MEDICATED FEED LABEL GUIDANCE

NOTE: California Department of Food and Agriculture Safe Animal Feed Education (SAFE) guidance materials are provided for educational purposes only and do not guarantee adequacy of procedures or compliance with regulations.

Feed manufacturers are responsible for creating a medicated feed label which conveys all necessary information to the consumer, so the medicated feed may be used in a *safe and effective* manner. The following requirements are outlined in California Code of Regulations (CCR) § 2701.

Basic Requirements on a Medicated Feed Label

- **A.** The term "MEDICATED" prominently displayed immediately above or below the name
- **B.** The indication(s) of use for each drug (specific to species and production class)
- **C.** The name and quantity of each drug (in units which are consistent with the drug approval)
- **D.** Relevant warnings, caution statements, withdrawal time as indicated in United States Food and Drug Administration (FDA) approval
- **E.** Adequate directions for use
- **F.** Lot number

Example Label # 1: Basic requirements on a medicated feed label

Lamb Pellet 123

A. MEDICATED

B. *For the prevention of coccidiosis in young sheep caused by Eimeria bakuensis, Eimeria crandalis, Eimeria ovinoidalis, and Eimeria parva.*

C. Active Drug Ingredient: Decoquinate.....45.4 g/ton

Guaranteed Analysis
Crude Protein (Min).....16%
Crude Fat (Min).....3%
Crude Fiber (Max).....6%
Ash (Max).....5%

Ingredients: Corn, Oats, Soybean Meal, Calcium Chloride, Mineral Oil, Salt.

D. Warning: Do not feed to sheep producing milk for human consumption.
D. Limitations for Use: Feed at least 28 days during periods of exposure to coccidiosis or when experience indicates that it is likely to be a hazard.
E. Feeding Directions: Feed 1 pound per 100 pounds of bodyweight per day.

Manufactured By: ABC Milling
123 Somewhere St.
Nowhere, CA 95601

50 lbs (22.6 kg)
F. Lot # 007

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Drug Approval and Warning Statements

The pure drug is a “Type A Medicated Article”.

“Type B Medicated Feeds” are manufactured at a concentration that requires further mixing prior to feeding; requiring adequate mixing directions on the label, in addition to feeding directions.

“Type C Medicated Feeds” are manufactured at a concentration that is ready to be fed.

When creating medicated feed labels, it is the manufacturer’s responsibility to ensure that:

- Indication for use & drug level on the medicated feed label are within the Code of Federal Regulations (CFR) Approval for the species and class of the animal being fed.
- All applicable caution statements are included (**See Figure 1).**
- Feeding and mixing directions are accurate, and likely to be followed.

***Figure 1**. Example: Applicable warning and caution statements for a Type C feed medicated with monensin for increased milk production efficiency in dairy cows as per FDA CFR 558.355.*

(6) All formulations containing monensin shall bear the following caution statement: Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal.

(vii) If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing (see paragraphs (d)(10)(i) and (d)(10)(ii) of this section).

(viii) A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(ix) You may notice the following: Reduced voluntary feed intake in dairy cows fed monensin. This reduction increases with higher doses of monensin fed. Rule out monensin as the cause of reduced feed intake before attributing to other causes such as illness, feed management, or the environment. Reduced milk fat percentage in dairy cows fed monensin. This reduction increases with higher doses of monensin fed. Increased incidence of cystic ovaries and metritis in dairy cows fed monensin. Reduced conception rates, increased services per animal, and extended days open and corresponding calving intervals in dairy cows fed monensin. Have a comprehensive and ongoing nutritional, reproductive, and herd health program in place when feeding monensin to dairy cows.

Monensin in grams/ton	Combination in grams/ton	Indications for use	Limitations
(v) 11 to 400	Dairy cows: For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake)	Feed continuously to dry and lactating dairy cows in a component feeding system (including top dress). The Type C medicated feed must be fed in a minimum of 1 lb of feed to provide 185 to 660 mg/head/day monensin to lactating cows or 115 to 410 mg/head/day monensin to dry cows. See special labeling considerations in paragraph (d) of this section	

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Adequate Directions for Use

Mixing and feeding directions are the primary method for a feed manufacturer to communicate with customers the safe and approved use of medicated feed. California Code of Regulations requires that medicated feeds are labeled with “adequate directions for use” (§2701 (d)), and that directions must be likely to be followed in usual feeding practices (§2690).

