4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-2474]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drugs for Minor Use and Minor Species

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0605. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

New Animal Drugs for Minor Use and Minor Species

OMB Control Number 0910-0605--Revision

This information collection supports FDA regulations that implement sections 572 and 573 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360ccc-1 and 21 U.S.C. 360ccc-2) which establish an index of legally marketed unapproved new animal drugs for minor species and requirements for the designation of minor use or minor species new animal drugs, respectively. Agency regulations are codified in part 516 (21 CFR part 516) and include recordkeeping and reporting requirements. 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. The general provisions in part 516, subpart A, set forth its purpose, scope, and applicable definitions.

Our regulations in 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. We use this information to allow for determining eligibility for designation and the associated incentives and benefits, including a 7-year period of exclusive marketing rights, as provided by section 573 of the FD&C Act. It enables us 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.

Regulations in part 516, subpart C, are intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species. 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 public index listing of legally marketed unapproved new animal drugs for minor species animals (Index), as provided for by section 572 of the FD&C Act. 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. Our regulations in 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 holders of an index listing. 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.

In the *Federal Register* of August 1, 2022 (87 FR 46961), FDA published a 60-day notice requesting public comment on the information collection requirements related to designation status for MUMS drugs. No comments were received. We are revising the information collection to add the information collection requirements associated with the index listing of legally marketed unapproved new animal drugs for minor species, for efficiency of Agency operations.

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.

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

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

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses[2]	Average Burden per Response	Total Hours[3]
Designated New Animal Drugs for Minor Use and Minor Species, Part 516, Subpart B					
516.20, 516.26, 516.27, 516.29, 516.30, and 516.36; Reporting burden associated with drug designation requests and termination of designation	26	~2.65	69	4 hours	276
Index of Legally Marketed Unapproved New Animal Drugs for Minor Species, Part 516, Subpart C					

516.119, 516.121, 516.123, 516.125, 516.141, 516.143, 516.145; 516.161, 516.163, and 516.165; Reporting burden associated with requests for index listing and modifying indexed drugs	30	~10.33	310	~16.954 hours	5,256
Total					5,532

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Decimal rounded.
[3] Rounded up.

Burden we attribute to reporting activities is assumed to be distributed among the individual elements and averaged among respondents. Our estimate of the burden per disclosure (4 and 16.954 hours, respectively) reflect what we believe is the average burden based on the reporting required by the information collection.

Table 2.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section, Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Designated New Animal Drugs for Minor Use and Minor Species, Part 516, Subpart B					
One-time recordkeeping burden associated with reading and understanding the rule[2]	474	1	474	0.68 (~41 minutes)[3]	323
Index of Legally Marketed Unapproved New Animal Drugs for Minor Species, Part 516, Subpart C					
516.141 and 516.165; recordkeeping associated with panel deliberations and the information pertinent to the safety and effectiveness from foreign sources	40	2	80	0.625 (37.5 minutes)	50
Total					373

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Direct Final Rule, "Defining 'Small Number of Animals' for Minor Use Determination; Periodic Reassessment" (September 15, 2022; 87 FR 56583). Preliminary Regulatory Impact Analysis (https://www.regulations.gov/document/FDA-2022-N-1128-0007).
[3]Rounded up.

Burden we attribute to recordkeeping activities for the indexing provisions is assumed to be distributed among the individual elements and averaged among respondents. Our estimate of the burden per record (0.625 hours) reflects what we believe is the average burden based on the recordkeeping required by the information collection.

For efficiency of Agency operations, we are consolidating the related information collection activities currently approved in OMB control numbers 0910-0605 and 0910-0620 into a single collection request. The burden estimates reflect our current experience with the information collection and requests received by respondents over the past 3 years. We also

include burden that may be attributable to rulemaking (RIN 0910-A146), which became effective on December 14, 2022. Although the rulemaking revised the definition of "small number of animals," for purposes of determining whether a particular intended use of a drug in a major species qualifies as a minor use, we believe only nominal adjustments in burden associated with designation status for MUMS drugs may result, other than a one-time recordkeeping burden. In addition, upon review of the previous information collection submission related to indexing, we include burden associated with recordkeeping to address a data-entry error in the RISC/ORIA Combined Information System (ROCIS system). Cumulatively, these changes and adjustments reflect an overall increase of 5,905 hours and a corresponding increase of 864 responses, annually, to the information collection.

Dated: June 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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