

5. The comment recommends that absorbed doses for individual subjects who are also representative subjects, or absorbed doses for individual subjects that are less than those estimated for a representative subject, be eliminated from the annual reporting requirements.

This comment is beyond the scope of the January 5, 2001, notice and would more appropriately be submitted as a comment on the proposed rule that FDA intends to publish.

6. The comment maintains that the estimated annual reporting burden stated in table 1 of the January 5, 2001, notice underestimates the time required for completion of Form FDA 2915 as it currently exists. The respondent estimates that the time expended to complete an annual summary on Form FDA 2915 is approximately 10 hours, rather than the 3.5 hours stated.

FDA appreciates the comment but believes that 3.5 hours is a reasonable estimate of the average time it takes to complete the form. However, FDA recognizes that the paperwork burden may vary from committee to committee. FDA's survey of RDRC chairpersons attempted to reflect differences in RDRC membership and scope of activities. Based on this comment, FDA may further examine and evaluate the role, functions, and activities of RDRC and its related paperwork burden in the future.

Dated: June 8, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N-0048]

#### Agency Information Collection Activities; Submission for OMB 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 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 July 16, 2001.

**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:** 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 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 No. 0910-0154)—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 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 at part 266 (21 CFR part 226). Type A medicated articles that are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the act. 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 act as to safety and also meet the articles, claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the 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.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

| 21 CFR Section | No. of Recordkeepers | Annual Frequency of Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|----------------|----------------------|-----------------------------------|----------------------|------------------------|-------------|
| 226.42         | 115                  | 260                               | 29,000               | 0.75                   | 22,425      |
| 226.58         | 115                  | 260                               | 29,000               | 1.75                   | 52,325      |
| 226.80         | 115                  | 260                               | 29,000               | 0.75                   | 22,425      |
| 226.102        | 115                  | 260                               | 24,000               | 1.75                   | 52,325      |
| 226.110        | 115                  | 260                               | 29,000               | 0.25                   | 7,475       |

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>—Continued

| 21 CFR Section | No. of Recordkeepers | Annual Frequency of Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|----------------|----------------------|-----------------------------------|----------------------|------------------------|-------------|
| 226.115        | 115                  | 10                                | 1,150                | 0.5                    | 575         |
| Total          |                      |                                   |                      |                        | 157,550     |

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

The estimate of the time required for record preparation and maintenance is based on agency communications with industry. Other information needed to calculate the total burden hours (i.e., manufacturing sites, number of Type A medicated articles being manufactured, etc.) is derived from agency records and experience.

Dated: June 8, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N-0046]

#### Agency Information Collection Activities; Submission for OMB 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 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 July 16, 2001.

**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:** 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 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 No. 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 for growth promotion and feed efficiency. Statutory requirements for CGMPs have been codified in 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 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 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. 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)<sup>1</sup>

| 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) | 1,150                | 260                                | 299,000              | 1                      | 299,000     |
| 225.58(c) and (d)           | 1,150                | 45                                 | 51,750               | .5                     | 25,875      |
| 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            | 0.15                   | 134,550     |