United States Food and Drug Administration

New Animal Drugs for Minor Use and Minor Species

OMB Control No. 0910-0605 -- EXTENSION

SUPPORTING STATEMENT

Terms of Clearance: None.

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of sections 572 and 573 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.SC. 360ccc-1 and 21 U.S.C. 360ccc-2) which establish requirements for the Designation of a Minor Use or Minor Species New Animal Drugs and Index of Legally Marketed Unapproved New Animal Drugs for Minor Species, respectively. Agency regulations are codified in 21 CFR part 516 and include recordkeeping and reporting requirements. The general provisions in 21 CFR 516 subpart A set forth its purpose, scope, and applicable definitions (21 CFR part 516 subpart A).

Regulations in 21 CFR part 516 subpart B provide for designation status for Minor Use and Minor Species (MUMS) drugs prior to their approval or conditional approval. MUMS-drug designation makes the sponsor eligible for incentives to support the approval or conditional approval of the designated use and is completely optional for drug sponsors. The regulations describe how to apply for designation, what needs to be submitted and other information pertaining to this option. Sponsors of designated new animal drugs are required to demonstrate "due diligence" toward approval or conditional approval through submission of annual reports documenting their progress for each designated use. The FDA uses this information to allow for determining eligibility for designation and the associated incentives and benefits described in section 573 of the act, including a 7-year period of exclusive marketing rights. It enables 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. Sponsors use FDA's "eSubmitter" system to fill out a series of system generated screens to submit their request and annual report electronically. To access the "eSubmitter" system, sponsors will use a previously established account.

Regulations in 21 CFR 516 subpart C are intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species (21 U.S.C. 360ccc). The purpose of these regulations is to encourage the development of these new animal drugs, while still ensuring appropriate safeguards for animal and human health. In some cases, a minor species drug is intended for use in species that are too rare or too varied to be the subject of adequate and well-controlled studies in support of a drug approval. In such cases, FDA may add the drug to the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species as provided for by Section 572 of the FD&C Act (21 U.S.C. 360ccc-2). Within limitations established by the statute, such indexing provides a basis for legally marketing an unapproved new animal drug intended for use in a minor species. FDA regulations in 21 CFR part 516 Subpart C 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, as well as modifications and removal of a drug from the index are also set forth. FDA uses the information for the activities described above. Requestors can either mail paper submissions to the FDA or use FDA's "eSubmitter" system to fill out a series of system generated screens to submit their request electronically. To access the "eSubmitter" system, sponsors will use a previously established account.

We therefore request extension of OMB approval of the information collection requirements found in 21 CFR part 516 as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The purpose of the information collection is to encourage the development of new animal drugs, while still ensuring appropriate safeguards for animal and human health. The FDA uses this information collection under 21 CFR part 516 to allow for determining eligibility for designation and the associated incentives and benefits described in section 573 of the FD&C Act, including a 7-year period of exclusive marketing rights, and requests for determination of index eligibility and, if determined eligible, subsequent requests for addition to the index, including a written report.

Description of Respondents: The respondents to this information collection are pharmaceutical companies that sponsor new animal drugs for designation or requesters wishing to add a new animal drug to the Index.

3. Use of Improved Information Technology and Burden Reduction

We encourage the submission of data electronically to facilitate review by the Agency and consider any such submissions to be more efficient for industry. Respondents use FDA's "eSubmitter" system to fill out a series of system-generated screens to submit their requests and annual reports electronically. To access the "eSubmitter" system, respondents use a previously established account. We currently receive all submissions regarding designation electronically. We estimate that 70% of respondents requesting indexing submit electronically. Information collection associated with electronic records is currently approved under OMB control number 0910-0303.

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 (approximately 60% 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. FDA aids small businesses in complying with its requirements through the Agency's Regional Small Business Representatives and through the scientific and administrative staffs within the Agency. FDA also provides a Small Business Guide on the Agency's website at

http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm. 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, dosage form, and intended use, the consequence of an ineffectual effort can 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 ensuring that drug development moves forward.

Periodic drug experience reports, as required by section 516.165, are submitted to FDA annually by the holder of an index listing. 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 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 February 20, 2026 (91 FR 8253). One comment was received. While the commenter supported the collection of information requirements, they raised concerns about the administrative and financial burden on smaller companies, recommending that FDA develop templates or guidance materials to ease the process for these companies.

