



This document is scheduled to be published in the Federal Register on 12/16/2014 and available online at <http://federalregister.gov/a/2014-29426>, and on FDsys.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1409]

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) 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 oir_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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Road; COLE-14526, Silver Spring, MD 20993-0002 PRStaff@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 on Paper Forms FDA 1932, 1932a, and 2301--21 CFR 514.80; OMB Control Number 0910-0284--Extension

Section 512(l) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C.360b(l) and 514.80 (21 CFR 514.80) of FDA regulations require applicants of approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to report adverse drug experiences and product/manufacturing defects (see 514.80)(b)). Additionally, section 571(e)(3) of the FD&C Act (21 U.S.C. 360ccc(e)(3)) requires that applicants for conditional approval of new animal drugs (CNADAs) maintain adequate reports and records of adverse drug experiences and product/manufacturing defects as applicable under section 512(l) of the FD&C Act.

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

Under 514.80(d), an applicant must report adverse drug experiences and product/manufacturing defects on Form FDA 1932, "Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report." Periodic drug experience reports and special drug experience reports must be accompanied by a completed Form FDA 2301, "Transmittal of

Periodic Reports and Promotional Material for New Animal Drugs,” (see 514.80). Form FDA 1932a, “Veterinary Adverse Drug Reaction, Lack of Effectiveness or Product Defect Report,” allows for voluntary reporting of adverse drug experiences or product/manufacturing defects.

In 2010, electronic versions of Forms FDA 1932 and 1932a were incorporated into the FDA Safety Reporting Portal. This electronic system is used for collecting, submitting, and processing adverse event reports and other safety information for all FDA regulated products. Burden for the electronic version of these forms is accounted for under OMB control number 0910-0645. This approval request accounts for the collection of information using existing paper Forms FDA 1932, 1932a, and 2301 and is currently approved under OMB control number 0910-0284. FDA estimates that, at this time, approximately 50 percent of the respondents utilize paper forms for submitting this information. We expect this number to decrease as more respondents avail themselves of the FDA Safety Reporting Portal.

In the Federal Register of September 29, 2014 (79 FR 58355), 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 Burden¹

21 CFR Section/ Section of the FD&C Act	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
514.80(b)(1), 514.80(b)(2)(i) and (ii), 514.80(b)(3)	1932	22	81.05	1,783	1	1,783
Voluntary reporting FDA Form 1932a for the public	1932a	197	1	197	1	197
514.80(b)(4)	2301	200	8.11	1,622	16	25,952
514.80(b)(5)(i)	2301	200	0.57	114	2	228
514.80(b)(5)(ii)	2301	200	20.12	4,024	2	8,048
514.80(b)(5)(iii)	2301	190	0.1	20	2	40
Total Hours						36,248

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

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
514.80(e)	646	7.20	4651	14	65,117

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

Dated: December 10, 2014.

Leslie Kux,

Associate Commissioner for Policy.

4164-01-P

[FR Doc. 2014-29426 Filed 12/15/2014 at 8:45 am; Publication Date: 12/16/2014]