

(i) *Indications for use.* For suppression of estrus (heat).

(ii) *Limitation.* Heifers intended for breeding. Do not exceed 24 days of feeding. Administer 0.5 to 2.0 pounds per head per day of Type C feed containing 0.25 to 1.0 milligram of melengestrol acetate per pound to provide 0.5 milligram of melengestrol acetate per head per day. Melengestrol acetate as provided by No. 000009 in § 510.600(c) of this chapter.

[42 FR 28535, June 3, 1977, as amended at 46 FR 18967, Mar. 27, 1981; 49 FR 39842, Oct. 11, 1984; 50 FR 1843, Jan. 14, 1985; 50 FR 16228, Apr. 25, 1985; 51 FR 7398, Mar. 3, 1986; 51 FR 36222, Oct. 9, 1986; 52 FR 2685, Jan. 26, 1987; 52 FR 33804, Sept. 8, 1987; 53 FR 27959, July 26, 1988; 55 FR 31828, Aug. 6, 1990; 57 FR 5053, Feb. 12, 1992; 59 FR 41241, Aug. 11, 1994; 60 FR 11028, Mar. 1, 1995; 62 FR 8373, Feb. 25, 1997; 62 FR 14304, Mar. 26, 1997]

§ 558.348 Mibolerone.

(a) *Approvals.* To No. 000009 in § 510.600(c) of this chapter for a canned dog food, each 6½ ounce can containing 30 or 60 micrograms of mibolerone.

(b) *Conditions of use*—(1) *Amount.* 30 micrograms for animals weighing up to 25 pounds; 60 micrograms for animals weighing 26 to 50 pounds; 120 micrograms for animals weighing 51 to 100 pounds; 180 micrograms for animals weighing over 100 pounds, or German Shepherds or German Shepherd mix weighing 30 to 80 pounds.

(2) *Indications for use.* For the prevention of estrus (heat) in adult female dogs not intended primarily for breeding purposes.

(3) *Limitations.* Administer daily at least 30 days before expected initiation of heat and continue as long as desired, but for not more than 12 months. Mibolerone should not be used in bitches before first estrous period or in purebred Bedlington terriers. It is not intended for animals being used primarily for breeding purposes. Use orally in adult female dogs only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 6617, Feb. 16, 1982]

§ 558.355 Monensin.

(a) *Specifications.* Monensin, as the base or the sodium salt, contains a minimum of 90 percent monensin activ-

ity derived from monensin A and a minimum of 95 percent derived from monensin A plus B. Using thin layer chromatography, the R_f value must be comparable to a reference standard (the R_f value is the distance the spots travel from the starting line divided by the distance the solvent front travels from the starting line). The loss on drying is not more than 10 percent when dried in vacuum at 60 °C for 2 hours.

(b) *Approvals.* Approvals for Type A medicated articles containing the specified levels of monensin activity granted to firms identified by sponsor numbers in § 510.600(c) of this chapter for the conditions of use indicated in paragraph (f) of this section are as follows:

(1) To 000986: 36.3 (for export only), 44, 45, or 60 grams per pound, paragraphs (f) (1)(i) and (4) of this section.

(2) To 000986: 110 grams per lb., paragraphs (f)(1) (i), (iii), (iv), (v), (ix), and (x).

(3) To 000986: 44 grams per lb. with 18 grams per lb. of roxarsone, 110 grams per lb. with 45 grams per lb. of roxarsone, paragraph (f)(1)(ii).

(4) To 000986: 45 and 60 grams per pound, as monensin sodium, paragraph (f)(2) of this section.

(5) To 000069: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraphs (f)(1)(xiii), (xx), and (xxi) of this section.

(6) To 000986: 45 and 60 grams per pound, as monensin sodium, paragraph (f)(5) of this section.

(7) To 000986: 20, 30, 45, 60, 80, and 90.7 grams per pound, as monensin sodium, paragraph (f)(3) of this section.

(8) To 000004: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraph (f)(1)(xiv) of this section.

(9) To 000004: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraphs (f)(1)(xv) and (xvi) of this section.

(10) To 012799: 45 and 60 grams per pound, as monensin sodium, paragraph (f)(1)(xvii) of this section.

(11) To 046573: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraphs (f)(1)(xviii), (xix), (xxiii), (xxiv), and (xxv) of this section.

