4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0155]

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: 202-395-7285, or emailed to oira_submission@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: 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: 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 558 (OMB Control Number 0910-0363)--(Extension)

With the passage of the Animal Drug Availability Act of 1996 (Public Law 104-250), Congress enacted legislation establishing a new class of restricted feed use drugs, VFD drugs, which may be distributed without involving State pharmacy laws. Although controls on the distribution and use of VFD drugs are similar to those for prescription drugs regulated under section 503(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(f)), the implementing VFD regulation (21 CFR 558.6) was tailored to the unique circumstances relating to the distribution of medicated feeds. All distributors of medicated feed containing VFD drugs must notify FDA of their intent to distribute such feed, and records must be maintained of the distribution and feeding (under the professional supervision of a licensed veterinarian) of all medicated feeds containing VFD drugs. The VFD regulation ensures the protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost-effectively as possible.

On December 12, 2013, FDA published a proposed rule in the Federal Register (78 FR 75515), intended to improve the efficiency of FDA's VFD program. The provisions included in the proposed rule were based on stakeholder input received in response to solicitations for public comment, including an advance notice of proposed rulemaking on March 29, 2010 (75 FR 15387), and draft text of proposed amendments to the current VFD regulations on April 13, 2012 (77 FR 22247).

In the Federal Register of September 25, 2014 (79 FR 57558), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was

received but it did not respond to any of the four collection of information topics solicited in the notice and therefore is not discussed in this document. At the same time, since publication of the 60-day notice, the burden for this information collection has been revised to reflect an update in the number of veterinarians, producers, and distributors, as well as updated cost burden information.

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

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

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
558.6(d)(1)(i) through (d)(1)(iii) A distributor must notify FDA prior to the first time it distributes a VFD drug.	300	1	300	.25 (15 minutes)	75
558.6(d)(1)(iv) A distributor must notify FDA within 30 days of any change in ownership, business name, or business address.	20	1	20	.25 (15 minutes)	5
514.1(b)(9) Sponsor submits 3 copies of VFD with new drug application	1	1	1	3	3
Total					83

[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 Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
558.6(c)(1) through (c)(4) Filing of VFD copies by veterinarians and producers[2]	13,050	114.9	1,500,000	.0167 (1 minute)	25,050
558.6(e)(1) through (e)(4) Filing of VFD copies by distributors only[3]	1,376	545.1	750,000	.0167 (1 minute)	12,525
Total	14,426		2,250,000		37,575

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The same recordkeeping requirement for distributors is listed in two separate sections of the codified; therefore, we have listed distributors separately (in reference to 558.6(e)(1) through (e)(4)) in order to avoid double counting their recordkeeping requirement.
[3] Distributors may receive an acknowledgement letter in lieu of a VFD when consigning VFD feed to another distributor (please see table 3.). Such letters, like VFDs, are also subject to a 2-year record retention requirement. Thus, the recordkeeping burden for acknowledgement letters is included as a subset of the VFD recordkeeping burden.

Table 3.--Estimated Annual Third-Party Disclosure[1]

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
558.6(a)(3) through (a)(5) Veterinarian issues VFD	3,050	246	750,000	0.125 (7 minutes)	93,750
558.6(d)(2) Acknowledgement letter generation[2]	1,000[2]	5	5,000	0.125 (7 minutes)	625
Total					94,375

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 1,000 VFD distributors (of the 1,376 total distributors) multiplied by 5 disclosures per distributor equals 5,000 annual acknowledgement letters, multiplied by 0.125 hours equals 625 hours annually.

The estimate of time required for record preparation and maintenance is based on Agency communication with industry and Agency records and experience.

Dated: December 18, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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