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]

BILLING CODE 4160–01–S

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

must be accompanied by certain information, including a prominently displayed statement that the information discusses a use (or uses) that has not been approved or cleared by FDA. Additionally, 60 days before dissemination, the manufacturer must submit to FDA a copy of the information to be disseminated, any other clinical trial information that the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience that pertain to the safety of the new use, and a summary of such information.

The final rule sets forth the criteria and procedures for making such submissions to FDA. Under the final rule, submissions include certification that the manufacturer has completed clinical studies necessary to submit a supplemental application to FDA for the new use, and will submit the supplemental application within 6 months after its initial dissemination of information. If the manufacturer has planned, but not completed, such studies, the submission includes proposed protocols and a schedule for conducting the studies, as well as certification that the manufacturer will complete the clinical studies and submit a supplemental application no later than 36 months after its initial dissemination of information. The final rule also permits manufacturers to request extensions of the time period for completing a study and submitting a supplemental application, and to request an exemption from the requirement to submit a supplemental application. The final rule prescribes the timeframe within which the manufacturer shall maintain records that would enable it to take corrective action. The final rule requires the manufacturer to submit lists pertaining to the disseminated articles and reference publications, the categories of persons (or individuals) receiving the information, and a notice and summary of any additional research or data (and a copy of the data) relating to the product's safety or effectiveness for the new use. The final rule requires the manufacturer to maintain a copy of the information, lists, records, and reports for 3 years after it has ceased dissemination of the information and to make the documents available to FDA for inspection and copying.

FDA based its estimates of the number of submissions it will receive, and the number of manufacturers who would be subject to part 99, on the average of the total number of required submissions received during 2002, 2003, and 2004. The estimated burden hours for these provisions are based on the following calculations:

Section 99.201(a)(1) requires the manufacturer to provide an identical copy of the information to be disseminated, including any information required under § 99.103. Because the manufacturer must compile this information in order to prepare its submission to FDA, FDA estimates that 40 hours will be required per submission. Because 10 annual responses are expected under § 99.201(a)(1), the estimated total burden for this provision is 400 hours (10 annual responses x 40 hours per response).

Section 99.201(a)(2) requires the manufacturer to submit clinical trial information pertaining to the safety and effectiveness of the new use, clinical experience reports on the safety of the new use, and a summary of the information. FDA estimates 24 burden hours per response for this provision for assembling, reviewing, and submitting the information and assumes that the manufacturer will have already acquired some of this information in order to decide whether to disseminate information on an unapproved use under part 99. The estimated total burden for this provision is 240 hours (10 annual responses x 24 hours per response).

Section 99.201(a)(3) requires the manufacturer to explain its search strategy when assembling its bibliography. FDA estimates that only 1 hour will be required for the explanation because the manufacturer would have developed and used its search strategy before preparing the bibliography. Because 10 annual responses are expected under § 99.201(a)(3), the estimated total burden for this provision is 10 hours (10 annual responses x 1 hour per response).

Section 99.201(b) simply requires the manufacturer's attorney, agent, or other authorized official to sign its submissions, certifications, and requests for an exemption. FDA estimates that only 30 minutes are necessary for such signatures. Because 10 annual responses are expected under § 99.201(b), the estimated total burden for this provision is 5 hours (10 annual responses x 0.5 hours per response).

Section 99.201(c) requires the manufacturer to provide two copies with its original submission. Copying the submission should not be time-consuming, so FDA estimates the burden to be 30 minutes. Because 10 annual responses are expected under § 99.201(c), the estimated total burden for this provision is 5 hours (10 annual responses x 0.5 hours per response).

While the act requires manufacturers to provide a submission to FDA before they disseminate information on unapproved/new uses, it also permits the following actions for manufacturers: (1) To have completed studies and promise to submit a supplemental application for the new use within 6 months after the date of initial dissemination; (2) to provide protocols, a schedule for completing studies, and submit a supplemental application for the new use within 36 months after the date of initial dissemination; (3) to have completed studies and have submitted a supplemental application for the new use; or (4) to request an exemption from the requirement to submit a supplemental application. These possible scenarios are addressed in §§ 99.201(a)(4)(i)(A), (a)(4)(ii)(A), (a)(5), and 99.205(b). Based on the average of the total number of required submissions received during 2002, 2003, and 2004, FDA has made the following burden estimates:

Section 99.201(a)(4)(i)(A) requires the manufacturer, if the manufacturer has completed studies needed for the submission of a supplemental application for the new use, to submit the protocol(s) for the completed studies, or, if the protocol(s) was submitted to an investigational new drug application (IND) or investigational device exemption (IDE), to submit the IND or IDE number(s), the date of submission of the protocol(s), the protocol number(s), and the date of any amendments to the protocol(s). FDA estimates that 30 hours will be required for this response because this is information that each manufacturer already maintains for its drugs or devices. The estimated total burden for this provision is 210 hours (7 annual responses x 30 hours per response).