(12) To 000069: 45 and 60 grams per pound, as monensin sodium provided by No. 000986, paragraph (f)(1)(xxii) of this section.

(13) To 021930: 60 and 80 grams per pound, paragraph (f)(3)(v) of this section.

(14) To 000986: 60, 80, and 90.7 grams per pound, as monensin sodium, paragraph (f)(6) of this section.

(c) [Reserved]

(d) *Special considerations.* (1) Type C chicken feed containing monensin as the mycelial cake shall bear an expiration date of 90 days after its date of manufacture.

(2) Type C cattle feeds containing 30 grams or less monensin sodium per ton shall bear an expiration date of 30 days after its date of manufacture.

(3) Type C goat feeds shall bear an expiration date of 30 days after date of manufacture.

(4) [Reserved]

(5) Liquid Type B feeds shall bear an expiration date of 8 weeks after its date of manufacture.

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

(7) The labeling of all Type A articles and Type B feeds (liquid and dry) containing monensin intended for use in cattle shall bear, in addition to the caution statement in paragraph (d)(6) of this section, the following caution statements:

(i) Monensin medicated cattle feed is safe for use in cattle only. Consumption by unapproved species may result in toxic reactions;

(ii) Feeding undiluted or mixing errors resulting in high concentrations of monensin could be fatal to cattle;

(iii) Must be thoroughly mixed in feeds before use;

(iv) Do not feed undiluted;

(v) Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result.

(vi) Do not feed to lactating dairy cows.

(8) The labeling of complete feeds containing monensin intended for use

in cattle shall bear the caution statements specified in paragraphs (d) (6) and (7) (i) and (v) of this section.

(9) The labeling of Type A articles containing monensin intended for use in chickens shall bear the caution statements specified in paragraphs (d) (6) and (7) (iii) and (iv) of this section.

(10) The labeling of all Type A articles and Type B feeds (liquid and dry) containing monensin intended for use in goats shall bear, in addition to the caution statement in paragraph (d)(6) of this section, the following caution statements:

(i) Monensin medicated goat feed is safe for use in goats only. Consumption by unapproved species may result in toxic reactions.

(ii) Feeding undiluted or mixing errors resulting in high concentrations of monensin could be fatal to goats.

(iii) Must be thoroughly mixed in feeds before use.

(iv) Do not feed undiluted.

(v) Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result.

(11) The labeling of complete feeds containing monensin intended for use in goats shall bear the caution statements specified in paragraphs (d)(6) and (d)(10) (i) and (v) of this section.

(e) *Related tolerances.* See §556.420 of this chapter.

(f) *Conditions of use.* It is used as follows:

(1) *Broiler chickens—(i) Amount per ton.* Monensin, 90–110 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as monensin or monensin sodium.

(ii) *Amount per ton.* Monensin, 90–110 grams, plus roxarsone 45.4 grams (0.005 percent).

(a) *Indications for use.* Growth promotion and feed efficiency, improving pigmentation; as an aid in the prevention of coccidiosis caused by *E.*

necatrix, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati* and *E. maxima*.

(b) *Limitations*. Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin or monensin sodium.

(iii) *Amount per ton*. Monensin, 90–110 grams plus bacitracin, 5–25 grams.

(a) *Indications for use*. For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations*. Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as bacitracin methylene disalicylate provided by No. 046573 in §510.600(c) of this chapter; as monensin sodium.

(iv) *Amount per ton*. Monensin, 90–110 grams plus bacitracin, 10 grams.

(a) *Indications for use*. For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations*. Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as zinc bacitracin provided by No. 000004 in §510.600(c) of this chapter; as monensin sodium.

(v) *Amount per ton*. Monensin, 90–110 grams plus bacitracin, 10–30 grams.

(a) *Indications for use*. For improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations*. Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as zinc bacitracin provided by No. 000004 in §510.600(c) of this chapter; as monensin sodium.

(vi) *Amount per ton*. Monensin, 90 to 110 grams plus bambermycins, 1 to 2 grams. See §558.95(b)(1)(vi).

(vii) *Amount per ton*. Monensin, 90 to 110 grams plus bambermycins, 1 gram plus roxarsone, 22.7 to 45.4 grams (.0025 to .005 percent). See §558.95(b)(1)(vii).

