



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-1303]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Experience/Events with Approved New Animal Drugs

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 [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 0910-0284. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kelly Covington, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-402-5661, PRASStaff@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.

Adverse Experience/Events With Approved New Animal Drugs

OMB Control Number 0910-0284-Extension

This information collection supports statutory and regulatory requirements governing reporting associated with certain animal drug products. With regard to adverse events and product/manufacturing defects associated with approved new animal drugs, section 512(l) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(l)) requires applicants with approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to establish and maintain records and reports of data relating to experience with uses of such drug, or with respect to animal feeds bearing or containing such drug, to facilitate a determination under section 512(e) as to whether there may be grounds for suspending or withdrawing approval of the NADA or ANADA under section 512(e) or 512(m)(4). Regulations in § 514.80 (21 CFR 514.80) require the electronic submission of postmarketing safety reports for approved new animal drugs but provide a procedure for requesting a temporary waiver from the requirement. We, therefore, retain use of certain paper-based forms. Section 514.80 requires applicants and nonapplicants to keep records of and report to us data, studies, and other information concerning experience with new animal drugs for each approved NADA and ANADA.

Following complaints from animal owners or veterinarians, or following their own detection of a problem, applicants or nonapplicants are required to submit adverse event reports and product/manufacturing defect reports under § 514.80(b)(1), (b)(2)(i) and (ii), (b)(3), and (b)(4)(iv)(A) and (C) on Form FDA 1932 (to include FDA 1932 and 1932a (e-form)). The information collection also includes Form FDA 2301; Transmittal of Periodic Reports and Promotional Material for New Animal Drugs.

The information collection also includes submissions under § 514.80(d)(2), by an applicant or nonapplicant requesting, in writing, a temporary waiver of the electronic submission requirements. The initial request may be by telephone or email to CVM's Division of

Pharmacovigilance and Surveillance, with prompt written follow-up submitted as a letter to the application(s). FDA will grant waivers on a limited basis for good cause shown. If FDA grants a waiver, the applicant or nonapplicant must comply with the conditions for reporting specified by FDA upon granting the waiver.

In the *Federal Register* of February 20, 2026 (91 FR 8245), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1.--Estimated Annual Reporting Burden^{1,2}

21 CFR Section	Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Medicated feed reports, 510.301(a) and (b)	N/A	7	1	7	.5 (30 minutes)	3.5
Submission of postmarketing safety reports under § 514.80(b)(1), (2)(i) and (ii), (3), and (4)(iv)(A) and (C)	1932	85	1262.94	107,350	1	107,350
Voluntary reporting FDA Form 1932a for the public	1932a	217	1	217	1	217
514.80(b)(4) Periodic Drug Experience Reports	2301	66	24.68	1,629	16	26,064
514.80(b)(5)(i) Special Drug Experience Reports	2301	52	363.2	18,886	2	37,772
514.80(b)(5)(ii) Advertisement and Promotional labeling	2301	35	326.71	11,435	2	22,870
514.80(b)(5)(iii) Distributor's Statements	2301	13	2.77	36	2	72
514.80(d)(2)	N/A	1	1	1	1	1
Total				139,561		194,349.5

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

² Sums may not total due to rounding.

Table 2.--Estimated Annual Recordkeeping Burden¹

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Recordkeeping, 510.301 ²	7	1	7	4	28
Recordkeeping, 21 U.S.C. 360b(1) and 514.80(e) ³	79	1,575.14	124,436	14	1,742,104
Total			124443		1,742,132

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

² This estimate includes all recordkeeping by licensed medicated feed manufacturers under § 510.301.

³ This estimate includes all recordkeeping by applicants of approved NADAs, ANADAs, and conditional NADAs under § 514.80(e).

Our estimated burden for the information collection reflects an overall increase of 22,073.50 hours and a corresponding increase of 15,117 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years. An increase of safety reports represents a pattern that aligns with expectations - as product availability and usage expand, adverse event reporting increases proportionally. The recent three-year increase appears to be a continuation of this established pattern rather than an indication of new safety concerns.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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