response, recordkeeping, and disclosure are based on our experience with the pilot program.

Our estimated burden for the information collection reflects an overall decrease of 3,129 hours and an increase of 94 responses/records. We attribute this adjustment to a decrease in the one-time burden for accreditation bodies and testing laboratories training and SOPs because much of this activity was completed during the pilot. In addition, there is an increase in the annual responses/records because there is an increase in renewal requests (by accreditation bodies to continue ASCA Recognition and by testing laboratories to continue ASCA Accreditation) since the pilot program was initiated.

Dated: June 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–13860 Filed 6–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0366]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Advisory Committee Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 July 31, 2023.

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 0910–0833. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

FDA Advisory Committee Regulations

OMB Control No. 0910–0833—Revision

This information collection helps support implementation of FDA regulations found in part 14 (21 CFR part 14). These regulations govern procedures applicable to presenting information and views before an FDA advisory committee in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2 and 3, Pub. L. 92–463). FACA is designed to assure that Congress and the public are kept informed with respect to the purpose, membership, and activities of advisory committees. It does not specify the manner in which advisory committee members and staff must be appointed.

Public advisory committee regulations in part 14 set forth requirements governing the administrative procedures to follow for the operation of advisory committees. Agency regulations in part 14, subpart A (§§ 14.1 through 14.15) identify scope of coverage, applicable definitions, and establish general provisions. The regulations in part 14, subpart B (§§ 14.20 through 14.39) set forth content and format requirements along with required schedules for submission of information. The regulations in part 14 subparts C, D, and E (§§ 14.40 through 14.95) set forth requirements governing advisory committee establishment, recordkeeping, and maintenance, respectively.

FDA will also require that nominees to serve on advisory committees submit a consent form authorizing FDA to post, without removing or redacting any information, to FDA's public website (*http://www.fda.gov/AdvisoryCommittees*) the curriculum vitae (CV) submitted as part of their nomination materials if the nominee is selected to serve on an advisory committee. The consent form requires that the nominee affirm that the CV does not include any confidential information, including information pertaining to third parties, that the nominee is not permitted to disclose. A nominee will be required to submit a signed consent form as a part of the nomination package for the nomination to be considered complete.

All nominations for new advisory committee members will be required to be submitted through FDA's website at *http://accessdata.test.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm,* or any successor system, and the submission will be required to be accompanied by the consent form, on or after the date of OMB approval for this information collection. Although we are developing collection instruments, as communicated on our website, respondents may submit information to: Advisory Committee Oversight and Management Staff, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993, 800–741–8138 or 301–443–0572.

In the **Federal Register** of February 13, 2023 (88 FR 9294), FDA published a 60-day notice requesting public comment on the proposed collection of information. Four comments were received but were not responsive to the information collection topics solicited under the PRA. On our own initiative, we are clarifying the scope of coverage for the information collections.

We estimate the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part 14	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Subpart E—Members of Advisory Committees					
Advisory Committee Membership Nominations	308	1	308	0.25 (15 minutes).	77
Member Submission of Updated Information	452	1	452	0.25 (15 minutes).	113
Total					190

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: June 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–13863 Filed 6–28–23; 8:45 am]

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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 July 31, 2023.

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