(viii) *Amount per ton*. Monensin, 90 to 110 grams plus oxytetracycline, 200 grams.

(a) *Indications for use*. As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for the control of complicated chronic respiratory disease (CRD or air-sac infection) caused by *Mycoplasma gallisepticum* and *Escherichia coli*.

(b) *Limitations*. In the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; do not feed to laying chickens; feed continuously as sole ration; as monensin sodium.

(ix) *Amount per ton*. Monensin, 90–110 grams plus lincomycin, 2 grams.

(a) *Indications for use*. For increase in rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations*. Do not feed to laying chickens; to be fed as a sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as monensin sodium.

(x) *Amount per ton*. Monensin, 90–110 grams plus lincomycin, 2 grams and roxarsone, 15–45 grams.

(a) *Indications for use*. For increase in rate of weight gain; as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations*. Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as roxarsone provided by No. 046573, §510.600(c) of this chapter; as monensin sodium provided by No. 000986, §510.600(c) of this chapter; as lincomycin provided by No. 000009,

§ 510.600(c) of this chapter; as a combination provided by No. 000009, § 510.600(c) of this chapter.

(xi) *Amount per ton.* Monensin, 90 to 110 grams, plus lincomycin, 2 grams and roxarsone, 15 to 30 grams.

(a) *Indications for use.* For increase in rate of weight gain, improved feed efficiency, improved pigmentation, and as an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati* and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as lincomycin provided by No. 000009 in § 510.600(c) of this chapter; as a combination provided by No. 000009 in § 510.600(c) of this chapter.

(xii) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 10 to 25 grams, and roxarsone, 11.3 to 45.4 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. maxima*, and *E. mivati*; for increased rate of weight gain and for improved feed efficiency.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in § 510.600 of this chapter; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600 of this chapter; as roxarsone provided by No. 011526 or 046573 in § 510.600 of this chapter.

(xiii) *Amount per ton.* Monensin, 90 to 110 grams, plus 5 grams virginiamycin.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. maxima*, and *E. mivati*; for increased rate of weight gain and improved feed efficiency.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; as monensin sodium provided by No. 000986 in § 510.600 of this chapter;

virginiamycin provided by No. 000007 in § 510.600 of this chapter.

(xiv) *Amount per ton.* Monensin, 90 to 110 grams, plus 500 grams chlortetracycline.

(a) *Indications for use.* As an aid in the reduction of mortality due to *Escherichia coli* infections susceptible to such treatment. As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed for 5 days as the sole ration; withdraw 24 hours before slaughter; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; not to be fed continuously for more than 5 days; as monensin sodium; as chlortetracycline hydrochloride provided by No. 000004 in § 510.600(c) of this chapter.

(xv) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin zinc, 10 grams, and roxarsone, 15 grams (0.0017 percent).

(a) *Indications for use.* For increase in rate of weight gain; for the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; feed must be used within 4 weeks of manufacture; as monensin sodium; as bacitracin zinc provided by Nos. 000004 and 046573 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xvi) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin zinc, 4 to 50 grams, and roxarsone, 15 to 45.4 grams (0.0017 percent to 0.005 percent).

(a) *Indications for use.* For improved feed efficiency; for improved pigmentation by enhancing carotenoid and xanthophyll utilization; for the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; feed must be used within 4 weeks of manufacture; as monensin sodium; as

bacitracin zinc provided by Nos. 000004 and 046573 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xvii) *Amount per ton.* Monensin, 90 to 110 grams plus bambarmycins, 1 to 2 grams plus roxarsone, 22.7 to 45.4 grams (0.0025 to 0.005 percent). See § 558.95(b)(1)(xiii) of this chapter.

(xviii) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 50 grams, and roxarsone, 22.7 to 34.0 grams (0.0025 percent to .00375 percent).

(a) *Indications for use.* For increase in rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium spp* or other organisms susceptible to bacitracin methylene disalicylate.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xix) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 50 grams, and roxarsone, 22.7 to 45.4 grams (0.0025 percent to .005 percent).

(a) *Indications for use.* For increased rate of weight gain; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium spp* or other organisms susceptible to bacitracin methylene disalicylate; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this

chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xx) *Amount per ton.* Monensin, 90 to 110 grams, plus virginiamycin, 5 to 15 grams, and roxarsone, 22.7 grams (0.0025 percent).