When the medicated feed is the sole ration for the animal, the concentration of drug in the feed must simply match the FDA approval. When the medicated feed is a supplement or a concentrate that will be administered to the animal as a part of the total diet, adequate and realistic feeding and/or mixing directions become an important aspect of “adequate directions for use”.

‘Likely to be followed’ feeding directions include consideration of:

- The approved use level per species, production class, and indication of use for the drug
- The intended animal’s typical daily feed intake compared to the directions for use
- The method of administration (top dress, mixed in TMR, milk replacer, etc.)

For example, in the “Lamb Pellet 123” **Example Label #1** above, feeding 1 pound per 100 lbs. of bodyweight per day of the 45.4 g/ton decoquinate feed will provide 22.7 mg of decoquinate per 100 lbs. of bodyweight, which is the approved administration level. However, it must also be determined *if it is realistic that a lamb will consume 1 lb. per 100 lbs. of bodyweight* under normal feeding practices to consider the feeding directions adequate and likely to be followed. In this case, a 50 lb. lamb consumes about 5% of their bodyweight per day (2.5 lbs. of feed), so the consumption of 0.5 lb. of “Lamb Pellet 123” along with 2 lbs. of forage is realistic.

Firms are encouraged to be realistic with mixing directions provided to their customers as well. For example, the only scale available at a dairy may be the mixer wagon scale, which can be inaccurate up to +/- 20 lbs. In this case, there is no way to accurately weigh Type B medicated feed to the nearest pound or to a tenth of a pound. One way to solve this problem is to formulate the Type B medicated feed for an on-farm inclusion rate of 1 full bag (50 lbs.) in the total mixed ration **(see Example Label # 2**).

A single feed label may be used for multiple indications for use, or even multiple species of livestock, so long as the following components are met on the feed label:

- The concentration of drug allows for the approved drug use level to be met under usual feeding practices for all species, classes, or indications included.
- The feeding and/or mixing directions are provided for each species, class, and indication of use. **(See Example Label # 2).**

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Example Label # 2: Type B medicated feed label with multiple indications of use

RUMENSIN 1000 GM LOOSE
Type B MEDICATED

For increased rate of gain in growing cattle;
For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake in dairy;
For prevention and control of coccidiosis caused by Eimeria bovis and Eimeria zuernii in calves (excluding veal calves)

ACTIVE DRUG INGREDIENT: Monensin (as Monensin Sodium)..... 1000 gm/ton

Guaranteed Analysis
...

Ingredients:.....

CAUTION: Do not allow horses or other equines access to feeds containing Monensin. Ingestion of Monensin by equines has been fatal. Monensin-medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not feed undiluted. Feeding undiluted or mixing errors resulting in high concentrations of Monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. If feed refusals containing Monensin are fed to other groups of cattle, the concentration of Monensin in the refusals and amount of refusals fed should be taken into consideration to prevent Monensin overdosing.
Warning: A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal.
YOU MAY NOTICE: Reduced voluntary intake in dairy cows fed Monensin. This reduction increases with higher doses of Monensin fed. Rule out Monensin as the cause of reduced feed intake before attributing to other causes such as illness, feed management, or the environment. Reduced milk fat percentage in dairy cows fed Monensin. This reduction increases with higher doses of Monensin. Reduced conception rates, increased services per animal, and extended days open and corresponding calving intervals in dairy cows fed Monensin. Have a comprehensive and ongoing nutritional, reproductive and herd health program in place when feeding Monensin to dairy cows.

Feeding and Mixing Directions:
Important: Must be thoroughly mixed into feed before use. Each pound of this Type B medicated feed contains 500 mg of Monensin. One 50 lb bag of this Type B medicated feed will provide the MAXIMUM dosage of 200 mg of Monensin per head per day to 125 head of calves or growing cattle and replacement heifers. Feeding directions according to production class and indication of use follow.