FDA appreciates the comment. FDA provides a Small Business Guide on the Agency's website at http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm. FDA has also published the following Guidance for Industry (GFI) documents to assist companies developing drugs for minor uses and minor species. Online or written comments on any guidance can be submitted at any time (see 21 CFR 10.115(g)(5)).

- CVM GFI #61 - Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species
- CVM GFI #170 - Animal Drug User Fees and Fee Waivers and Reductions
- CVM GFI #200 - SECG for Designation of New Animal Drugs for Minor Uses/Minor Species
- CVM GFI #201 - SECG for Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

In addition, we are currently revising CVM GFI#210 - The Index of Legally Marketed Unapproved New Animal Drugs for Minor Species to help companies navigate the indexing process.

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

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

The Privacy Act of 1974

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted is name, address, telephone number, fax number, and email. FDA determined that although PII is collected it 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 retrieve records from the information collected. Through appropriate instruction, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

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

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Designated New Animal Drugs for Minor Use and Minor Species, Subpart B					
516.20; content and format of MUMS-drug designation request	5	2	10	16	160
516.26; requirements for amending MUMS-drug designation	3	1	3	2	6
516.27; change in sponsorship of MUMS-drug designation	1	1	1	1	1
516.29; termination of MUMS-drug designation	2	1	2	1	2
516.30; requirements of annual reports from sponsor(s) of MUMS-designated drugs	26	2	52	2	104
516.36; consequences for insufficient quantities of MUMS-designated drugs	1	1	1	3	3
Subtotal					276

Index of Legally Marketed Unapproved New Animal Drugs for Minor Species, Subpart C					
516.119; requires a foreign drug company to submit and update the name and address of a permanent U.S. resident agent.	10	1	10	1	10
516.121; written request for a meeting with FDA to discuss the requirements for indexing a new animal drug.	15	2	30	4	120
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.	20	2	40	20	800
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.	10	1	10	20	200
516.161; content and format of a request for modification of an indexed drug.	10	1	10	4	40
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.	25	10	250	5	1250
Subtotal					5,286
Total					5,562

Table 2. – Estimated Annual Recordkeeping Burden

21 CFR Section, Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Index of Legally Marketed Unapproved New Animal Drugs for Minor Species, Subpart C					
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 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.	25	2	50	1	50
Total					80

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Compliance Officer[1]	5,562	$64.06	$356,301.72
Clerical Worker[2]	80	$32.05	$2,564
Total			$358,865.72

[1]Occupation Employment and Wages, Bureau of Labor Statistics, Compliance Officers, $49.28 per hour plus 30% for benefits.
[2]Occupation Employment and Wages, Bureau of Labor Statistics, Clerical Worker, $24.65 per hour plus 30% for benefits.

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

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

14. Annualized Cost to the Federal Government

We estimate the cost to the Federal government to respond to requests for designation is approximately $146,135. 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, DC-MD-VA-WV-PA in 2026, spending half of their time reviewing requests ($158,306 /year) (0.50 FTE x $158,306 = $79,153), plus a second FTE at the GS-13/Step 4 level in the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA in 2026, spending half of their time reviewing requests ($133,964/year) (0.50 FTE x $133,964 = $66,982). Thus, the total cost is estimated to be $146,135 ($79,153 + $66,982) (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2026/general-schedule/).

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 $441,468.50. 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, DC-MD-VA-WV-PA in 2026, spending a quarter of their time reviewing requests ($158,306 /year) (0.25 FTE x $158,306 = $39,576.50), plus four additional FTEs at the GS-13/Step 4 level in the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA in 2026, spending a three-quarters of their time reviewing requests ($133,964/year) (0.75 FTE x $133,964 = $100,473 x 4 = $401,892) Thus, the total cost is estimated to be $441,468.50 ($39,576.50 + $401,892) (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2026/general-schedule/).

The total estimated annual cost to the Federal government for this information collection is approximately $ 587,603.50 ($146,135+$441,468.50).

15. Explanation for Program Changes or Adjustments

Our estimated reporting and recordkeeping burden for the information collection reflects an overall increase of 60 hours and a corresponding increase of 120 responses and records. We

attribute this adjustment to an increase in the number of submissions we received over the last few years.

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 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.