

Dated: June 29, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy  
Coordination.*

[FR Doc. 98-18402 Filed 7-9-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 97N-0510]

#### Agency Information Collection Activities; Submission for OMB Review; Comment Request

**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 August 10, 1998.

**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, Attention: 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 section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Current Good Manufacturing Practice Regulations for Medicated Feeds (21 CFR Part 225) (OMB Control Number 0910-0152—Reinstatement)

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351), FDA has the statutory authority to issue current good manufacturing practice (cGMP) regulations for drugs, including medicated feeds. Medicated feeds are administered to animals for the prevention, cure, mitigation or treatment of disease, or growth promotion and feed efficiency. Statutory requirements for cGMP's have been codified under part 225 (21 CFR part 225). Medicated feeds that are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the act. Under part 225, a manufacturer is required to establish, maintain, and retain records for a medicated feed, including records to document procedures required during the manufacturing process to ensure proper

quality control is maintained. Such records would, for example, contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (i.e., batch and stability testing), labels, and product distribution.

This information is needed so that FDA can monitor drug usage and possible misformulation of medicated feeds, to investigate violative drug residues in products from treated animals and to investigate product defects when a drug is recalled. In addition, FDA will use the cGMP criteria in part 225 to determine whether or not the systems and procedures used by manufacturers of medicated feeds are adequate to ensure that their feeds meet the requirements of the act as to safety and also meet their claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the act. A license is required when the manufacturer of a medicated feed involves the use of a drug or drugs which FDA has determined requires more control because of the need for a withdrawal period before slaughter or carcinogenic concerns. Conversely, for those medicated feeds for which FDA has determined that the drugs used in their manufacture need less control, a license is not required and the recordkeeping requirements are less demanding. The respondents to this collection of information are commercial feed mills and mixer-feeders.

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (REGISTERED LICENSE HOLDERS)<sup>1 2</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
225.42(b)(5) through (b)(8)	1,600	24	38,400	0.41	16,000
225.58(c) and (d)	1,600	24	38,400	0.25	9,600
225.80(b)(2)	1,600	24	38,400	0.16	6,400
225.102(b)(1) through (b)(5)	1,600	24	38,400	1.0	38,400
225.110(b)(1) and (b)(2)	1,600	24	38,400	0.25	9,600
225.115(b)(1) and (b)(2)	1,600	24	38,400	0.25	9,600
Total burden hours					89,600

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

<sup>2</sup> Commercial feed mills.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (REGISTERED LICENSE HOLDERS)<sup>1 2</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
225.42(b)(5) through (b)(8)	200	3	600	0.16	100
225.58(c) and (d)	200	3	600	0.16	100
225.80(b)(2)	200	3	600	0.083	50
225.102(b)(1) through (b)(5)	200	3	600	0.5	300
225.110(b)(1) and (b)(2)	200			3	
225.115(b)(1) and (b)(2)	200			3	

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (REGISTERED LICENSE HOLDERS)<sup>1 2</sup>—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Total burden hours					550

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

<sup>2</sup> Mixer-feeders.

<sup>3</sup> There is no burden because medicated feeds are consumed on site (§ 225.110 *Distribution records*; § 225.115 *Complaint files*).

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (NONREGISTERED)<sup>1 2</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
225.142	13,000	24	316,800	0.41	132,000
225.158	13,000	24	316,800	0.25	79,200
225.180	13,000	24	316,800	0.16	52,800
225.202	13,000	24	316,800	1.5	475,200
Total burden hours					739,200

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

<sup>2</sup> Commercial feed mills.

TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (NONREGISTERED)<sup>1 2</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
225.142	45,000	3	135,000	0.16	22,500
225.158	45,000	3	135,500	0.16	22,500
225.180	45,000	3	135,500	0.083	11,250
225.202	45,000	3	135,500	0.5	67,500
Total burden hours					123,750

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

<sup>2</sup> Mixer-feeders.

The estimate of the times required for record preparation and maintenance is based on agency communications with industry. Other information needed to calculate the total burden hours (i.e., number of recordkeepers, number of medicated feeds being manufactured, etc.) is derived from agency records and experience.

Dated: June 30, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 96E-0452]

### Determination of Regulatory Review Period for Purposes of Patent Extension; VERLUMA™

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for VERLUMA™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

**ADDRESSES:** Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6620.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years

so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the