Calves (excluding veil calves): For the prevention and control of coccidiosis caused by Eimeria bovis and Elmeria zuernii.
Mix a Type C medicated feed containing between 10 and 200 g/ton Monensin. Feed at the rate to provide 0.1 to 0.4 pounds per head per day (50 to 200 mg of Monensin) to provide 0.14 – 1.0 mg/lb bw/day of Monensin up to 200 mg/head/day depending on the severity of the challenge. DO NOT EXCEED 0.4 pounds per head per day (200 mg/head/day monensin).

Growing cattle and dairy replacement heifers: For increased rate of weight gain.
Mix a Type C medicated feed containing between 15-400 g/ton on a 90% dry-matter basis. Feed at the rate of 0.1 to 0.2 pounds per head day to provide 50 to 100 mg Monensin for the first 5 days. After the first 5 days, feed at the rate of 0.1 to 0.4 pounds per head per day contained in not less than 1 lb. of feed to provide 50 -200 mg Monesin.

Dairy cows: For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake).
For TMR herds: Feed continuously to dry and lactating dairy cows a total mixed ration containing 11-22 g/ton Monensin on a 100% DM basis. Table below shows mixing directions based on 50% and 60% dry matter TMRs.

Dry Matter Percentage of Total Mixed Ration (TMR)	Desired Monensin Concentration (g/ton) in TMR on a 100% Dry Matter Basis		
	11	15	22
	Pounds of this premix needed per ton of TMR (As-Fed)		
50%	44	60	88
60%	53	72	106

For component-fed herds: Feed continuously to dry and lactating dairy cows a Type C medicated feed containing 11-400 g/ton Monensin. The Type C feed must be fed in a minimum of 1 pound of feed per cow per day to provide 185-660 mg/head/day to lactating cows or 115-410 mg/head/day to dry cows. Feed continuously to dairy cattle at a rate of 0.4 pounds to 0.8 pounds per head per day as part of a component feeding system. This feeding rate will provide Monensin at a rate of 200 mg to 400 mg per head per day. One 50 pound bag of this Type B medicated feed will provide 100 head of dairy cows with 250 mg of Monensin per head per day.

MEDICATED FEED LABEL GUIDANCE

Medicated Feeds with Multiple Drugs, Pesticides, or Selenium

Medicated feeds may also contain selenium over 0.3 ppm, a combination of drugs, or a pesticide such as insect growth regulator for fly control. This complicates feeding and mixing directions with the necessity of being accurate and compliant with the approvals for all agents simultaneously. A single set of feeding directions must provide accurate information for all components of the feed. In this case, it is important that feeds are properly formulated to provide an appropriate level of each agent within one dose of the feed **(See Example Label # 3).**

Important Considerations:

- The mixing and feeding instructions for medicated feed containing selenium should not exceed the 0.3 ppm approval for selenium in the total mixed ration (CCR §2697(d)).
- Ensure that any combination of drugs used in a medicated feed is an approved combination.
- Ensure feeding directions for feeds with multiple drugs and/or pesticides result in the approved use level for both drugs and pesticides concurrently.
- Non-medicated feed containing pesticides may need to be registered with Environmental Protection Agency (EPA) except when custom blending per the provisions of 40 CFR 167.3. When pesticides are added to medicated feeds, no EPA registration is needed as long as the ingredient used is an EPA-registered product.

Verification of Feeding Directions

It is the feed manufacturer's responsibility to ensure the medicated feed is accompanied by a label which provides adequate direction for use within the FDA approved levels for safe and effective use of medicated feeds. This requires proper calculation of dosage and feeding rate, which is often performed by a computer program, a nutritionist, the formulator for the company, or another designated employee.

- Double check any labels created using automated systems for accuracy and ease of use.
    - *Labels created using automated systems need to be verified for correct approvals and cautionary statements.*
    - *The feeding directions are often unrealistic with automated system labels.*
- If a nutritionist or a customer submits a custom medicated formulation, verify that mixing and feeding directions will provide the approved and correct dosage of the drug.

