4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-3208]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Records and Reports Concerning Experiences with Approved New Animal Drugs: Adverse Event Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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 0910-0284. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, 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.

Records and Reports Concerning Experiences with Approved New Animal Drugs: Adverse Event Reports

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 (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).

In 2020, FDA amended § 514.80 (21 CFR 514.80) to require electronic submission of certain postmarketing safety reports for approved new animal drugs and to provide a procedure for requesting a temporary waiver of 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.

The information collection includes electronic submission of 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) using Form FDA 1932. 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 the Center for Veterinary Medicine's Division of Pharmacovigilance and Surveillance, with prompt written followup 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.

Description of Respondents: Respondents to this collection of information are applicants and nonapplicants as defined in 21 CFR 514.3. Respondents include individuals and the private sector (for-profit businesses).

In the *Federal Register* of December 22, 2022 (87 FR 78694) FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received it was not responsive to any of the four information collection topics solicited in our notice.

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

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

21 CFR Section	FDA 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	8	1	8	0.25 (15 minutes)	2
Submission of postmarketing safety reports under § 514.80(b)(1), (2)(i) and (ii), (3) , and (4)(iv)(A) and (C)	1932	85	1,249	98,639	1	98,639
Voluntary reporting FDA Form 1932a for the public	1932a	106	1	106	1	106
514.80(b)(4) Periodic Drug Experience Reports	2301	79	20	1,582	16	25,312
514.80(b)(5)(i) Special Drug Experience Reports	2301	78	215	16,790	2	33,580
514.80(b)(5)(ii) Advertisement and Promotional labeling	2301	38	192	7,282	2	14,564
514.80(b)(5)(iii) Distributor's Statements	2301	22	2	36	2	72
514.80(d)(2)	N/A	1	1	1	1	1
Total						172,276

[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
Recordkeeping, 510.301[2]	8	1	8	4	32
Recordkeeping, 21 U.S.C. 360b(1) and 514.80(e)[3]	79	1,575.14	124,436	14	1,742,104
Total					1,742,136

[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).

Upon review of the information collection, we have adjusted our estimated burden to reflect an overall increase of 136,029.75 hours and 1,677,019 responses/records, annually.

Dated: April 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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