and community-based services whenever possible; ensuring EPSDT screening and appropriate treatment for children in foster care; and assisting the Department in maintaining linkages with schools for out-of-home placement, facilitate return to school for the child and family, and assist students who are new to the school district due to foster or adoptive placements.

To accomplish these services, WV proposes a two-phase demonstration. Phase one would pair community social services agencies with middle schools in Cabell County as resources for information, assessments, and referrals. Phase two proposes the hiring of full-time prevention coordinators for each school, beginning with two schools and phasing in additional schools as resources permit. Coordinators would be school-based during the school year, would serve as initial case managers and advocates for the child/family, provide direct services, and provide follow-up with families over the summer months.

The State's hypothesis is that middle school-based prevention and early intervention programs would result in a reduction of the number of children in foster care, the average expense and intensity of foster care, and the average number of days children are in foster care. This project would be limited to Cabell County, in southwestern WV, which includes six middle schools. The project is proposed to begin in September 1998 and would run through August 2003.

The State requests waivers of title IV–E to permit reimbursement for amounts expended for children and families and for purposes that are not normally eligible under IV–E.

For evaluation purposes, the state proposes to identify a control-group county. Outcome measures would include the number of children entering foster care, the number of placements in community-based or family settings, and the number of days the children are in foster care. Process evaluation components include frequency and types of intervention activities. An outside evaluator would conduct the evaluation.

Contact Person: Joan E. Ohl, Secretary, Department of Health and Human Resources, Bureau of Children & Families/Office of Social Services, Charleston, West Virginia 25305, Phone: (304) 558–0684, Fax: (304) 558–1130.

Dated: June 25, 1998.

James A. Harrell,

Deputy Commissioner, Administration on Children, Youth and Families.

[FR Doc. 98–18437 Filed 7–9–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0482]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection provisions relating to the regulation of FDA's adverse experience reporting (AER) for licensed biological products and general records.

DATES: Submit written comments on the collections of information by September 8, 1998.

ADDRESSES: Submit written comments on the collections of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonnalynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collections of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Adverse Experience Reporting for Licensed Biological Products—21 CFR 600.80, 600.81, and 600.90; and General Records—21 CFR 600.12 (OMB Control Number 0910–0308)—Extension

Under the Public Health Service Act (42 U.S.C. 262), FDA is required to ensure the marketing of only those biological products that are safe and effective. FDA must therefore be informed of all adverse experiences occasioned by the use of licensed biological products. FDA issued the adverse experience reporting requirements to enable FDA to take actions necessary for the protection of the public health in response to reports of adverse experiences related to licensed biological products. The primary purpose of FDA's adverse experience reporting system is to flag potentially serious safety problems with licensed biological products, focusing especially on newly licensed products. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the licensed biological product provides the opportunity to collect information on rare, latent, and long-term effects. Reports are obtained from a variety of sources, including patients, physicians, foreign regulatory agencies, and clinical investigators. Information derived from

the adverse experience reporting system contributes directly to increased public health protection because such information enables FDA to recommend important changes to the product's labeling (such as adding a new warning), to initiate removal of a biological product from the market when necessary, and to assure the manufacturer has taken adequate corrective action if necessary.

Manufacturers of biological products for human use must also keep records of each step in the manufacture and distribution of products including any recalls of the product. The recordkeeping requirements serve preventative and remedial purposes. These requirements establish accountability and traceability in the manufacture and distribution of products, and enable FDA to perform meaningful inspections.

Section 600.12 (21 CFR 600.12) requires that all records of each step in the manufacture and distribution of a product be made and retained for no less than 5 years after the records of manufacture have been completed or 6 months after the latest expiration date for the individual product, whichever represents a later date. In addition, records of sterilization of equipment and supplies, animal necropsy records, and records in cases of divided manufacturing of a product are required to be maintained. Section 600.12(b)(2) requires complete records to be maintained pertaining to the recall from distribution of any product.

Section 600.80(c)(1) (21 CFR 600.80(c)(1)) requires the licensed manufacturer to report each adverse experience that is both serious and unexpected, regardless of source, as soon as possible but in any case within 15 working days of initial receipt of the information. Section 600.80(e) requires licensed manufacturers to submit a 15-day alert report obtained from a postmarketing clinical study only if there is a reasonable possibility that the product caused the adverse experience. Section 600.80(c)(2) requires the licensed manufacturer to report each adverse experience not reported under paragraph (c)(1) at quarterly intervals, for 3 years from the date of issuance of the product license, and then at annual intervals. The majority of the periodic reports will be submitted annually since a large percentage of the current licensed biological products have been licensed longer than 3 years. Section 600.80(i) requires the licensed manufacturers to maintain for a period of 10 years records of all adverse experiences known to the licensed manufacturer, including raw data and any correspondence relating to the adverse experiences. Section 600.81 (21 CFR 600.81) requires the licensed manufacturer to submit information about the quantity of the product distributed under the product license, including the quantity distributed to distributors at an interval of every 6 months. The semiannual distribution report informs FDA of the quantity, the lot number, and the dosage of different products. Section 600.90 (21 CFR 600.90) requires a licensed manufacturer to submit a waiver request with supporting documentation when asking for waiving the requirement that applies to them under §§ 600.80 and 600.81.

Respondents to this collection of information are manufacturers of biological products. In fiscal year (FY) 1996, there were approximately 72 licensed manufacturers, 3 of which submitted waiver requests under § 600.90 and were exempt from these AER requirements. This number excludes those manufacturers who produce blood and blood components and in vitro diagnostic licensed products because they are specifically exempt from the regulations. In FY 1996, there were 1,616 15-day alert reports, 5,903 periodic reports and 464 distribution reports submitted to FDA. The number of 15-day alert report for postmarketing studies as stated in § 600.80(e) was minimal and is included in the total number of 15-day alert reports. The burden hours required to complete the MedWatch Form for § 600.80(c)(1), (e), and (f) are reported under OMB Control No. 0910–0291. FDA estimates the burden of this collection of information as follows:

TABLE 1.—Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
600.80(c)(1) and 600.80(e)	69	23.4	1,616	1	1,616
600.80(c)(2)	69	85.6	5,903	1	5,903
600.81	69	6.7	464	1	464
600.90	3	1	3	1	3

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

There are approximately 391 licensed manufacturers of biological products. However, the number of recordkeepers listed for § 600.12(a) through (e) excluding (b)(2) is estimated to be 102. This number excludes manufacturers of blood and blood components because their burden hours for recordkeeping have been reported under 21 CFR 606.160 in OMB Control No. 0910–0116. The recordkeeping burden is based on the number of lots released (9,027), the number of recalls made (710) and the total number of AER reports received (7,519) for FY 1996. FDA estimates that the average time associated with recordkeeping per lot is 32 hours, for recalls is 24 hours, and for adverse experience reports is 1 hour. FDA estimates the burden of this recordkeeping as follows:

TABLE 2.—Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
600.12	102	88.5	9,027	2,832	288,864
600.12(b)(2)	391	1.8	710	43	16,813
600.80(i)	69	109	7,519	109	7,519

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

Dated: June 29, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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

BILLING CODE 4160–01–F

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)[1] [2]

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

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (REGISTERED LICENSE HOLDERS)[1] [2]

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]	