4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on adverse event reporting by FDA on new animal drugs and product/manufacturing defects collected on paper forms.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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 Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 make use of the FDA Safety Reporting Portal.

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

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

21 CFR Section or 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

[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 Record Keepers	No. of Records per Record Keeper	Total Annual Records	Average Burden per Record Keeping	Total Hours
514.80(e)	646	7.20	4651	14	65117

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

Dated: September 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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