

# MEDICATED ADDITIVES

## Medicated Additives in Liquid Feed Supplements, Medicated Blocks and Free Choice Feeds



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The inclusion of additives in liquid feed supplements, medicated blocks and free choice feeds offers unique opportunities to add value and deliver benefits to livestock producers. When liquid feeds are included in mixed rations, they contribute to improved mixing of the diet, and reduced physical separation and animal sorting at the bunk. This translates into better distribution and more consistent intake of additives, and potentially greater animal response. In grazing situations, free-choice liquids and medicated feeds offer a practical means to deliver these management tools. In both scenarios, incorporating additives into the supplement eliminates the need for inventory, measurement and mixing of these relatively expensive, low-inclusion and dated ingredients.

However, it is critical that these products -- especially those regulated as medicated additives -- **only be delivered in appropriate products, to approved classes of animals, within the parameters outlined by the approval process and required by federal law.**

## Medicated Additives

The Federal Food, Drug and Cosmetic Act defines a "drug" as any compound intended to cure, treat, prevent or mitigate a disease or condition or a product that is intended to alter the structure or function of the body (unless it is a food that does that itself). If the compound is an animal drug by this definition, then federal law requires the compound to be approved by FDA through a thorough review of the safety of the product in animals and human food, and a review of its efficacy.

The approval for use of an animal drug in liquid feed and blocks and for free-choice feeding requires feeding trials, manufacturing tests, safety data, chemical and other information required by FDA regulations. Animal drugs approved for use in liquid feed and blocks and for free-choice feeding require more tests and data than those animal drugs approved for use in dry feed. This has to do with the unique nature of these feeds, pH, settling, and exposure to heat/cold and the elements, among other things. The FDA approves animal drugs based on the data submitted by the drug sponsor and reviewed by FDA, and the approval is specific for the animal species, class of animal, type of product (e.g., dry or liquid feed, free-choice and/or block), conditions of use, any manufacturing requirements (agitation, pH or temperature), and any limitations and/or warning statements or conditions. The approval process takes many months, and firms pursuing this approach expend considerable resources obtaining the final approval. The approval can only be changed by FDA through a similar review process, and the approval is granted specifically to a firm. Other firms wanting the same approval must file data and go through the same process.

When used as approved, FDA has deemed the approved animal drugs to be safe and efficacious for their labeled use. If any withdrawal times are followed, the drugs will not result in a violative tissue residue in meat, milk, eggs or fish.

## Serious Business

Approved animal drugs can ONLY be used in feed, handled and positioned as outlined by the FDA. It is a violation of federal law to knowingly distribute an unapproved animal drug or to use it in an unapproved manner. **No company, nutritionist or veterinarian may change the type of feed, animal species, animal class, use level or indications for use of these approved animal drugs.**

The feed and livestock industry has a huge stake in preventing misuse of these products. It is irresponsible and, in fact, illegal, to do any of the following:

- Add a Type A medicated article (the ingredient (premix) form of an additive) to liquid feed outside of a licensed manufacturing facility (e.g., local dosing by distributors);
- Include a medicated additive in a free-choice liquid feed that does not follow the approved formula;
- Ignore recirculation requirements or expiration dates;
- Add an additive or form of an additive that has dry feed but not liquid feed/supplement approval to a liquid feed;
- Feed a medicated feed to an unapproved class of animals;
- Formulate dosage rates that fall outside approved ranges;
- Add multiple drug additives to the same feed that do not have a specific combination approval;
- Position a medicated supplement for a use that is not specifically approved (e.g., free-choice vs. hand fed; open top tank vs. covered lick wheel feeder); or
- Ignore any of the warnings, limitations or other use directions on the approved label of a medicated feed, premix or supplement.

Such violations may result in illegal drug residues in meat, milk, eggs or fish and may result in serious reactions in humans eating these products.

These violations, if prosecuted by FDA, may result in criminal sanctions, such as fines and/or jail sentences or civil sanctions, such as forfeiture of profits, fines and other civil penalties.

Manufacturers and distributors of liquid feeds, blocks and free choice feeds have a responsibility to adhere to all medicated additive regulations. Besides being against the law, the actions cited above can lead to:

- Reduced, or even no, response to the additive;
- Safety concerns;
- Potential for residues in meat and milk, or environmental contamination;
- Discovery by anti-animal agriculture activists, and subsequent negative publicity, additional regulation, and potentially even loss of additive availability for the industry; and/or
- In the case of antibiotics, add fuel to the campaign to take these management tools away from livestock producers.

#### Approved Medicated Additives for Liquid Feeds, Medicated Blocks and Free Choice Feeds

***Ionophores.*** These include monensin, lasalocid and laidlomycin. Specific regulations include class of animal, indications for use, directions for use, approved additive level in the supplement, expiration date (where applicable), agitation requirements, and formulation limitations. Lasalocid is the only ionophore cleared for use in free-choice liquid feed, and that inclusion is strictly limited to approved formulas.

***Antimicrobials/Anthelmintics.*** A form of tylosin is approved for use in liquid supplements that are part of a mixed ration. The lack of clearances for other commonly used feed antibiotics can be at least partially attributed to the fact that the currently available form of these compounds will not remain stable in the liquid feed environment. Fenbendazole may be delivered to acclimated beef and dairy cattle in a specified liquid feed formula, via lick wheel feeders. Decoquinatate is approved for use

in force-fed liquids for the prevention of coccidiosis. This product has closely defined regulations regarding dosage and feeding protocols.

***Growth promotion/feed efficiency.*** Bambermycin is approved for liquid feeds and free-choice feeds, but the latter requires use of the formula in the federal regulation for this drug. Ractopamine and zilpaterol, beta-agonists are approved for liquid feed for these types of claims as well.

***Heat suppression.*** Melegesterol acetate is approved for inclusion in force-fed liquids for suppression of estrus (heat) in heifers fed for slaughter, both alone and in combination with specific ionophores.

***Pesticides.*** S-Methoprene is available in a liquid form for addition to liquid feeds to aid in the control of horn flies. This particular product is classed as a pesticide rather than feed additive and is regulated by the EPA rather than FDA if added to a non-medicated feed. If added to a medicated feed, then FDA will regulate it. The dry premix may not be substituted for the liquid ingredient. Tetrachlorvinphos may be added to liquids going into mixed rations for control of specific insect pests. Users of all pesticides should be aware of appropriate feeding directions and expiration dates. Diflubenzuron may be used in liquid feeds when suspension agents are used to maximize the positional stability of other feed ingredients.

***Bloat control.*** Poloxalene may be fed as part of a specified formula offered in covered lick wheel feeders.

#### Information Sources

Complete information on approvals and regulations may be obtained from your liquid feed, medicated block, or free choice feed company or from the drug sponsor on the product label or from the drug sponsor's online information. FDA's Center for Veterinary Medicine also maintains an approval list online via [www.fda.gov/cvm](http://www.fda.gov/cvm), but it is a complex listing that includes all approved animal drugs, including injectables.

The information in this document is no substitute for the regulatory and label requirements for approved medicated additives for liquid feed, medicated block or free choice feed. Firm and producers must follow labeled directions.

For more information, contact your liquid feed, medicated block or free choice feed supplier or the American Feed Industry Association at [afia@afia.org](mailto:afia@afia.org) or (703) 524-0810.

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