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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 9-4-08
Publication Date 9-5-08
Certifier A. Corbin

Food and Drug Administration

[Docket No. FDA-2005-N-0474] (formerly Docket No. 2005N-0210)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Veterinary Feed Directive

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: 202-395-6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0363. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

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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.

Veterinary Feed Directive—21 CFR Part 558 (OMB Control Number 0910-0363)—Extension

With passage of the Animal Drug Availability Act, Congress enacted legislation establishing a new class of restricted feed use drugs called Veterinary Feed Directive (VFD) drugs. The VFD class of drugs may be distributed without involving State pharmacy laws. Although controls on the distribution and use of VFD drugs are similar to controls for prescription drugs regulated under section 503(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 503(f)), the implementing VFD regulation under section 558.6 (21 CFR 558.6) is tailored to the unique circumstances relating to the distribution of medicated feeds. The content of the VFD is spelled out in the regulation. All distributors of medicated feed containing VFD drugs must notify FDA of their intent to distribute, and the distribution records of all medicated feeds containing VFD must be maintained. The VFD regulation ensures the protection of the public health while enabling animal producers to obtain and use needed drugs as efficiently and cost-effectively as possible.

In the **Federal Register** of June 5, 2008 (73 FR 32029), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
558.6(a)(3) through (a)(5)	15,000	25	375,000	.25	93,750
558.6(d)(1)(i) through (d)(1)(iii)	300	1	300	.25	75
558.6(d)(1)(iv)	20	1	20	.25	5

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
558.6(d)(2)	1,000	5	5,000	.25	1,250
514.1(b)(9)	1	1	1	3.00	3
Total	16,321				95,083

¹ There 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 Records	Hours per Record	Total Hours
558.6(c)(1) through (c)(4)	112,500	10	1,125,000	.0167	18,788
558.6(e)(1) through (e)(4)	5,000	75	375,000	.0167	6,263
Total	117,500				25,051

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

Dated: 8/28/08

August 28, 2008.

Jeffrey Shuren

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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[Signature]