

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 98D-0727]

**Interpretation of On-Farm Feed Manufacturing and Mixing Operations;
Withdrawal of Draft Guidance**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal of draft guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance for industry (#77) entitled "Interpretation of On-farm Feed Manufacturing and Mixing Operations," that was issued on September 23, 1998. FDA has decided to withdraw the draft guidance. FDA has decided that the draft guidance did not address adequately the industry practices of on-farm mixers. Instead, the agency directs you to FDA guidance for industry (#69) entitled "Small Entities Compliance Guide for Feeders of Ruminant Animals With On-farm Feed Mixing Operations," which addresses on-farm mixing practices more completely.

FOR FURTHER INFORMATION CONTACT: Neal Bataller, Center for Veterinary Medicine (HFV-214), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0163, e-mail: nbatalle@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

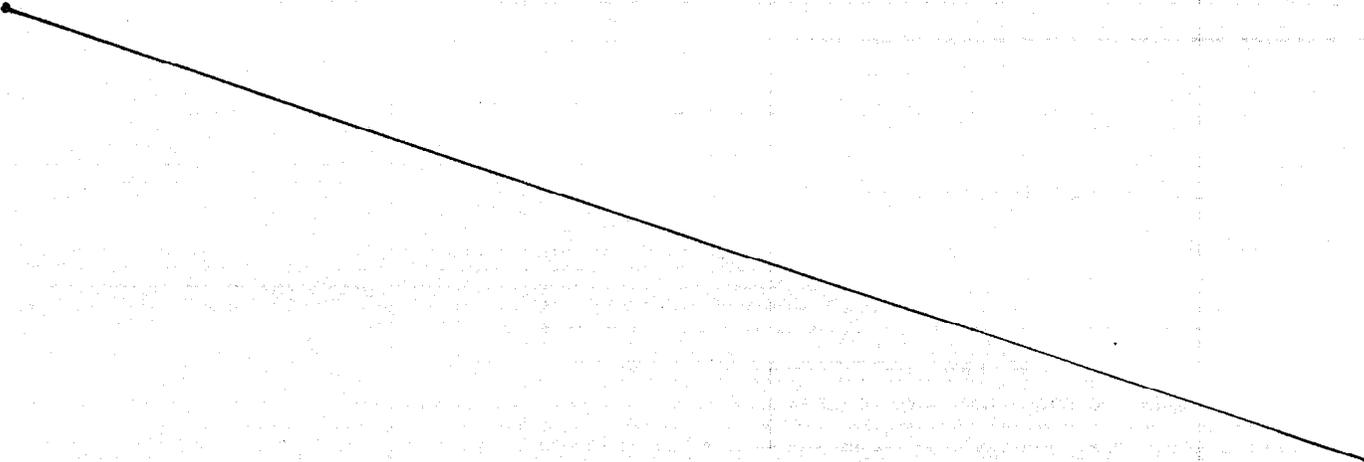
I. Background

In a notice published in the **Federal Register** of September 23, 1998 (63 FR 50918), FDA announced the availability of a draft guidance for industry

(#77) entitled "Interpretation of On-farm Feed Manufacturing and Mixing Operations." The draft guidance discusses the applicability of certain paragraphs of 21 CFR 589.2000 *Animal proteins prohibited in ruminant feed*. Written comments were to be received by November 23, 1998.

FDA received one letter containing several comments from an industry association on the draft guidance. The comments from the association expressed that they were "extremely concerned" that the draft guidance would be "extremely difficult to monitor and administer" in the section concerning commingling or cross-contamination of prohibited with nonprohibited mammalian protein. The comment further indicated that the draft guidance did not capture the regulation's requirements regarding equipment clean-out procedures.

After further consideration, FDA has decided to withdraw the draft guidance. FDA has decided that the draft guidance did not address adequately the industry practices of on-farm mixers. Instead, the agency directs you to FDA guidance for industry (#69) entitled "Small Entities Compliance Guide for Feeders of Ruminant Animals With On-farm Feed Mixing Operations," which addresses on-farm mixing practices more completely.



II. Electronic Access

Persons with access to the Internet may obtain FDA guidance for industry #69 at <http://www.fda.gov/cvm/guidance/guidance.html>.

Dated: 6/4/03
June 4, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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