

Dated: September 16, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-25360 Filed 9-22-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0510]

Agency Information Collection Activities; Announcement of OMB Approval; 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 collection of information entitled "Current Good Manufacturing Practice Regulations for Medicated Feeds" 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 Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 10, 1998 (63 FR 37396), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (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 0910-0152. The approval expires on August 31, 2001.

Dated: September 16, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0515]

Agency Information Collection Activities; Announcement of OMB Approval; Current Good Manufacturing Practice for Type A Medicated Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Current Good Manufacturing Practice for Type A Medicated Articles" 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 Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 21, 1998 (63 FR 39092), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (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 0910-0154. The approval expires on August 31, 2001.

Dated: September 16, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0727]

Draft "Guidance for Industry: Interpretation of On-farm Feed Manufacturing and Mixing Operations"; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Interpretation of On-farm Feed Manufacturing and Mixing Operations." The draft guidance is intended to clarify the applicability of certain sections of the Animal Proteins Prohibited from Use in Animal Feed regulation to ruminant feeders. The agency is requesting comments on this draft guidance.

DATES: Submit written comments by November 23, 1998.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Gloria J. Dunnava, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1726, E-mail:

gdunnava@bangate.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 589.2000 *Animal proteins prohibited from use in animal feed* (21 CFR 589.2000) defines "feed manufacturer" to include "on-farm feed manufacturing and mixing operation." This draft guidance makes it clear that an operation that mixes, but does not manufacture feed onfarm is not considered a feed manufacturer by FDA. Rather such mixing operations are ruminant feeders. While all ruminant feeders are subject to the regulation, the regulation imposes significantly different requirements on ruminant feeders that are also "feed manufacturers." For this reason, FDA finds it necessary to clarify the phrase "on-farm feed manufacturing and mixing operations."

FDA believes that a ruminant producer who mixes total mixed rations (TMR's), a complete mix of the cow's daily diet, for the animals under the producer's control is not