For manufacturers who submit the protocol(s) and a schedule for conducting studies, § 99.201(a)(4)(ii)(A) requires the manufacturer to include, in its schedule, the projected dates on which the manufacturer expects the principal study events to occur. FDA estimates a manufacturer will need approximately 60 hours to include the projected dates because it would have to contact the studies' principal investigator(s) and other company officials. The estimated total burden for this provision is 420 hours (7 annual responses x 60 hours per response).

If the manufacturer has submitted a supplemental application for the new use, § 99.201(a)(5) requires a cross-reference to that supplemental application. FDA estimates that only 1

hour will be needed because manufacturers already maintain this information. The estimated total burden for this provision is 2 hours (2 annual responses x 1 hour per response).

FDA has not received any requests for an exemption under § 99.205(b). However, for purposes of this request for OMB approval, FDA estimates that annually one manufacturer may submit one exemption request under § 99.205(b). FDA estimates that the reporting burden for each exemption request will be 82 hours. Therefore, the estimated total burden for this provision is 82 hours (1 annual response x 82 hours per response).

Under § 99.203, a manufacturer that has certified that it will complete studies necessary to submit a supplemental application within 36 months after its submission to FDA, but later finds that it will be unable to complete such studies or submit a supplemental application within that time period, may request an extension of time from FDA. Such requests for extension should be limited, occurring less than 1 percent of the time, because manufacturers and FDA, when developing or reviewing study protocols, should be able to identify when a study will require more than 36 months to complete. Section 99.203 contemplates extension requests under two different scenarios. Under § 99.203(a), a manufacturer may make an extension request before it makes a submission to FDA regarding the dissemination of information under part 99. The agency expects such requests to be limited, occurring less than 1 percent of the time (or one annual response), and that such requests will result in a reporting burden of 10 hours per request. The estimated total burden for this provision, therefore, is 10 hours (1 annual response x 10 hours per response). Section 99.203(b) specifies the contents of a request to extend the time for completing planned studies after the manufacturer has provided its submission to FDA. The required information includes a description of the studies, the current status of the studies, reasons why the studies cannot be completed on time, and an estimate of the additional time needed. FDA estimates that 10 hours will be needed for reporting the required information under § 99.203(b) because it would require consultation between the manufacturer and key individuals (such as the studies' principal investigator(s)). As in the case of § 99.203(a), the expected number of responses is very small (one annual response), and the estimated total burden for this provision is 10 hours (1 annual response x 10 hours per response).

Section 99.203(c) requires two copies of an extension request (in addition to the request required under section 554(c)(3) of the act (21 U.S.C. 360aaa-3(c)(3))). FDA estimates that these copies will result in a minimal reporting burden of 30 minutes. However, this requirement would apply to extension requests under § 99.203(a) and (b), so the estimated total number of annual responses is two, resulting in an estimated total burden for this provision of 1 hour (2 annual responses x 0.5 hours per response).

The remaining reporting and recordkeeping burdens are as shown in the following estimates:

Section 99.501(a)(1) requires the manufacturer to maintain records that identify recipients by category or individually. Under § 99.301(a)(3), FDA will notify the manufacturer if it needs to maintain records identifying individual recipients because of special safety considerations associated with the new use. This means that, in most cases, the manufacturer will only have to maintain records identifying recipients by category. In either event, the manufacturer will know if it must maintain records that identify individual recipients before it begins disseminating information. The time required to identify recipients individually should be minimal, and the time required to identify recipients by category should be even less. Therefore, FDA estimates the burden for this provision to be 10 hours, and, because 8 annual records are expected under § 99.501(a)(1), the estimated total burden for this provision is 80 hours (8 annual records x 10 hours per record).

Section 99.501(a)(2) requires the manufacturer to maintain a copy of the information it disseminates. This task is not expected to be time-consuming, so FDA estimates the burden to be 1 hour. Because eight annual records are expected under § 99.501(a)(2), the estimated total burden for this provision is 8 hours (8 annual records x 1 hour per record).

Section 99.501(b)(1) requires the manufacturer to submit to FDA semiannually a list containing the articles and reference publications that were disseminated in the preceding 6-month period. FDA estimates a burden of 8 hours for this provision. The burden may be less if the manufacturer develops and updates the list while it disseminates articles and reference publications during the 6-month period (as opposed to generating a completely new list at the end of each 6-month period), and if the volume of disseminated materials is small. The estimated total burden for this provision is 160 hours (10 responses submitted semiannually x 8 hours per response).

Section 99.501(b)(2) requires manufacturers that disseminate information to submit to FDA semiannually a list that identifies the categories of providers who received the articles and reference publications. Section 99.501(b)(2) also requires the list to identify which category of recipients received each particular article or reference publication. If each of the 10 submissions under part 99 results in disseminated information, § 99.501(b)(2) would result in 20 lists (10 submissions x 2 submissions semiannually) identifying which category of recipients received each particular article or reference publication. The agency estimates the burden to be only 1 hour per response because this type of information is maintained as a usual and customary business practice, and the estimated total burden for this provision is 20 hours (20 responses submitted semiannually x 1 hour per response).