(a) *Indications for use.* For increase in rate of weight gain; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium; as roxarsone provided by Nos. 046753 and 011526 in § 510.600(c) of this chapter.

(xxi) *Amount per ton.* Monensin, 90 to 110 grams, plus virginiamycin, 5 to 15 grams.

(a) *Indications for use.* For increase in rate of weight gain; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; as monensin sodium provided by No. 000986 in § 510.600 of this chapter; virginiamycin provided by No. 000007 in § 510.600 of this chapter.

(xxii) *Amount per ton.* Monensin, 90 to 110 grams plus oxytetracycline, 500 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. Mivati*, and *E. maxima*; as an aid in the reduction of mortality due to air-sacculitis (air-sac infection) caused by *Escherichia coli* sensitive to oxytetracycline.

(b) *Limitations.* Feed for 5 days as sole ration. Do not feed to laying chickens. Withdraw 24 hours before slaughter. As monensin sodium provided by No. 000986 in § 510.600(c) of this chapter. As mono-alkyl (C₈-C₁₈) trimethylammonium oxytetracycline provided by No. 000069 in § 510.600(c) of this chapter.

(xxiii) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin zinc, 4 to 50 grams, and roxarsone, 22.7 to 45.4 grams (0.0025 percent to 0.005 percent).

(a) *Indications for use.* For improved feed efficiency; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic; as monensin sodium provided by No. 000986 in § 510.600(c) of this chapter; as bacitracin zinc provided by No. 046573 in § 510.600(c) of this chapter; as roxarsone provided by No. 046573 in § 510.600(c) of this chapter.

(xxiv) *Amount per ton.* Monensin, 90 to 110 grams, plus bacitracin methylene disalicylate, 4 to 50 grams.

(xxv) *Amount per ton.* Monensin, 90 to 110 grams plus bacitracin, 4 to 50 grams.

(a) *Indications for use.* For increased rate of weight gain and improved feed efficiency; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(b) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as bacitracin zinc provided by No. 046573 in § 510.600(c) of this chapter, as monensin sodium.

(2) *Turkeys—(i) Amount per ton.* Monensin, 54 to 90 grams.

(a) *Indications for use.* For the prevention of coccidiosis in turkeys caused by *E. adenoides*, *E. meleagritidis*, and *E. gallopavonis*.

(b) *Limitations.* For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis.

(ii) *Amount per ton.* Monensin, 54 to 90 grams, and bacitracin methylene disalicylate, 4 to 50 grams.

(a) *Indications for use.* For prevention of coccidiosis caused by *Eimeria*

adenoides, *E. meleagritidis*, and *E. gallopavonis*, for increased rate of weight gain, and for improved feed efficiency.

(b) *Limitations.* For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.

(3) *Cattle—(i) Amount per ton.* Monensin, 5-30 grams.

(a) *Indications for use.* Improved feed efficiency.

(b) *Limitations.* (1) Feed only to cattle being fed in confinement for slaughter. Feed continuously in complete feed at a rate of 50 to 360 milligrams of monensin per head per day; as monensin sodium. Complete feeds may be manufactured from monensin liquid Type B feeds. The liquid Type B feeds have a pH of 4.3 to 7.1 and their labels must bear appropriate mixing directions. Mixing directions for liquid Type B feeds stored in recirculating tank systems are: Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily, as directed in this paragraph, even when Type B feed is not used. Mixing directions for liquid Type B feeds stored in mechanical, air, or other agitation-type tank systems are: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily, as directed in this paragraph, even when Type B feed is not used. The liquid Type B feed must bear directions to mix thoroughly with grain and/or roughage prior to feeding and must bear caution statements as follows: Inadequate mixing, (recirculation or agitation), of liquid Type B feeds has resulted in increased monensin concentration which has been fatal to cattle.

