4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-2428]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Drug Adverse Event Reporting and Recordkeeping

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: Fax written comments 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 faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0284. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, 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.

Animal Drug Adverse Event Reporting and Recordkeeping--21 U.S.C. 360b(l), 21 CFR 510.301, and 514.80

OMB Control Number 0910-0284--Extension

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). Sections 571(e)(3) and 512(e)(2) of the FD&C Act (21 U.S.C. 360ccc(e)(3) and 360b(e)(2)) require that applicants with conditionally approved new animal drug applications (CNADAs) maintain adequate records and make reports in accordance with a regulation or order issued under section 512(l). Finally, section 512(m)(5) of the FD&C Act requires an applicant for a license to manufacture animal feeds bearing or containing new animal drugs to maintain adequate records and make reports "as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine" whether there may be grounds for suspending or withdrawing approval of the new animal drug under section 512(e) or a license to manufacture animal feeds bearing or containing new animal drugs under section 512(m)(4).

Section 514.80 of our regulations (21 CFR 514.80) sets forth the recordkeeping and reporting requirements for applicants and nonapplicants of approved NADAs and ANADAs. Section 510.301 of our regulations (21 CFR 510.301) sets forth the recordkeeping and reporting requirements for licensed medicated feed manufacturing facilities.

Recordkeeping and reporting requirements for applicants of approved NADAs and ANADAs. Section 514.80 requires applicants 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 are required to submit adverse event reports and product defect reports under § 514.80(b)(1), (b)(2)(i) and (ii), (b)(3), and (b)(4)(iv)(A) on Form FDA 1932. Form FDA 1932a (the voluntary reporting form) is used by veterinarians and the general public to submit adverse event reports, product defects, and lack of effectiveness complaints directly to FDA. Form FDA 2301 is used by applicants to submit the required transmittal of periodic reports (§ 514.80(b)(4)); special drug experience reports (§ 514.80(b)(5)(i)); promotional material for new animal drugs (§ 514.80(b)(5)(ii)); and distributor statements (§ 514.80(b)(5)(iii)). We review the records and reports required in § 514.80 and the voluntary reports to facilitate a determination under section 512(e) of the FD&C Act as to whether there may be grounds for suspending or withdrawing approval of the new animal drug. We have made minor editorial revisions to Form FDA 1932a to clarify how to report adverse drug events associated with compounded products using that form. Submitters are already reporting adverse drug events associated with compounded products on Form FDA 1932a. The clarifications include: the addition of a new question, "Is this a compounded product?"; the addition of a new field to allow the submitter to provide product strength, "Strength of Active Ingredient(s)";

modifying the title of the existing field requesting the name of manufacturer, so that it reads, "Name of Manufacturer or Compounding Pharmacy/Compounder of Suspected Product"; and a request for contact information for the manufacturer or compounder. We estimate that the revisions will not change the average amount of time necessary to complete the form.

Recordkeeping and reporting requirements for applicants of CNADAs. As noted, sections 571(e)(3) and 512(e)(2) of the FD&C Act require that applicants for CNADAs maintain adequate records and make reports in accordance with a regulation or order issued under section 512(l) of the FD&C Act. Moreover, section 512(l) requires submission of such information as required "by general regulation, or by order …" Conditional approval letters explicitly establish an order requiring the submission of postmarketing information in accordance with the requirements of § 514.80. Applicants submit adverse event reports and product defect reports on Form FDA 1932.

Recordkeeping and reporting requirements for licensed medicated feed manufacturing facilities. Section 510.301 requires a licensed medicated feed manufacturer to keep records of and report to us information concerning experience with animal feeds bearing or containing approved new animal drugs. Under § 510.301(a), a licensed medicated feed manufacturer must immediately report to us information concerning any mixup in the new animal drug or its labeling; any bacterial or significant chemical, physical, or other change or deterioration in a drug; and any failure of one or more distributed batches of a drug to meet the specifications established for it. Under § 510.301(b), a licensed medicated feed manufacturer must report to us within 15 working days of receipt of information concerning any unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof, and any unusual failure of the new animal drug to exhibit its expected pharmacological activity. OMB initially

approved the information collection provisions of § 510.301 under control number 0910-0012. That approval was subsequently consolidated into this collection in 2004. We reviewed the records and reports required by § 510.301 to facilitate a determination as to whether there may be grounds for suspending or withdrawing approval of the new animal drug under section 512(e) of the FD&C Act, or grounds for revoking a license to manufacture medicated feed under section 512(m)(4).

