United States Food and Drug Administration

Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

OMB Control No. 0910-0620

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations that implement section 572 of the Minor Use 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 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.

We therefore request OMB extension of our regulations related to public index listing of legally-marketed unapproved new animal drugs for minor species animals found in 21 CFR Part 516 as discussed in this supporting statement.

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, is 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 regarding 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 electronic submission of data and will consider any such electronic submission which will be more efficient for industry and facilitate review by the Agency. Currently 50% of submissions are electronic.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

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, 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 business 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

There are no special circumstances associated with this collection.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

FDA published a 60-day notice for public comment in the *Federal Register* of January 7, 2020 (85 FR 714). Although one comment was received, it was not responsive to the four collection of information topics solicited.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

This ICR collects personally identifiable information (PII) or information of a personal nature. The PII collected within the proprietary index file may include point of contact information for the requestor drug company; point of contact information for the veterinarian and/or pet owner that reported the adverse event; and, CVs and conflict of interest information, which may include personal financial information, for proposed outside expert panel members.

FDA further determined this information 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.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA minimized the PII to be collected to protect the privacy of the individuals.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden[1]

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.	5	1	5	1	5
516.121; written request for a meeting with FDA to discuss the requirements for indexing a new animal drug.	30	2	60	4	240
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.	3	1	3	4	12
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	10	100	5	500
Total					5,223

[1] There are no capital costs or operating and maintenance costs 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	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	.5 (30 min.)	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

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

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry Compliance Officer[1]	5,223	$45.32	$236,706.36
Clerical Worker[2]	50	$22.00	$1,100
Total			$237,806.36

[1,2] May 2018 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/Recordkeepers or 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 $151,454.50. 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 2020 ($133,447 /year), plus one quarter of an FTE at the GS-11/Step 1 level in the locality pay area of Washington-Baltimore-Arlington in 2020 ($72,030/year) (0.25 FTE x $72,030 = $18,007.50). Thus, the total cost is estimated to be $151,454.50 ($133,447+ $18,007.50).

15. Explanation for Program Changes or Adjustments*

Our estimated burden for the information collection reflects an overall increase of 401 reporting hours. We attribute this adjustment, generally, to an increase in the number of submissions we received over the last few years. We also reduced our burden hour estimate for drug experience reports and distributor statements under 21 CFR 516.165 from 8 hours per submission to 5 hours per submission based on our experience with this type of reporting.

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 ourwebsite at www.fda.gov/animal-veterinary/minor-useminor-species/index-legally-marketed-unapproved-new-animal-drugs-minor-species. 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 approval to not display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.