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 October 28, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (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.

Extralabel Drug Use in Animals—21 CFR Part 530 (OMB Control No. 0910–0325)—Extension

Description: The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) (Public Law 103–396) allows a veterinarian to prescribe the extralabel use of approved new animal drugs. Also, AMDUCA permits FDA, if it finds that there is a reasonable probability that the extralabel use of an animal drug may present a risk to the public health, to establish a safe level for a residue from the extralabel use of an animal drug and to require the development of an analytical method for the detection of residues above that established safe level. Although to date, we have not established a safe level for a residue from the extralabel use of any new animal drug, and therefore have not required the development of analytical methodology, we believe that there may be instances when analytical methodology will be required. We are, therefore, estimating the reporting burden based on two methods being required annually. The requirement to establish an analytical method may be fulfilled by any interested person. We believe that the sponsor of the drug will be willing to develop the method in most cases. Alternatively, FDA, the sponsor, and perhaps a third party may cooperatively arrange for method development. The respondents may be sponsors of new animal drugs, State or Federal government, or individuals.

In the **Federal Register** of May 3, 2005 (70 FR 22884), the agency published a 60-day notice requesting public comment on the collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
530.22(b)	2	1	2	4,160	8,320

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

The Center for Veterinary Medicine (CVM) has not found circumstances to require the establishment of a safe level and subsequent development of an analytical methodology. However, CVM believes there will be instances when an analytical methodology will be required.

Dated: September 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–19392 Filed 9–27–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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 October 28, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, inlcuding first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (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.

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

With the passage of the Animal Drug Availability Act (ADAA), Congress enacted legislation establishing a new class of restricted feed use drugs called Veterinary Feed Directive, which can 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 under 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 feeds containing VFD drugs must notify FDA of their intent to distribute, and records must be maintained of the distribution 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.

In the **Federal Register** of June 10, 2005 (70 FR 33907), FDA published a 60-day notice soliciting comments on this collection of information. In response to this notice, no comments were received.

The respondents for VFD drugs are Veterinarians, distributors of animal feeds containing VFD drugs, and clients utilizing medicated feeds containing VFD drugs.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
558.6(a)(3) through 558.6(a)(5)	15,000	25	375,000	0.25	93,750
558.6(d)(1)(i) through 558.6(d)(1)(iii)	1,500	1	500	0.25	125
558.6(d)(1)(iv)	20	1	20	0.25	5
558.6(d)(2)	1,000	5	5,000	0.25	1,250
514.1(b)(9)	1	1	1	3.00	3
Total Hours					95,133

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record	Total Hours
558.6(c)(1) through 558.6(c)(4)	112,500	10	1,125,000	.0167	18,788
558.6(e)(1) through 558.6(e)(3)	5,000	75	375,000	.0167	6,263
Total Hours					25,051

[1]There are no capitals cost or operating and maintenance cost 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 are derived from agency records and experience.

Dated: September 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–19393 Filed 9–27–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0208]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices

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 October 28, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices (OMB Control Number 0910–0390)—Extension

In the **Federal Register** of November 20, 1998 (63 FR 64556), FDA published a final rule that added a new part 99 (21 CFR part 99) entitled ''Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices.''

The final rule implemented section 401 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115). In brief, section 401 of FDAMA amended the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aaa through 360aaa-6) to permit drug, biologic, and device manufacturers to disseminate certain written information concerning the safety, effectiveness, or benefits of a use that is not described in the product's approved labeling to health care practitioners, pharmacy benefit managers, health insurance issuers, group health plans, and Federal and State Government agencies, provided that the manufacturer complies with certain statutory requirements. For example, the information that is to be disseminated must be about a drug or device that is being marketed legally; it must be in the form of an unabridged reprint or copy of a peer-reviewed journal article or reference publication; and it must not be derived from another manufacturer's clinical research, unless that other manufacturer has given its permission for the dissemination. The information