses no greater burden to small business than it does to large pharmaceutical firms. We aid small businesses in complying with our requirements through our Regional Small Business Representatives and through our scientific and administrative staffs. We have provided a Small Business Guide on our website at http://www.fda.gov/oc/industry/. Furthermore, we encourage animal drug companies, whether small or large businesses, to meet with us to discuss questions concerning submissions.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. New animal drug requestors will not be allowed to make their drug legally available to veterinarians and animal owners for the treatment of minor animal species if the information is not submitted. Periodic drug experience reports are submitted to OMUMS annually (21 CFR 516.165). This reporting frequency is the same as is currently required for approved drugs under 21 CFR 514.80(b)(4). The reporting frequency is dictated by the need to identify potential problems concerning the safety and effectiveness of new animal drugs. Less frequent data collection would hinder early detection of threats to human and animal health.

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

There are no special circumstances associated with 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), we published a 60-day notice for public comment in the Federal Register of December 21, 2016 (81 FR 93689). One comment was received, but was not responsive to the information collection topics solicited.

9. Explanation of Any Payment or Gift to Respondents

We do not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

We expect that requests for eligibility for indexing and for addition to the Index, as well as the periodic drug experience reports submitted by index holders, will contain trade secret and confidential commercial information. Confidentiality of data and information in an index file is provided for in 21 CFR 516.171. As a result, all files are maintained in a secured area. 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 index. 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

This information collection does not involve any questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
516.119; requires a foreign drug company to submit and update the name and address of a permanent U.S. resident agent.	2	1	2	1	2
516.121; written request for a meeting with FDA to discuss the requirements for indexing a new animal drug.	30	2	60	4	240

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
516.123; written request for an informal conference and a requestor's written response to an FDA initial decision denying a request.	3	1	3	8	24
516.125; correspondence and information associated with investigational use of new animal drugs intended for indexing.	2	3	6	20	120
516.129; content and format of a request for determination of eligibility for indexing.	30	2	60	20	1,200
516.141; information to be submitted to FDA by a requestor seeking to establish a qualified expert panel.	20	1	20	16	320
516.143; content and format of the written report of the qualified expert panel.	20	1	20	120	2,400
516.145; content and format of a request for addition to the Index.	20	1	20	20	400
516.161; content and format of a request for modification of an indexed drug.	1	1	1	4	4
516.163; information to be contained in a request to FDA to transfer ownership of a drug's index file to another person.	1	1	1	2	2
516.165; requires drug experience reports and distributor statements to be submitted to FDA.	10	2	20	8	160
Total					4,872

Table 2.--Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
516.141, requires the qualified expert panel leader to maintain a copy of the written report and all notes or minutes relating to panel deliberations that are submitted to the requestor for 2 years after the report is submitted.	30	2	60	0.5 (30 minutes)	30
516.165, requires the holder of an indexed drug to maintain records of all information pertinent to the safety or effectiveness of the indexed drug, from foreign and domestic sources.	10	2	20	1	20
Total					50

We based our estimates in tables 1 and 2 on our experience with the MUMS indexing program and the requests for eligibility for indexing and for addition to the Index, as well as the periodic drug experience reports submitted during the past three years.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry Compliance Officer[1]	4872	$43.24	$210,665.28
Clerical Worker[2]	50	$19.93	$996.50
Total			$211,661.78

[1,2] May 2015 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics and including 30% for benefits

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

We estimate the cost to the Federal government to respond to the current level of requests for eligibility for indexing and for addition to the Index, as well as submission of periodic drug experience reports, is approximately $139,851. This estimate is based on the salary of an FTE at the GS-14/Step 4 level in the locality pay area of Washington-Baltimore-Arlington in 2017 ($123,223/year), plus one quarter of an FTE at the GS-11/Step 1 level in the locality pay area of Washington-Baltimore-Arlington in 2017 ($66,510/year) (0.25 FTE x $66,510 = $16,628). Thus, the total cost is estimated to be $139,851 ($123,223+ $16,628).

15. Explanation for Program Changes or Adjustments

The burden remains unchanged for the information collection. However, we have revised the IC list appearing at www.reginfo.gov by consolidating the previously itemized regulatory provisions into reporting and recordkeeping categories. We believe this will assist the reader by more easily identifying the summary of cumulative fluctuations for the collection. At the same time, readers may still view estimated burden associated with individual provisions by referring to the agency's 60-day and 30-day notices and in the burden tables found in Q.12: *Estimates of Annualized Burden Hours and Costs* of this supporting statement.

16. Plans for Tabulation and Publication and Project Time Schedule

Section 572(a) of the FD&C Act requires us to establish an index of legally marketed unapproved new animal drugs for minor species, which we make available on our website at https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/ucm125452.htm. We have no plans to tabulate and publish other information from this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are not seeking an exemption from displaying the expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.