(2) An approved positionally stable monensin liquid Type B feed will not be subject to the requirements for mixing directions and cautionary labeling prescribed in paragraph (f)(3)(i)(b)(1) of this section. A manufacturer may secure approval of a positionally stable liquid Type B feed by (i) either filing an NADA for the product or by establishing a master file containing data to support the stability of its product; (ii) authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental NADA to establish positional stability; and (iii) requesting No. 000986 in § 510.600(c) of this chapter to file a supplemental NADA to provide for the use of its monensin Type A article in the manufacture of the liquid Type B feed specified in the appropriate master file. If the data demonstrate the stability of the liquid Type B feed described in the master file, the agency will approve the supplemental NADA. Approval of the Type B feed need not be published in the FEDERAL REGISTER because approval will not affect or alter the content of the regulation. The approval will, however, provide a basis for the individual liquid feed manufacturer to submit, and for the agency to approve, a medicated feed application under section 512(m) of the act for the liquid Type B feed. A manufacturer who seeks to market a positionally unstable monensin liquid Type B feed with mixing directions different from the standard established in paragraph (f)(3)(i)(b)(1) of this section may also follow this procedure.

(ii) *Amount per ton.* Monensin, 5 to 30 grams, plus tylosin, 8 to 10 grams.

(a) *Indications for use.* Improved feed efficiency; for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*.

(b) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously as sole ration at the rate of 50 to 360 milligrams of monensin and 90 milligrams of tylosin per head per day; as monensin sodium; as tylosin phosphate.

(iii) *Amount per ton.* Monensin, 25 to 400 grams.

(a) *Indications for use.* Increased rate of weight gain.

(b) *Limitations.* Feed to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). Feed at the rate of not less than 50 nor more than 200 milligrams per head per day in not less than 1 pound of feed or, after the fifth day feed at the rate of 400 milligrams per head per day every other day in not less than 2 pounds of feed, as monensin sodium. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day.

(iv) *Amount per ton.* Monensin, 5 to 30 grams per ton (to provide 50 to 360 milligrams per head per day), plus melengestrol acetate, 0.25 to 1.6 grams per ton (to provide 0.25 to 0.40 milligram per head per day). See § 558.342(c)(2).

(a) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).

(b) *Limitations.* Heifers being fed in confinement for slaughter: Administer melengestrol acetate and monensin by: (1) Adding melengestrol acetate from a separate Type B feed containing 0.125 to 0.8 milligram per pound to Type C medicated feeds containing monensin at 5 to 30 grams per ton, (2) adding melengestrol acetate from a separate Type B feed containing 0.125 to 0.8 milligram per pound and monensin from a separate Type B feed containing 50 to 1,200 grams per ton to Type C medicated feeds, (3) adding melengestrol acetate and monensin which are contained in the same dry Type B feed at the ranges in paragraph (f)(3)(iv)(b) (1) and (2) of this section to Type C medicated feeds, or (4) using a liquid Type B feed containing 0.125 to 0.8 milligram melengestrol acetate per pound and 25 to 600 milligrams monensin per pound (50 to 1,200 grams per ton) to make Type C medicated feeds. Type C medicated feeds in paragraph (f)(3)(iv)(b) (1) and (2) of this section may be manufactured from monensin liquid Type B feeds in accordance with paragraph (f)(3)(i)(b) of this section.

(v) *Amount.* 150 milligrams per pound (0.033 percent).

(a) *Indications for use.* Increased rate of weight gain.

(b) *Limitations.* As protein-mineral blocks to be fed free choice to cattle (slaughter, stocker, feeder, and dairy

and beef replacement heifers) on pasture which may require supplemental feed. Provide 50 to 200 milligrams of monensin (0.34 to 1.33 pounds) per head per day, at least 1 block per 10 to 12 head of cattle. Roughage must be available at all times. Do not allow animals access to other protein blocks, salt or mineral, while being fed this product. Do not allow horses or other equines access to formulations containing monensin (ingestion of monensin by equines has been fatal). Block's effectiveness in cull cows and bulls has not been established. Approval must comply with §510.455 of this chapter.

(vi) *Amount per ton.* Monensin, 25 to 400 grams.

(a) *Indications for use.* Improved feeding efficiency for mature reproducing beef cows receiving supplemental feed.

(b) *Limitations.* Thoroughly mix the appropriate amount of Type A medicated article or Type B medicated feed with grain and roughage to provide a supplemental feed having a final concentration of 25 to 400 grams of monensin per ton. The final concentration should be contained in a minimum of 1 pound of feed. Either hand-feed or mix into the total ration. Feed continuously at a rate of not less than 50 nor more than 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per head per day.

(vii) *Amount per ton.* Monensin, 10 to 30 grams.

(a) *Indications for use.* For the prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.