In relation to § 99.201(a)(2), § 99.501(b)(3) requires the manufacturer to provide, on a semiannual basis, a notice and summary of any additional clinical research or other data relating to the safety and effectiveness of the new use and, if it possesses such research or data, to provide a copy to FDA. This burden should not be as extensive as that in § 99.201(a)(2), so FDA estimates the burden to be 20 hours per response, for an estimated total burden of 400 hours for this provision (10 responses submitted semiannually x 20 hours per response).

If a manufacturer discontinues or terminates a study before completing it, § 99.501(b)(4) requires the manufacturer to state the reasons for discontinuing or terminating the study in its next progress report. FDA estimates that annually this will affect only 1 percent of all applications (8 x 0.01 = 0.08, rounded up to 1) and only one manufacturer. FDA estimates 2 hours of reporting time for this requirement because the manufacturer should know the reasons for discontinuing or terminating the study and would only need to provide those reasons in its progress report. The estimated total burden for this provision is 2 hours (1 annual response x 2 hours per response).

Section 99.501(b)(5) requires the manufacturer to submit any new or additional information that relates to whether the manufacturer continues to meet the requirements for the exemption after an exemption has been

granted. FDA estimates that 10 percent of all submissions will contain an exemption request (8 annual submissions x 0.10 = 0.8, rounded up to 1), and has assumed that all exemption requests will be granted, for an estimated total of 1 annual response. The information sought under § 99.501(b)(5) pertains solely to new or additional information and is not expected to be as extensive as the information required to obtain an exemption. Thus, FDA estimates the burden for § 99.501(b)(5) to be 41 hours per response (or half the burden associated with an exemption request), for an estimated total burden of 41 hours for this provision (1 annual response x 41 hours per response).

Section 99.501(c) requires the manufacturer to maintain records for 3 years after it has ceased dissemination of the information. FDA estimates the burden for this provision to be 1 hour. Because eight annual records are expected under § 99.501(c), the estimated total burden for this provision is 8 hours (8 annual records x 1 hour per record).

The estimates for §§ 99.201(a)(1), (a)(2), (a)(3), (b), (c), 99.501(b)(1), (b)(2), and (b)(3) have been increased by two responses each to account for manufacturer resubmissions. In addition, the estimate for § 99.201(a)(4)(i)(A) and (a)(4)(ii)(A) has been increased by one response each to account for manufacturer resubmissions.

Respondents are all manufacturers (persons and businesses, including small businesses) of drugs, biologics, and device products.

In the **Federal Register** of June 16, 2005 (70 FR 35099), FDA published a 60-day notice requesting public comment on the information collection provisions. 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 Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
99.201(a)(1)	5	1	10	40	400
99.201(a)(2)	5	1	10	24	240
99.201(a)(3)	5	1	10	1	10
99.201(a)(4)(i)(A)	6	1	7	30	210
99.201(a)(4)(ii)(A)	6	1	7	60	420
99.201(a)(5)	1	1	2	1	2
99.201(b)	5	1	10	0.5	5
99.201(c)	5	1	10	0.5	5
99.203(a)	1	1	1	10	10
99.203(b)	1	1	1	10	10
99.203(c)	1	1	2	0.5	1
99.205(b)	1	1	1	82	82
99.501(b)(1)	5	3	20	8	160
99.501(b)(2)	5	1	20	1	20
99.501(b)(3)	5	1	20	20	400
99.501(b)(4)	1	1	1	2	2
99.501(b)(5)	1	1	1	41	41
Total Hours					2,018

[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	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
99.501(a)(1)	5	1	8	10	80
99.501(a)(2)	5	1	8	1	8
99.501(c)	5	1	8	1	8
Total Hours					96

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

The estimated burden associated with the information collection requirements for these provisions is 2,114 hours.

Dated: September 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–19394 Filed 9–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–04–4007]

Memorandum of Understanding between the Food and Drug Administration, Forensic Chemistry Center and the Federal Bureau of Investigation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Food and Drug Administration and the Federal Bureau of Investigation (FBI). The purpose of this MOU is to establish the general policies and procedures that will govern administrative, logistical, and operational support to FBI missions including cost reimbursable activities.

DATES: The agreement became effective December 22, 2004.

FOR FURTHER INFORMATION CONTACT:

For the FDA: Fred Fricke, Food and Drug Administration, Forensic Chemistry Center, 6751 Steger Dr., Cincinnati, OH 45237, 513–679–2700.

For the FBI: David L. Wilson, Federal Bureau of Investigation Laboratory, Chemical Biological Sciences Unit, Quantico, VA 22135, 703–632–7766.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: September 20, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S