

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 01N-0231]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

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.

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Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report—21 CFR Part 510 (OMB Control No. 0910–0012)—Extension

Section 512(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C 360b(l)) and 21 CFR 510.300, 510.301, and 510.302 require that applicants of approved new animal drug applications (NADAs) submit within 15 working days of receipt, complete records of reports of certain adverse drug reactions and unusual failure of new animal drugs. Other reporting requirements of adverse reactions to these drugs must be reported annually or semiannually in a specific format. This continuous monitoring of approved new animal drugs, affords the primary means by which FDA obtains information regarding potential problems in safety and effectiveness of marketed animal drugs and potential manufacturing problems. Data already on file with FDA is not adequate because animal drug effects can change over time and less apparent effects may take years to manifest themselves. Reports are reviewed along with those previously submitted for a particular drug to determine if any change is needed in the product or labeling, such as package insert changes, dosage changes, additional warnings or contraindications, or product reformulation.

Adverse reaction reports are required to be submitted by the drug manufacturer on FDA Forms 1932 or 1932a (voluntary reporting form), following complaints from animal owners or veterinarians. Likewise, product defects and lack of effectiveness complaints are submitted to FDA by the drug manufacturer following their own detection of a problem or complaints from product users or their veterinarians using FDA Forms 1932 and 1932a . FDA Form 2301 is available for the required transmittal of periodic reports and promotional material for new animal drugs. Respondents to this collection of information are applicants of approved NADAs.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Form FDA 2301	510.302(a)	190	13.16	2,500	0.5	1,250
Form FDA 1932	510.302(b)	190	94.74	18,000	1.0	18,000
Form FDA 1932a (voluntary)	510.302(b)	100	1.0	100	1.0	100

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total burden hours						19,350

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	Annual Frequency per Recordkeeping	Total Annual Response per Recordkeeper	Hours per Recordkeeper	Total Hours
510.300(a) and 510.301(a)	190	13.16	2,500	10.35	25,875
510.300(b) and 510.301(b)	190	94.74	18,000	0.50	9,000
Total burden hours					34,875

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

The estimate of the times required for record preparation and maintenance is based on agency communication with industry. Other information needed to calculate the total burden hours (i.e.,

adverse drug reaction, lack of effectiveness, and product defect reports) are derived from agency records and experience.

Dated: 10/29/01
October 29, 2001.

Margaret M. Dotzel

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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Regis Sedes