(b) *Limitations.* Feed continuously to feedlot cattle during periods of exposure to coccidia or when coccidiosis is likely to be a hazard. Feed at the rate of not less than 100 nor more than 360 milligrams of monensin per head per day depending on the body weight of the cattle.

(viii) *Additional combinations.* Monensin may be used for heifers being fed in confinement for slaughter with melengestrol acetate with or without tylosin as in §558.342.

(ix) *Amount.* To 000986: To make liquid Type B medicated feed containing

400 grams per ton monensin sodium with 150 grams per ton tylosin phosphate used to make a dry Type C medicated feed containing 21.4 to 26.8 grams per ton monensin plus 8 to 10 grams per ton tylosin.

(a) *Indications for use.* Improved feed efficiency; for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes*.

(b) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously at the rate of 8.2 to 10.2 kilograms (18 to 22.5 pounds) of Type C medicated feed per head per day to supply 240 milligrams of monensin and 90 milligrams of tylosin per head per day; as monensin sodium; as tylosin phosphate. Do not allow horses or other equines access to feeds containing monensin. Ingestion of monensin by equines has been fatal. Safe use in unapproved species and breeding cattle has not been established. The liquid Type B medicated feed must bear an expiration date of 14 days after date of manufacture. The mixing directions for this liquid Type B medicated feed stored in recirculation or agitation tank systems are: Recirculate or agitate immediately prior to use for not less than 10 minutes, moving at least 1 percent of the tanks contents per minute from the bottom of the tank to the top. Recirculate or agitate as directed daily, even when the Type B medicated feed is not used. Inadequate mixing (recirculation or agitation) of liquid Type B medicated feeds may result in increased monensin concentrations which have been fatal to cattle. Both an approved NADA and an approved medicated feed application are required to make this liquid Type B medicated feed.

(x) *Amount per ton.* Monensin, 1,620 grams as monensin sodium (810 milligrams per pound).

(a) *Indications for use.* For increased rate of weight gain.

(b) *Specifications.* Use as free-choice Type C medicated feed formulated as mineral granules as follows:

Ingredient	Percent	International feed no.
Monocalcium phosphate (21% phosphorus, 15% calcium)	29.49	6-01-082

Ingredient	Percent	International feed no.
Sodium chloride (salt)	24.25	6-04-152
Dried cane molasses	20.0	4-04-695
Ground limestone (33% calcium) or calcium carbonate (38% calcium)	13.75	6-02-632
Cane molasses	3.0	4-04-696
Processed grain by-products (as approved by AAFCO)	5.0	
Vitamin/trace mineral premix ¹	2.5	
Monensin Type A article, 80 grams per pound	1.01	
Antidusting oil	1.0	

¹Content of the vitamin/trace mineral premix may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. The amount of selenium and ethylenediamine dihydroiodide (EDDI) must comply with the published requirements. (For selenium see 21 CFR 573.920; for EDDI see 51 FR 11483 (April 3, 1986).)

(c) *Limitations.* Medicated mineral granules to be fed free-choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers). Feed continuously on a free-choice basis at the rate of 50 to 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or water deprived cattle should be adapted to the pasture and to unmedicated mineral supplement before using this product. Do not feed to lactating dairy cattle. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. The product's effectiveness in cull cows and bulls has not been established. Each use of this free-choice Type C feed must be the subject of an approved medicated feed application (MFA or Form FDA 1900) or supplemental MFA as required by §510.455 of this chapter.

(4) *Replacement chickens intended for use as cage layers—(i) Amount per ton.* Monensin, 90 to 110 grams.

(ii) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(iii) *Limitations.* Do not feed to laying chickens; feed continuously as sole ration; as monensin sodium; do not feed to chickens over 16 weeks of age.

(5) *Bobwhite quail—(i) Amount per ton.* Monensin, 73 grams.

(ii) *Indications for use.* For the prevention of coccidiosis in growing bob-

white quail caused by *Eimeria dispersa* and *E. Lettyae*.

(iii) *Limitations.* Feed continuously as the sole ration; do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin.

(6) *Goats—(i) Amount per ton.* Monensin, 20 grams.

(a) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria crandallis*, *E. christensenii*, and *E. ninakohlyakimovae*.