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Example Label #3. Type B medicated feed label with pesticide and selenium.

R1200 MONENSIN PREMIX FOR DAIRY COWS WITH CLARIFY AND SELENIUM

For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake).

As an insect growth regulator, which prevents the development of house, stable, face and horn flies in the manure of treated beef and dairy cattle.

MEDICATED

ACTIVE DRUG INGREDIENT: Monensin……1200 gm/ton (600 mg/lb)

Diflubenzuron……..136 mg/lb

Guaranteed Analysis

Selenium Minimum……...20 ppm

Selenium Maximum ……24 ppm

Ingredients……

Caution: Follow label directions: Feeding added selenium at levels in excess of 0.3 ppm in the total diet is prohibited. This feed contains selenium at 11 mg/lb. Do not feed at more than 1.25 % of the total daily ration. Do not exceed 25 pounds of this premix per ton to provide a maximum of 0.3 ppm Selenium in the total mixed ration.

CAUTION: Do not allow horses or other equines access to feeds containing Monensin. Ingestion of Monensin by equines has been fatal. Monensin-medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not feed undiluted. Feeding undiluted or mixing errors resulting in high concentrations of Monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. If feed refusals containing Monensin are fed to other groups of cattle, the concentration of Monensin in the refusals and amount of refusals fed should be taken into consideration to prevent Monensin overdosing.

Warning: A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal.

YOU MAY NOTICE: Reduced voluntary intake in dairy cows fed Monensin. This reduction increases with higher doses of Monensin fed. Rule out Monensin as the cause of reduced feed intake before attributing to other causes such as illness, feed management, or the environment. Reduced milk fat percentage in dairy cows fed Monensin. This reduction increases with higher doses of Monensin. Reduced conception rates, increased services per animal, and extended days open and corresponding calving intervals in dairy cows fed Monensin. Have a comprehensive and ongoing nutritional, reproductive and herd health program in place when feeding Monensin to dairy cows.

Caution Statement: Keep out of reach of children. Discard empty container according to local regulations. Never reuse empty container.

Feeding directions: Feed at a rate 0.4 – 0.5 lbs/hd/day to provide 240-300 mg/head per day Monensin and 54 to 68 mg per head per day diflubenzuron (0.10 mg/kg of bodyweight diflubenzuron per head per day).

For component-fed herds:
Feed 0.5 pounds per 1500-pound cow per day to provide 300 mg of Monensin and 68 mg of diflubenzuron per head per day.
Feed 0.4 pounds per 1200-pound cow per day to provide 240 mg of Monensin and 54 mg of diflubenzuron per head per day.

For TMR herds: Feed continuously to dry and lactating dairy cows a TMR containing 11-22 g/ton Monensin. One 50 lb bag of this Type B premix per 2 tons feed will contain 0.3 ppm selenium, 15 g/ton Monensin on a 100% dry matter basis, and 1.7 mg/lb diflubenzuron.

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Calculations to Verify Feeding and Mixing Directions

There are basic steps to check the feeding and mixing directions of a medicated feed label. Further assistance in performing the calculations may be provided through the Association of American Feed Control Officials Medicated Feed Calculators, including a unit conversion calculator.

Verification of Example Label #3:

Step 1: Convert all units to milligrams per pound (mg/lb.):

- Monensin: Convert 1,200 grams per ton (gm/ton) to mg/lb. by dividing by 2 lb.

  1,200 gm/ton ÷ 2 lb = 600 mg/lb.

- Selenium: Convert 24 parts per million (ppm) to mg/lb. by dividing 24 ppm by 2.2 lb.

  24 ppm ÷ 2.2 lb = 11 mg/lb.

- Diflubenzuron is already shown as *136 mg/lb.* on the label.

Step 2: Verify feeding rates provide the approved daily dosage per FDA CFR drug approval:

Example: Feeding 0.5 pound to a 1,500-pound cow.

