

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. Dunnavan, 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

"manufacturing and mixing." This draft guidance provides our rationale for this interpretation.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance is issued as a Level 1 guidance consistent with GGP's. If finalized, this document will represent current FDA thinking on on-farm feed manufacturing and mixing operations and their responsibilities under § 589.2000. The guidance will not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternate approaches may be used if they satisfy the requirements of applicable statutes, regulations, or both.

II. Comments

Interested persons should submit written comments on or before November 23, 1998, to the Dockets Management Branch (address above) regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance using the World Wide Web (WWW). For WWW access, connect to CVM at "http://www.fda.gov/cvm".

Dated: September 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-1047-NC]

Medicare and Medicaid Programs; Announcement of Additional Applications From Hospitals Requesting Waivers for Organ Procurement Service Area

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice announces two additional applications that HCFA has received from hospitals requesting waivers from entering into agreements with their designated organ procurement organizations (OPOs) in accordance with section 1138(a)(2) of the Social Security Act. It supplements notices published in the **Federal Register** on January 19, 1996, May 17, 1996, November 8, 1996, April 21, 1997, and September 17, 1997, that announced hospital waiver requests received by us. This notice requests comments from OPOs and the general public for our consideration in determining whether these waivers should be granted.

COMMENT DATE: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 23, 1998.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-1047-NC, P.O. Box 7517, Baltimore, MD 21244-0517.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments may also be submitted electronically to the following e-mail address: HCFA1047NC@hcfa.gov. E-mail comments must include the full name, postal address, and affiliation (if applicable) of the sender and must be submitted to the referenced address to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1047-NC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue, SW, Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

FOR FURTHER INFORMATION CONTACT: Mark A. Horney (410) 786-4554.

SUPPLEMENTARY INFORMATION:

I. Background

On January 19, 1996, May 17, 1996, November 8, 1996, and April 21, 1997, and September 17, 1997, we published notices in the **Federal Register** (61 FR 1389, 61 FR 24941, 61 FR 57876, 62 FR 19326, and 62 FR 48872) that announced applications that HCFA had received from hospitals requesting waivers from entering into agreements with their designated organ procurement organizations (OPOs) in accordance with section 1138(a)(2) of the Social Security Act (the Act). This notice supplements these five notices. Section 1138(a)(1)(A)(iii) of the Act provides that a hospital must notify the designated OPO (for the service area in which it is located), as defined under section 1138(a)(3)(B) of the Act, of potential organ donors. Under section 1138(a)(1)(C) of the Act, the hospital must have an agreement to identify potential donors only with that designated OPO.

Section 1138(a)(2) of the Act provides that the hospital may obtain a waiver from the Secretary of these requirements. A waiver allows the hospital to have an agreement with an OPO other than the designated OPO if conditions specified in section 1138(a)(2)(A) of the Act are met.

Section 1138(a)(2)(A) further states that in granting a waiver, the Secretary must determine that such a waiver: (1) Is expected to increase organ donations; and (2) will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver. In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider, among other factors: (1) Cost effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO service area due to the changes made in definition of metropolitan statistical areas (MSAs); and (4) the length and continuity of a hospital's relationship with the OPO other than the designated OPO. Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver application within 30 days of receiving the application and offer interested parties an opportunity to comment in writing within 60 days of the published notice.

The regulations at 42 CFR 486.316(d) provide that if we change the OPO