(b) *Limitations. (1) Feed only to goats being fed in confinement. Do not feed to lactating goats. Feed continuously in Type C feed as monensin sodium. Type C feeds may be manufactured from monensin liquid Type B feeds. The liquid Type B feeds have a pH of 4.3 to 7.1 and their labels must bear appropriate mixing directions. Mixing directions for liquid Type B feeds stored in recirculating tank systems are: Recirculate immediately prior to use for no less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily, as directed in this paragraph, even when Type B feed is not used. Mixing directions for liquid Type B feeds stored in mechanical, air, or other agitation-type tank systems are: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily, as directed in this paragraph, even when Type B feed is not used. The liquid Type B feed must bear directions to mix thoroughly with grain and/or roughage prior to feeding and must*

bear caution statement as follows: Inadequate mixing (recirculation or agitation), of liquid Type B feeds has resulted in increased monensin concentration which could be fatal to goats.

(2) An approved positionally stable monensin liquid Type B feed will not be subject to the requirements for mixing directions and cautionary labeling prescribed in paragraph (f)(6)(i)(b)(I) of this section. A manufacturer may secure approval of a positionally stable liquid Type B feed by (i) either filing an NADA for the product or by establishing a master file containing data to support the stability of its product; (ii) authorizing the agency to reference and rely upon the data in the master file to support approval of a supplemental NADA to establish positional stability; and (iii) requesting No. 000986 in §510.600(c) of this chapter to file a supplemental NADA to provide for the use of its monensin Type A article in the manufacture of the liquid Type B feed specified in the appropriate master file. If the data demonstrate the stability of the liquid Type B feed described in the master file, the agency will approve the supplemental NADA. Approval of the Type B feed need not be published in the FEDERAL REGISTER because approval will not affect or alter the content of the regulation. The approval will, however, provide a basis for the individual liquid feed manufacturer to submit, and for the agency to approve, a medicated feed application under section 512(m) of the act for the liquid Type B feed. A manufacturer who seeks to market a positionally unstable monensin liquid Type B feed with mixing directions different from the standard established in paragraph (f)(6)(i)(b)(I) of this section may also follow this procedure.

(ii) [Reserved]

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.355, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 558.360 Morantel tartrate.

(a) *Approvals.* Type A medicated articles: 88 grams per pound to 000069 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.425 of this chapter.

(c) *Special considerations.* (1) Do not use in Type B or Type C medicated feeds containing bentonite.

(2) Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(d) *Conditions of use*—(1) *Amount.* 0.44 to 4.4 grams of morantel tartrate per pound of feed.

(2) *Indications for use*—(i) *Cattle.* For removal and control of mature gastrointestinal nematode infections of cattle including stomach worms (*Haemonchus* spp., *Ostertagia* spp., *Trichostrongylus* spp.), worms of the small intestine (*Cooperia* spp., *Trichostrongylus* spp., *Nematodirus* spp.), and worms of the large intestine (*Oesophagostomum radiatum*).

(ii) *Goats.* For removal and control of mature gastrointestinal nematode infections of goats including *Haemonchus contortus*, *Ostertagia (Teladorsagia) circumcincta*, and *Trichostrongylus axei*.

(3) *Limitations.* Feed as a single therapeutic treatment at 0.44 gram of morantel tartrate per 100 pounds of body weight. Fresh water should be available at all times. When medicated feed is consumed, resume normal feeding. Conditions of constant worm exposure may require retreatment in 2 to 4 weeks. Do not treat cattle within 14 days of slaughter; do not treat goats within 30 days of slaughter.

[46 FR 50950, Oct. 16, 1981, as amended at 47 FR 53352, Nov. 26, 1982; 51 FR 7399, Mar. 3, 1986; 51 FR 9005, Mar. 17, 1986; 52 FR 11642, Apr. 10, 1987; 59 FR 17922, Apr. 15, 1994]

§ 558.363 Narasin.

(a) *Approvals.* Type A medicated articles containing specified levels of narasin approved for sponsors identified in § 510.600(c) of this chapter for use as in paragraph (d) of this section are as follows:

(1) To 000986: 36, 45, 54, 72, and 90 grams per pound, paragraph (d)(1)(i) of this section.

(2) To 000986: 36, 45, 54, 72, and 90 grams per pound, with 10, 20, 50, and 80 percent roxarsone, paragraph (d)(1)(ii) of this section.