

• Establishment type: Query has been made of CDRH's registration/listing databank and has counted 8,188 domestic firms subject to CGMPs. In addition, hospitals which reuse or remanufacture devices are now considered manufacturers under new FDA guidance. During the last report, it was estimated that out of the 6,000 hospitals in the United States, one third of them (or 2,000 hospitals) will reuse or remanufacture single use medical devices. After investigations of many hospitals and the changes in enforcements of FDA's requirements for hospitals, the number of reuse or remanufactures of single-use medical devices have decreased from the estimated 2,000 to an estimated 66 hospitals. Thus, the number of manufacturers will increase from 7,229 to 8,188, but the total number of firms subject to CGMPs will decrease from 9,229 to 8,254.

• Potentially affected establishments: Except for manufacturers, not every type of firm is subject to every CGMP/QS requirement. For example, all are subject to FDA's quality policy regulations (§ 820.20(a)), document control regulations (§ 820.40), and other requirements, whereas only manufacturers and specification developers are subject to FDA's design controls regulations (§ 820.30). The type of firm subject to each requirement was identified by ERG.

FDA estimated the burden hours (and costs) for the previous CGMP regulation in 1992. That estimate was submitted to OMB on May 4, 1992. It was approved by OMB on July 16, 1992, and expired on June 30, 1995. The methodology used is different than that used by ERG in estimating incremental tasks when the new CGMP/QS became final. Nevertheless, the agency believes its 1992 estimate adequately represents labor hours (and costs) needed to comply with previous CGMP requirements carried over into the new CGMP/QS regulation. The 1992 estimate used 9,289 respondents (rather than 8,254 respondents), which compensates for differences in methodology.

FDA estimates that some 650 "new" establishments (marketing devices for the first time) will expend some 143,052 "development" hours on a one-time startup basis to develop records and procedures for the CGMP/QS regulation.

FDA estimates that annual labor hours are apportioned as follows: 40 percent goes to requirements dealing with manufacturing specifications, process controls and the DHR; 20 percent goes to requirements dealing with components and acceptance activities; 25 percent goes to requirements dealing

with equipment, records (the DMR and QSR), complaint investigations, labeling/packaging and reprocessing/ investigating product nonconformance; and 15 percent goes to quality audit, traceability, handling, distribution, statistical, and other requirements.

Dated: June 4, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-13212 Filed 6-10-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0425]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

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 the **Federal Register** of January 16, 2004 (69 FR 2602), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0339. The approval expires on May 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: June 4, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-13213 Filed 6-10-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0542]

Agency Information Collection Activities; Announcement of OMB Approval; Premarket Notification Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Premarket Notification Submissions" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 9, 2004 (69 FR 11022), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0120. The approval expires on May 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: June 4, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-13214 Filed 6-10-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0245]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Medicated Feeds

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 the recordkeeping requirements for manufacturers of medicated animal feeds.

DATES: Submit written or electronic comments on the collection of information by August 13, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (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: Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

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

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 cGMPs 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 assure that 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 assure that their feeds meet the requirements of the act as to safety and also that they 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 that FDA has determined requires more control because of the need for a withdrawal period before slaughter or because of carcinogenic concerns. Conversely, a license is not required and the recordkeeping requirements are less demanding for those medicated feeds for which FDA has determined that the drugs used in their manufacture need less control. Respondents to this collection of information are commercial feed mills and mixer-feeders.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (REGISTERED LICENSED COMMERCIAL FEED MILLS)¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Recordkeeper	Total Hours
225.42(b)(5) through (b)(8)	1,150	260	299,000	1	299,000
225.58(c) and (d)	1,150	45	51,750	.5	28,875
225.80(b)(2)	1,150	1,600	1,840,000	.12	220,800
225.102(b)(1)	1,150	7,800	8,970,000	.08	717,600
225.110(b)(1) and (b)(2)	1,150	7,800	8,970,000	.015	134,550
225.115(b)(1) and (b)(2)	1,150	5	5,750	.12	690

