

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 510 and 558****[Docket No. 93P-0174]****Requirements for Liquid Medicated Animal Feed and Free-Choice Medicated Animal Feed****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to change the regulations for liquid medicated feed and free-choice medicated feed. By changing the regulations for liquid medicated feed, FDA wants to clarify: What data are required to demonstrate chemical and physical stability of a drug in liquid feed; how such data may be submitted for use in the new animal drug approval process; and which liquid medicated feeds may be manufactured in a feed manufacturing facility that has not obtained a medicated feed mill license from FDA. By changing the regulations for free-choice medicated feed, FDA wants to ensure that they are consistent with the requirements for liquid medicated feed, and that provisions for free-choice medicated feed and liquid medicated feed comply with the terms of the Animal Drug Availability Act (ADAA) of 1996.

**DATES:** We invite you to comment on this proposed rule. We will consider all comments that we receive by August 26, 2003. Send comments on the information collection provisions by July 28, 2003.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to [sshapiro@omb.eop.gov](mailto:sshapiro@omb.eop.gov) or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202-395-6974. Comments must be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Dragan Momcilovic, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0169, e-mail: [dmomcilo@cvm.fda.gov](mailto:dmomcilo@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Section I of the preamble addresses the proposed changes in the regulation for liquid medicated feeds. Section II addresses the proposed changes for free-choice medicated feeds.

**I. Liquid Medicated Feed***A. Current Regulations*

According to the new animal drugs for use in animal feeds regulations under part 558 (21 CFR part 558), provided specifically in § 558.3(b) are three types of medicated products for use in feed; a Type A medicated article and two types of medicated feed, Type B and Type C. A Type A medicated article is a new animal drug that is used for the manufacture of another Type A medicated article or a Type B or Type C medicated feed. Under the current rule, the use of a drug in the manufacture of a liquid Type B medicated feed requires that the feed mill obtain an approved new animal drug application (NADA) (§ 558.5(a)) and an approved medicated feed mill license (§ 558.5(b)). A Type B medicated feed is used solely for the manufacture of other medicated feeds, Type B or Type C (§ 558.3(b)(3)). A Type C medicated feed can be either fed as the complete feed, "top dressed" (added on top of usual ration), offered "free-choice" in conjunction with other animal feed, or further diluted to produce another Type C medicated feed (§ 558.3(b)(4)).

*B. Chronology of the American Feed Industry Association (AFIA) Citizen Petitions on Liquid Feed Regulations, FDA Responses, and ADAA*

On April 30, 1993, the AFIA filed a citizen petition (docket number 93P-0174/CP1), requesting that FDA:

1. Amend § 558.5 to clarify the information and data needed to demonstrate chemical and positional (physical) stability in liquid medicated feeds, and
2. Describe the circumstances under which a medicated feed application (MFA) (Form FDA 1900) will or will not be required.

In our November 10, 1993, tentative response to AFIA, we stated that we agreed "in principle" to modify § 558.5 to include appropriate directions on submission of chemical and positional (physical) stability data. We stated, however, that we disagreed with the

request to eliminate the requirement for an approved MFA for the manufacture of Type B or Type C liquid medicated feeds from a Type A medicated article, Category I drug. Finally, we stated that we were preparing to propose a change to § 558.5 and would provide a final response to the citizen petition once the notice of proposed rulemaking was published in the **Federal Register**.

AFIA modified the requested actions in letters of March 3, 1994, and January 6, 1995, to ask that no MFA be required where a specific formula or the specifications for the finished liquid Type B product is published in a regulation for a Category I drug.

On April 19, 1995, we sent a second tentative response to AFIA that modified some of what was explained in our letter of November 10, 1993. We stated, in the April 19, 1995, letter that we agreed "in principle that an MFA (Form FDA-1900) should not be required if a specific formula or the specifications for the finished liquid Type B product is published in the regulations and the drug is a Category I product." We explained that our position is based on the text of 21 CFR 558.5(a), "which addresses the concern for drug stability in liquid feeds, except where specific approval has been granted for such use" and that "We interpret this exception to be the basis for not requiring MFA approval for these Category I Type B liquid feeds 21 CFR 558.5(b)." We continued to believe, however, that the manufacture of a liquid Type B medicated feed from an approved Category I drug will require an approved MFA if a formula or the specifications for the liquid Type B product were not published in the regulation. Also stated in the letter, we considered that since "the formula or specifications are not published and are privileged information, the MFA is needed to ensure that only the manufacturer is authorized to utilize the intended formula or specifications." We also noted that an approved MFA was required to manufacture all Category II Type B liquid feeds.

In a letter of May 19, 1995, AFIA requested that we convert the process for development of an amendment to § 558.5 into a negotiated rulemaking. However, in a letter of June 15, 1995, AFIA asked that its request for negotiated rulemaking be held "in abeyance." The letter stated that AFIA anticipated that its concerns would be addressed in the proposed rule and that "If further rulemaking is necessary, then we believe negotiated rulemaking would be in order."

On October 9, 1996, the ADAA became a law. The ADAA provided for