Since the consolidation of the 0910-0012 collection into this collection in 2004, we have included the estimated number of medicated feed adverse event reports as part of our estimate of the number of all mandatory adverse event reports for new animal drugs. To improve the clarity of our estimates, we have added a row to table 1, on which we separately report our estimates of medicated feed reports.

The continuous monitoring of approved NADAs, ANADAs, CNADAs, and animal feeds bearing or containing new animal drugs affords the primary means by which we obtain information regarding potential problems with the safety and efficacy of marketed approved new animal drugs, as well as potential product/manufacturing problems. Postapproval marketing surveillance is important because data previously submitted to us may not be adequate as animal drug effects can change over time and less apparent effects may take years to manifest.

Description of respondents: Respondents to this collection of information are animal drug manufacturers with approved NADAs, ANADAs, or CNADAs, as well as licensed commercial feed mills and licensed mixer-feeders.

In the *Federal Register* of July 18, 2017 (82 FR 32829), 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 the four collection of information topics solicited and therefore will not be discussed in this document.

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

Table 1--Estimated Annual Reporting Burden[1]

Activity	FDA Form	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	5	1	5	0.25 (15 minutes)	1.25
Mandatory adverse event reporting, 21 U.S.C. 360b(l); § 514.80(b)(1); (b)(2)(i) and (ii); (b)(3); and (b)(4)(iv)(A)	1932	22	81	1,782	1	1,782
Voluntary adverse event reporting by veterinarians and the general public	1932a	197	1	197	1	197
Periodic drug experience reports, § 514.80(b)(4)	2301	200	8.11	1,622	16	25,952
Special drug experience reports, § 514.80(b)(5)(i)	2301	200	0.57	114	2	228
Submission of advertisements and promotional labeling, § 514.80(b)(5)(ii)	2301	200	20.12	4,024	2	8,048
Submission of distributor statements, § 514.80(b)(5)(iii)	2301	190	0.1	19	2	38
Total						36,246.25

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

Table 2--Estimated Annual Recordkeeping Burden[1]

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Recordkeeping, § 510.301[2]	5	1	5	4	20
Recordkeeping, 21 U.S.C. 360b(l) and § 514.80(e)[3]	646.70	7.19	4,649.8	14	65,097
Total					65,117

[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 CNADAs under § 514.80(e).

We base our reporting and recordkeeping estimates on our experience with adverse event reporting for approved new animal drugs and the number of reports received in the previous 3

years. Since the consolidation of the 0910-0012 collection into this collection in 2004, we have included the estimated recordkeeping burden for medicated feed adverse event reports as part of our estimate of the recordkeeping burden of all mandatory adverse event reports for new animal drugs. To improve the clarity of our estimates we have added a row to table 2, on which we separately report our recordkeeping estimate for medicated feed adverse event reports (20 hours).

The burden of this collection has changed. There was a slight increase in the estimated number of reports submitted to FDA under total annual responses (by 7.8 responses) and there was a slight overall decrease in burden hours (by 1.75 hours). This minor fluctuation in responses and hours is due to the normal variation in the submission of reports to FDA, the correction of mathematical errors, and a change in reporting methodology (addition of a new row to table 1 and table 2).

We continually strive to improve our systems for collecting and analyzing drug experience reports and adverse event reports. To that end, we have developed an electronic submission system by which Form FDA 2301 may be submitted to the Agency. For Form FDA 1932a, we have a fillable electronic form available online, which can be submitted by email to FDA Center for Veterinary Medicine. We specifically invite comment from respondents on the utility of these reporting forms. Electronic adverse event reporting for approved new animal drugs (including mandatory reporting under § 514.80(b) and voluntary reporting) has been approved under OMB control number 0910-0645. Reporting and recordkeeping associated with the index of legally marketed unapproved new animal drugs for minor species (21 CFR part 516) is approved under OMB control number 0910-0620.

Dated: January 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-02234 Filed: 2/2/2018 8:45 am; Publication Date: 2/5/2018]