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (REGISTERED LICENSED COMMERCIAL FEED MILLS)¹—
Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Recordkeeper	Total Hours
Total					1,397,825

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (REGISTERED LICENSED MIXER-FEEDERS)¹

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)	100	260	26,000	.15	3,900
225.58(c) and (d)	100	36	3,600	.5	1,800
225.80(b)(2)	100	48	4,800	.12	576
225.102(b)(1) through (b)(5)	100	260	26,000	.4	10,400
TOTAL					16,676

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

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (NONREGISTERED UNLICENSED COMMERCIAL FEED MILLS)¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
225.142	8,000	4	32,000	1	32,000
225.158	8,000	1	8,000	4	32,000
225.180	8,000	96	768,000	.12	92,160
225.202	8,000	260	2,080,000	.65	1,352,000
TOTAL					1,508,160

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

TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN (NONREGISTERED UNLICENSED MIXER-FEEDERS)¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
225.142	45,000	4	180,000	1	180,000
225.158	45,000	1	45,000	4	180,000
225.180	45,000	32	1,440,000	.12	172,000
225.202	45,000	260	11,700,000	.33	3,861,000
TOTAL					4,393,000

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

The estimate of the times required for record preparation and maintenance is based on agency communications with industry. Other information needed to finally 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 4, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-13215 Filed 6-10-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0483]

Agency Information Collection Activities; Announcement of OMB Approval; Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Food Labeling Regulations" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the *Federal Register* of February 18, 2004 (69 FR 7643), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0381. The approval expires on May 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: June 4, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-13216 Filed 6-10-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Summaries of Medical and Clinical Pharmacology Reviews of Pediatric Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for Cipro (ciprofloxacin), Corlopam (fenoldopam), Glucovance (glyburide and metformin), Arava (leflunomide), Viracept (nelfinavir), Concerta (methylphenidate), Zemplar (paricalcitol), Zomig (zolmitriptan), and Ortho Tri-Cyclen (norgestimate and ethinyl estradiol). The summaries are being made available consistent with the Best Pharmaceuticals for Children Act (BPCA). For all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of the pediatric studies conducted for the supplement.

ADDRESSES: Submit written requests for single copies of the summaries to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please specify by product name which summary or summaries you are requesting. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries.

FOR FURTHER INFORMATION CONTACT: Grace Carmouze, Center for Drug Evaluation and Research (HFD-960), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-7337, carmouzeg@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies conducted for Cipro (ciprofloxacin), Corlopam (fenoldopam), Glucovance (glyburide and metformin), Arava (leflunomide), Viracept (nelfinavir), Concerta (methylphenidate), Zemplar (paricalcitol), Zomig (zolmitriptan), and

Ortho Tri-Cyclen (norgestimate and ethinyl estradiol). The summaries are being made available consistent with section 9 of the BPCA (Public Law 107-109). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the pediatric exclusivity program described in section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a). Section 505A permits certain applications to obtain 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

One of the provisions the BPCA added to the pediatric exclusivity program pertains to the dissemination of pediatric information. Specifically, for all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement (21 U.S.C. 355a(m)(1)). The summaries are to be made available not later than 180 days after the report on the pediatric study is submitted to FDA (21 U.S.C. 355a(m)(1)). Consistent with this provision of the BPCA, FDA has posted on the Internet (<http://www.fda.gov/cder/pediatric/index.htm>) summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for Cipro (ciprofloxacin), Corlopam (fenoldopam), Glucovance (glyburide and metformin), Arava (leflunomide), Viracept (nelfinavir), Concerta (methylphenidate), Zemplar (paricalcitol), Zomig (zolmitriptan), and Ortho Tri-Cyclen (norgestimate and ethinyl estradiol). Copies are also available by mail (see **ADDRESSES**).

II. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/pediatric/index.htm>.

Dated: June 3, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-13217 Filed 6-10-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Environmental Planning Program

AGENCY: Department of the Homeland Security.

ACTION: Notice of proposed directive; request for comments.