

Food and Drug Administration, HHS

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need not include efficacy data as required by §514.111 of this chapter but may require bioequivalency or safety data.

(c) *Conditions of use*—(1) *Ducks*—(i) *Amount per ton*. 100 to 200 grams.

(ii) *Indications for use*. For increased rate of weight gain and improved feathering in growing ducks.

(2) *Dairy cows*—(i) *Amount per pound*. ½ to 1½ grams per 100 lb of body weight.

(ii) *Indications for use*. For increased milk production in dairy cows.

(iii) *Limitations*. This drug is effective for limited periods of time, and the effectiveness is limited to the declining phase of lactation. Administration

must be accompanied with increased feed intake; administration may increase heat sensitivity of the animal.

[45 FR 41631, June 20, 1980]

§ 558.300 Ivermectin.

(a) *Specifications*. Type A medicated article containing 2.72 grams ivermectin per pound (g/lb).

(b) *Sponsor*. See No. 050604 in §510.600(c) of this chapter.

(c) *Related tolerances*. See §556.344 of this chapter.

(d) *Special considerations*. See §500.25 of this chapter.

(e) *Conditions of use in swine*. It is used in feed as follows:

Ivermectin in g/ton of feed	Combination in g/ton of feed	Indications for use	Limitations	Sponsor
(1) 1.8 (to provide 0.1 milligram per kilogram (mg/kg) of body weight per day)		Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms (<i>Ascaris suum</i> , adults and fourth-stage larvae; <i>Ascarops strongylina</i> , adults; <i>Hyostrogylus rubidus</i> , adults and fourth-stage larvae; <i>Oesophagostomum</i> spp., adults and fourth-stage larvae); kidneyworms (<i>Stephanurus dentatus</i> , adults and fourth-stage larvae); lungworms (<i>Metastrongylus</i> spp., adults); threadworms (<i>Strongyloides ransomi</i> , adults and somatic larvae); lice (<i>Haematopinus suis</i>); and mange mites (<i>Sarcoptes scabiei</i> var. <i>suis</i>).	Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604
(2) 1.8 (to provide 0.1 mg/kg of body weight per day)	Bacitracin methylene disalicylate, 10 to 30	Weaned, growing-finishing swine: As in paragraph (e)(1) of this section; and for increased rate of weight gain and improved feed efficiency.	For use in swine feed only. Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604
(3) 1.8 (to provide 0.1 mg/kg of body weight per day)	Bacitracin methylene disalicylate, 250	Weaned, growing-finishing swine: As in paragraph (e)(1) of this section; and for control of swine dysentery associated with <i>Treponema hyodysenteriae</i> on premises with a history of swine dysentery, but where symptoms have not yet occurred, or following an approved treatment of disease condition.	For use in swine feed only. Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604

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Ivermectin in g/ton of feed	Combination in g/ton of feed	Indications for use	Limitations	Sponsor
(4) 1.8 (to provide 0.1 mg/kg of body weight per day)	Lincomycin, 20	Weaned, growing-finishing swine: For treatment and control of gastrointestinal roundworms (<i>Ascaris suum</i> , adults and fourth-stage larvae; <i>Hyostrogylus rubidus</i> , adults and fourth-stage larvae; <i>Oesophagostomum</i> spp., adults and fourth-stage larvae); kidneyworms (<i>Stephanurus dentatus</i> , adults and fourth-stage larvae); lungworms (<i>Metastrongylus</i> spp., adults); lice (<i>Haematopinus suis</i>); and mange mites (<i>Sarcoptes scabiei</i> var. <i>suis</i>); and for increased rate of weight gain.	Feed as the only feed for 7 consecutive days. Not to be fed to swine that weigh more than 250 lbs. Withdraw 5 days before slaughter. Also see paragraphs (c)(1) and (c)(2) in § 558.325 of this chapter.	050604
(5) 1.8 (to provide 0.1 mg/kg of body weight per day)	Lincomycin, 40	Weaned, growing-finishing swine: As in paragraph (e)(4) of this section; and for control of swine dysentery on premises with a history of swine dysentery, but where symptoms have not yet occurred.	Feed as the only feed for 7 consecutive days. Not to be fed to swine that weigh more than 250 lbs. Also see paragraphs (c)(1) and (c)(2) in § 558.325 of this chapter. Withdraw 5 days before slaughter. A separate feed containing 40 g/ton lincomycin may be continued to complete the lincomycin treatment.	050604
(6) 1.8 (to provide 0.1 mg/kg of body weight per day)	Lincomycin, 100	Weaned, growing-finishing swine: As in paragraph (e)(4) of this section; and for treatment of swine dysentery.	Feed as the only feed for 7 consecutive days followed by a separate feed containing 100 g/ton lincomycin for an additional 14 days to complete the lincomycin treatment. Withdraw 6 days before slaughter. Not to be fed to swine that weigh more than 250 lbs. Also see paragraphs (c)(1) and (c)(2) in § 558.325 of this chapter.	050604
(7) 1.8 (to provide 0.1 mg/kg of body weight per day)	Lincomycin, 200	Weaned, growing-finishing swine: As in paragraph (e)(4) of this section; and for reduction in severity of swine mycoplasmal pneumonia caused by <i>Mycoplasma hyopneumoniae</i> .	Feed as the only feed for 7 consecutive days followed by a separate feed containing 200 g/ton lincomycin for an additional 14 days to complete the lincomycin treatment. Withdraw 6 days before slaughter. Not to be fed to swine that weigh more than 250 lbs. Also see paragraphs (c)(1) and (c)(2) in § 558.325 of this chapter.	050604

