organizations. These accreditation organizations represent almost all registered blood establishments. The total annual responses in the reporting chart for fatality reporting are based on an annual average of fatality reports submitted to FDA. The annual frequency of recordkeeping and total annual records, and the estimated reporting and recordkeeping burden hours are based on information provided by industry, and FDA's experience. Under § 606.110(b), licensed establishments submit supplements to their biologics license applications to request prior CBER approval of plasmapheresis donors who do not meet donor requirements. The information collection requirements for § 606.110(b) are reported under OMB control number 0910–0315.

In the **Federal Register** of July 6, 2000 (65 FR 41674), the agency requested comments on the proposed collections of information. No significant comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section[2]	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
606.170(b)	75	1	75	20	1,500

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]The reporting requirement in § 640.73, which addresses the reporting of fatal donor reactions, is included in the estimate for § 606.170(b).

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section[2]	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
606.100(b)	322[3]	1	322	24	7,728
606.100(c)	152[4]	26	4,000	1	4,000
606.110(a)	68[5]	5	340	0.5	170
606.151(e)	322[3]	12	3,864	0.083	321
606.160	322[3]	1,677	540,000	0.5	270,000
606.165	152[4]	3,553	540,000	0.083	44,820
606.170(a)	322[3]	12	3,864	1	3,864
Total					330,903

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]The recordkeeping requirements in §§ 640.3(a)(1), 640.4(a)(1), and 640.66, which address the maintenance of SOP's, are included in the estimate for § 606.100(b); the recordkeeping requirements in § 640.27(b), which address the maintenance of donor health records for plateletpheresis, are included in the estimate for § 606.110(a); and the recordkeeping requirements in §§ 640.2(f), 640.3(a)(2), 640.3(f), 640.4(a)(2), 640.25(b)(4) and (c)(1), 640.31(b), 640.33(b), 640.51(b), 640.53(c), 640.53(c), 640.56(b) and (d), 640.61, 640.63(b)(3), (e)(1), and (e)(3), 640.65(b)(2), 640.71(b)(1), 640.72, and 640.76(a) and (b), which address the maintenance of various records, are included in the estimate for § 606.160.
[3]5 percent of HCFA and FDA-registered blood establishments (0.05 X (3,400+3,032))
[4]5 percent of FDA-registered establishments (3,032)
[5]5 percent of pheresis establishments (1,349)

Dated: October 2, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–25698 Filed 10–5–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1395]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medicated Feed Mill License

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.

DATES: Submit written comments on the collection of information by November 6, 2000.

ADDRESSES: Submit written comments on the collection of information to 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 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medicated Feed Mill License 21 CFR Part 515—(OMB Control Number 0910–0337)—Extension

Description: This rule sets forth the information to be included in a medicated feed mill license application and subsequent supplemental applications. In addition, it provides criteria for the approval and nonapproval of a medicated feed mill license application and the criteria for the revocation and/or suspension of a license. More specifically, § 515.10(b) specifies requirements for submitting a completed medicated feed mill license application, using Form FDA 3448. Section 515.11(b) specifies requirements for supplemental medicated feed applications for a change in ownership and/or a change in mailing address for the facility cite, using Form FDA 3448. Section 515.23 sets forth written requirements for voluntary revocation of a medicated feed mill license by a sponsor on the grounds that the facility

no longer manufacture any animal feed. Section 515.30(c) details requirements for filing a request for a hearing by a sponsor to give reasons why a medicated feed mill license application should not be refused or revoked and § 510.305(b) (21 CFR 510.305 (b)), requires maintenance of approved labeling for each Type B and/or Type C medicated feed being manufactured on the premises of the manufacturing establishment or the facility where the feed labels are generated.

Description of Respondents: Respondents to this collection of information are individuals or firms that manufacture medicated animal feed. In the **Federal Register** of July 26, 2000 (65 FR 45987), FDA published a 60-day notice concerning the proposed extension of this collection of information and requested comments. In response to this notice, no comments were received on the estimated annual reporting and recordkeeping burden. We therefore believe that the total burden estimate of 72 hours for the annual reporting and recordkeeping burden should remain unchanged.

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
515.10(b)	100	1	100	0.25	25
515.11(b)	25	1	25	0.25	6.25
515.23	50	1	50	0.25	12.25
515.30(c)	0.15	1	0.15	24	3.6
Total burden hours					47.10

[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 Recordkeeper	Total Hours
510.305(b)	100	1	100	.25	25

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

The estimate for the number of respondents is derived from agency data, i.e. the number of medicated feed manufacturers entering the market each year, change in ownership or address, requests for voluntary revocation of a medicated feed mill license, revocation and/or suspension of a license. The estimate of the time required for the reporting and recordkeeping requirements is based on the agency communication with industry.

Dated: October 2, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–25699 Filed 10–5–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1309]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Suggested Documentation for Demonstrating Compliance With the Channels of Trade Provision

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.

DATES: Submit written comments on the collection of information by November 6, 2000.

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, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Suggested Documentation for Demonstrating Compliance With the Channels of Trade Provision

Description: Under the pesticide tolerance reassessment process that the Environmental Protection Agency (EPA) was mandated to carry out under the Food Quality Protection Act (FQPA), EPA has proposed to revoke the tolerances for the pesticide chemical methyl parathion on several food commodities. The FQPA includes a provision in section 408(l)(5) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 346a(l)(5)), referred to as the ''channels of trade provision,'' that addresses the circumstances under which a food is not unsafe solely due to the presence of a residue from a pesticide chemical whose tolerance has been revoked, suspended, or modified by EPA. These circumstances are met if the party responsible for the food can demonstrate to FDA that the residue in the food resulted from application of the pesticide chemical to the food commodity at a time and in a manner that was lawful under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA).

In general, FDA anticipates that the party responsible for food found to contain methyl parathion residues (within the former tolerance) after the