- Monensin at 600 mg/lb. with a 0.5 lb./day feeding rate results in 300 mg/head(hd)/day.

  600 mg/lb. × 0.5 lb. = 300 mg/hd/day

  Check: Yes, this is within the approval of 185-660 mg/hd/day for lactating cows.

- Diflubenzuron at 136 mg/lb. with a 0.5 lb./day feeding rate will provide 68 mg/hd/day.

  136 mg/lb. × 0.5 lb. = 68 mg/hd/day

  Check: CFR approval for Diflubenzuron is 0.10 mg/kg of bodyweight (BW)/day. Convert 1,500-pounds to kilograms by dividing by 2.2, then multiply by approved dosage of 0.1 mg/kg BW:

  1,500 ÷ 2.2 lb = 680 kg × 0.1 mg/kg BW = 68 mg

  Yes, this feeding rate matches the approval for Diflubenzuron.

- Selenium at a 0.5 lb./day feeding rate will provide 5.5 mg/hd/day

  11 mg/lb. x 0.5 lbs. = 5.5 mg/hd/day

  Check: 1,500 lb. cow will consume about 3% of bodyweight (45 lbs.).

  5.5 mg ÷ 45 lbs. = 0.12 mg/lb.

  0.12 mg/ lb selenium x 2.2 lb = 0.268 ppm

  Yes, this feeding rate does not exceed 0.3 ppm in total ration.

The intake levels described in feeding directions in **Example Label # 3** are consistent with the approval levels for selenium, monensin, and diflubenzuron.

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Veterinary Feed Directive Labels

While many medicated feeds are available for sale “over-the counter”, or without the approval of a veterinarian, certain medicated feeds require a veterinary feed directive (VFD) for lawful administration. In addition to all previously mentioned medicated feed label requirements, feeds medicated with a VFD drug also require the caution statement “Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian” (**See Example Label # 4**). Additional information regarding the proper sale and use of VFD medicated feeds can be found on the SAFE Medicated Feeds and VFD webpage.

Example Label # 4: Veterinary feed directive feed label

MASTER LINC SWINE FEED

FOR PIGS WEIGHING 45LBS TO MARKET

TYPE B MEDICATED FEED

CAUTION: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.

For the treatment and control of swine dysentery and the control of porcine proliferative enteropathies (ileitis) caused by Lawsonia intracellularis. For the reduction in the severity of the effects of respiratory disease associated with Mycoplasma hypopneumoniae.

ACTIVE DRUG INGREDIENTS

Lincomycin..... 4,000 g/ton (2 grams/lb.)

Guaranteed Analysis

Crude Protein ,(Min).....	16.0	%
Crude Fat, (Min).....	4.0	%
Crude Fiber, (Max).....	2.7	%
Calcium, (Min).....	0.6	%
Calcium, (Max).....	1.0	%
Phosphorus-Total, (Min).....	0.6	%
Sodium, (Max).....	0.4	%

Ingredients: Corn, Soybean Meal, Wheat Millrun, Dried Whey, Monocalcium Phosphate, Calcium Carbonate, Soybean Oil, Salt, Brewers Liquid Yeast

IMPORTANT: See mixing instructions. Must be thoroughly mixed in feeds before use. Do not feed undiluted. Store bulk feed or open bag in a dry place to prevent caking. Store at room temperature

WARNING: A zero day withdrawal time is required. Do not allow rabbits, hamsters. guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects.

MIXING INSTRUCTIONS: Mix MASTER LINC Type B Medicated Feed with base feed as directed below to achieve desired grams per ton of MASTER LINC Type C medicated feed in accordance with VFD. Feed for three weeks or until signs of disease (watery, mucoid, or bloody stools) disappear.

MASTER LINC..... 2oz BASE FEED.....5.0 lbs Grams/Ton.....100g/ton

MASTER LINC.....4oz BASE FEED.....5.0 lbs Grams/Ton.....200g/ton

310638
Manufactured by
ABC MILLING, LLC
1234 West Main St. Somewhere, CA
54321

NET WEIGHT: 5.25 lbs (2.38 kg) bag

MEDICATED