

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| 21 CFR Section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total Hours |
|----------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| 516.119 | 2 | 1 | 2 | 1 | 2 |
| 516.121 | 30 | 2 | 60 | 4 | 240 |
| 516.123 | 3 | 1 | 3 | 8 | 24 |
| 516.125 | 2 | 3 | 6 | 20 | 120 |
| 516.129 | 30 | 2 | 60 | 20 | 1200 |
| 516.141 | 20 | 1 | 20 | 16 | 320 |
| 516.143 | 20 | 1 | 20 | 120 | 2400 |
| 516.145 | 20 | 1 | 20 | 20 | 400 |
| 516.161 | 1 | 1 | 1 | 4 | 4 |
| 516.163 | 1 | 1 | 1 | 2 | 2 |
| 516.165 | 10 | 2 | 20 | 8 | 160 |
| Total | | | | | 4,872 |

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

| 21 CFR Section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|----------------|-------------------------|------------------------------------|----------------------|----------------------------------|-------------|
| 516.141 | 30 | 2 | 60 | ² 0.5 | 30 |
| 516.165 | 10 | 2 | 20 | 1 | 20 |
| Total | | | | | 50 |

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

² 30 minutes.

Dated: June 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-14473 Filed 6-19-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0193]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 July 21, 2014.

ADDRESSES: 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: FDA Desk Officer, FAX: 202-395-7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0152. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, *PRAStaff@fda.hhs.gov*.

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.

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 FD&C 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 FD&C 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 FD&C Act as to safety and that they

meet their claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the FD&C 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.

In the **Federal Register** of April 7, 2014 (79 FR 19091), FDA published a 60-day notice requesting public

comment on the proposed collection of information. Although one comment was received, it was not responsive to the four elements solicited in the notice and therefore will not be discussed in this document.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN

[Registered licensed commercial feed mills]¹

| 21 CFR Section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeper | Total hours |
|-----------------------------------|-------------------------|------------------------------------|----------------------|---------------------------------|------------------|
| 225.42(b)(5) through (b)(8) | 840 | 260 | 218,400 | 1 | 218,400 |
| 225.58(c) and (d) | 840 | 45 | 37,800 | 0.50 (30 minutes) | 18,900 |
| 225.80(b)(2) | 840 | 1,600 | 1,344,000 | 0.12 (7 minutes) | 161,280 |
| 225.102(b)(1) | 840 | 7,800 | 6,552,000 | 0.08 (5 minutes) | 524,160 |
| 225.110(b)(1) and (b)(2) | 840 | 7,800 | 6,552,000 | .015 (1 minute) | 98,280 |
| 225.115(b)(1) and (b)(2) | 840 | 5 | 4,200 | 0.12 (7 minutes) | 504 |
| Total | | | | | 1,021,524 |

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 | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeper | Total hours |
|------------------------------------|-------------------------|------------------------------------|----------------------|---------------------------------|---------------|
| 225.42(b)(5) through (b)(8) | 100 | 260 | 26,000 | 0.15 (9 minutes) | 3,900 |
| 225.58(c) and (d) | 100 | 36 | 3,600 | 0.50 (30 minutes) | 1,800 |
| 225.80(b)(2) | 100 | 48 | 4,800 | 0.12 (7 minutes) | 576 |
| 225.102(b)(1) through (b)(5) | 100 | 260 | 26,000 | 0.40 (24 minutes) | 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 | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeper | Total hours |
|--------------------|-------------------------|------------------------------------|----------------------|---------------------------------|----------------|
| 225.142 | 4,186 | 4 | 16,744 | 1 | 16,744 |
| 225.158 | 4,186 | 1 | 4,186 | 4 | 16,744 |
| 225.180 | 4,186 | 96 | 401,856 | 0.12 (7 minutes) | 48,223 |
| 225.202 | 4,186 | 260 | 1,088,360 | 0.65 (39 minutes) | 707,434 |
| Total | | | | | 789,145 |

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 | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeper | Total hours |
|----------------|-------------------------|------------------------------------|----------------------|---------------------------------|-------------|
| 225.142 | 3,400 | 4 | 13,600 | 1 | 13,600 |
| 225.158 | 3,400 | 1 | 3,400 | 4 | 13,600 |
| 225.180 | 3,400 | 32 | 108,800 | 0.12 (7 minutes) | 13,056 |
| 225.202 | 3,400 | 260 | 884,000 | 0.33 (20 minutes) | 291,720 |

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued
[Nonregistered unlicensed mixer-feeders]¹

| 21 CFR Section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeper | Total hours |
|----------------|-------------------------|------------------------------------|----------------------|---------------------------------|-------------|
| Total | | | | | 331,976 |

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

The estimate of time 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 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-14472 Filed 6-19-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0389]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Regulations for Type A Medicated Articles

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 July 21, 2014.

ADDRESSES: 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: FDA Desk Officer, FAX: 202-395-7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0154. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, *PRAStaff@fda.hhs.gov*.

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.

Current Good Manufacturing Practice Regulations for Type A Medicated Articles—21 CFR Part 226 (OMB Control Number 0910-0154)—Extension

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), FDA has the statutory authority to issue current good manufacturing practice (cGMP) regulations for drugs, including Type A medicated articles. A Type A medicated article is a feed product containing a concentrated drug diluted with a feed carrier substance. A Type A medicated article is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease or for growth promotion and feed efficiency.

Statutory requirements for cGMPs for Type A medicated articles have been codified in part 226 (21 CFR part 226). Type A medicated articles which are not manufactured in accordance with these

regulations are considered adulterated under section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)). Under part 226, a manufacturer is required to establish, maintain, and retain records for Type A medicated articles, including records to document procedures required under 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) and product distribution.

This information is needed so that FDA can monitor drug usage and possible misformulation of Type A medicated articles. The information could also prove useful to FDA in investigating product defects when a drug is recalled. In addition, FDA will use the cGMP criteria in part 226 to determine whether or not the systems used by manufacturers of Type A medicated articles are adequate to assure that their medicated articles meet the requirements of the FD&C Act as to safety and also meet the article's claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the FD&C Act. The respondents for Type A medicated articles are pharmaceutical firms that manufacture both human and veterinary drugs, those firms that produce only veterinary drugs, and commercial feed mills.

In the **Federal Register** of April 7, 2014 (79 FR 19093), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

| 21 CFR Section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeper | Total hours |
|----------------|-------------------------|------------------------------------|----------------------|---------------------------------|-------------|
| 226.42 | 65 | 260 | 16,900 | 0.75 (45 minutes) | 12,675 |
| 226.58 | 65 | 260 | 16,900 | 1.75 | 29,575 |
| 226.80 | 65 | 260 | 16,900 | 0.75 (45 minutes) | 12,675 |