Ivermectin in g/ton of feed	Combination in g/ton of feed	Indications for use	Limitations	Sponsor
(8) 1.8 to 11.8 (to provide 0.1 mg/kg of body weight per day)		Adult and breeding swine: For treatment and control of gastrointestinal roundworms (<i>Ascaris suum</i> , adults and fourth-stage larvae; <i>Hyostrogylus rubidus</i> , adults and fourth-stage larvae; <i>Oesophagostomum</i> spp., adults and fourth-stage larvae); kidneyworms (<i>Stephanurus dentatus</i> , adults and fourth-stage larvae); lungworms (<i>Metastrongylus</i> spp., adults); threadworms (<i>Strongyloides ransomi</i> , adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation); lice (<i>Haematopinus suis</i>); and mange mites (<i>Sarcoptes scabiei</i> var. <i>suis</i>).	Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter.	050604
(9) 1.8 to 11.8 (to provide 0.1 mg/kg of body weight per day)	Bacitracin methylene disalicylate, 250	Pregnant sows: As in paragraph (e)(8) of this section; and for control of clostridial enteritis caused by <i>Clostridium perfringens</i> in suckling piglets.	Feed as the only feed for 7 consecutive days. Withdraw 5 days before slaughter. Feed bacitracin methylene disalicylate Type C medicated feed to sows from 14 days before through 21 days after farrowing on premises with a history of clostridial scours.	050604
(10) 18.2 to 120 (to provide 0.1 mg/kg of body weight per day)		Adult and breeding swine: As in paragraph (e)(8) of this section.	Top dress on daily ration for individual treatment for 7 consecutive days. Withdraw 5 days before slaughter.	050604

[72 FR 37437, July 10, 2007]

§ 558.305 Laidlomycin.

(a) *Specifications.* Type A medicated articles containing 50 grams laidlomycin propionate potassium per pound.

(b) *Approvals.* See No. 046573 in § 510.600(c) of this chapter.

(c) *Tolerances.* See § 556.346 of this chapter.

(d) *Special considerations.* (1) Laidlomycin liquid Type B feeds may be manufactured from dry laidlomycin Type A articles. The liquid Type B feeds must have a pH of 6.0 to 8.0, dry matter of 62 to 75 percent, and bear appropriate mixing directions as follows:

(i) For liquid feeds stored in recirculating tank systems: 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 described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation type tank systems: 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 described even when not used.

(2) The expiration date for the liquid Type B feed is 21 days after date of manufacture. The expiration date for the dry Type C feed made from the liquid Type B feed is 7 days after date of manufacture.

(3) Labeling for all Type B feeds (liquid and dry) and Type C feeds containing laidlomycin shall bear the following statements:

(i) Do not allow horses or other equines access to feeds containing laidlomycin propionate potassium.