

§ 558.485

21 CFR Ch. I (4-1-13 Edition)

D and/or trace minerals may be added. One free-turning lick wheel per 25 head of cattle must be provided.

(4) The medicated liquid Type C feed must be introduced at least 2 to 5 days before legume consumption to accustom the cattle to the medicated liquid Type C feed and to lick wheel feedings. If the medicated liquid wheel Type C feed feeding is interrupted, this 2- to 5-day introductory feeding should be repeated.

[40 FR 13959, Mar. 27, 1975, as amended at 42 FR 21281, Apr. 26, 1977; 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 56 FR 50654, Oct. 8, 1991; 60 FR 55660, Nov. 2, 1995; 66 FR 47963, Sept. 17, 2001]

§ 558.485 Pyrantel.

(a) *Specifications.* Type A medicated articles containing 9.6, 19.2, 48, or 80 grams per pound pyrantel tartrate.

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (e) of this section:

(1) No. 066104: 9.6, 19.2, 48, and 80 grams per pound for use as in paragraph (e)(1) of this section.

(2) [Reserved]

(3) Nos. 016968, and 017790: 9.6 and 19.2 grams per pound for use as in paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(4) [Reserved]

(5) No. 051311: 19.2 and 48 grams per pound for use as in paragraphs (e)(1)(i) through (e)(1)(iii) of this section.

(6) No. 034936: 9.6 and 19.2 grams per pound for use as in paragraphs (e)(1)(i) and (e)(1)(ii) of this section.

(7) Nos. 000069 and 017135: 48 grams per pound for use as in paragraph (e)(2) of this section.

(c) *Related tolerances.* See § 556.560 of this chapter.

(d) *Special considerations.* (1) See § 500.25 of this chapter. Consult a veterinarian before using in severely debilitated animals.

(2) Do not mix in Type B or Type C medicated feeds containing bentonite.

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

(1) *Swine*—(i) *Amount per ton.* 96 grams (0.0106 percent).

(A) *Indications for use.* Aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention

of establishment of nodular worm (*Oesophagostomum*) infections.

(B) *Limitations.* Feed continuously as the sole ration in a Type C feed; withdraw 24 hours prior to slaughter.

(ii) *Amount per ton.* 96 grams (0.0106 percent).

(A) *Indications for use.* For the removal and control of large roundworm (*Ascaris suum*) infections.

(B) *Limitations.* Feed for 3 days as the sole ration in a Type C feed; withdraw 24 hours prior to slaughter.

(iii) *Amount per ton.* 800 grams (0.0881 percent).

(A) *Indications for use.* For the removal and control of large roundworm (*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections.

(B) *Limitations.* As sole ration for a single therapeutic treatment in Type C feed; feed at the rate of 1 lb of feed per 40 lb of body weight for animals up to 200 lb, and 5 lb of feed per head for animals 200 lb or over; withdraw 24 hours prior to slaughter.

(iv) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and carbadox, 50 grams (0.0055 percent).

(A) *Indications for use.* For control of swine dysentery (vibronic dysentery, bloody scours or hemorrhagic dysentery); control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections.

(B) *Limitations.* Do not feed to swine weighing over 75 pounds; do not feed within 10 weeks of slaughter; consult a veterinarian before feeding to severely debilitated animals; feed continuously as sole ration. Do not use in Type C feeds containing less than 15 percent crude protein.

(v) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and tylosin, 40 to 100 grams, as tylosin phosphate.

(A) *Indications for use.* For prevention of swine dysentery (vibronic); aid in the prevention of migration and establishment of large roundworms (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum spp.*) infections.

(B) *Limitations.* Use 100 grams tylosin per ton for at least 3 weeks followed by 40 grams tylosin per ton until market weight; withdraw 24 hours before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(vi) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and tylosin 40 to 100 grams, as tylosin phosphate.

(A) *Indications for use.* Treatment and control of swine dysentery (vibronic); aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.

(B) *Limitations.* Administer tylosin in feed as tylosin phosphate after treatment with tylosin in drinking water as tylosin base; 0.25 grams per gallon in drinking water for 3 to 10 days, 40 to 100 grams tylosin per ton in feed for 2 to 6 weeks; withdraw 24 hours before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(vii) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 40 grams, as lincomycin hydrochloride monohydrate.

(A) *Indications for use.* For control of swine dysentery; aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.

(B) *Limitations.* Feed as sole ration; for use in swine on premises with a history of swine dysentery but where symptoms have not yet occurred; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(viii) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 100 grams, then 40 grams, as

lincomycin hydrochloride monohydrate.

(A) *Indications for use.* For treatment and control of swine dysentery; aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.

(B) *Limitations.* Feed 100 grams per ton for 3 weeks or until signs of disease disappear, followed by 40 grams per ton; feed as sole ration; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(ix) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 100 grams, as lincomycin hydrochloride monohydrate.

(A) *Indications for use.* For treatment of swine dysentery; aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.

(B) *Limitations.* Feed 100 grams per ton 3 weeks or until signs of disease disappear, followed by 40 grams per ton; feed as sole ration; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter. Consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(x) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 100 or 40 grams.

(A) *Indications for use.* For treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) infections.

(B) *Limitations.* Administer in accordance with paragraph (c)(2)(i), (c)(2)(ii), or (c)(2)(iii) of § 558.325 and paragraph (e)(1)(ii)(B) of this section.

(xi) *Amount per ton.* Pyrantel tartrate, 800 grams (0.0881 percent) and lincomycin, 100 or 40 grams.

(A) *Indications for use.* For treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) and nodular

§ 558.500

21 CFR Ch. I (4-1-13 Edition)

worm (*Oesophagostomum* spp.) infections.

(B) *Limitations.* Administer in accordance with paragraph (c)(2)(i), (c)(2)(ii), or (c)(2)(iii) of § 558.325 and paragraph (e)(1)(iii)(B) of this section.

(xii) *Amount per ton.* Pyrantel tartrate, 96 grams (0.0106 percent) and lincomycin, 200 grams as lincomycin hydrochloride monohydrate.

(A) *Indications for use.* For the reduction in severity of swine mycoplasma pneumonia caused by *Mycoplasma hyopneumoniae*; aid in the prevention of migration and establishment of large roundworms (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum* spp.) infections.

(B) *Limitations.* Feed as sole ration for 21 days; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter; consult your veterinarian before feeding to severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

(C) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(2) *Horses*—(i) *Amount.* Feed continuously at the rate of 1.2 milligrams per pound (2.64 milligrams per kilogram) of body weight.

(A) *Indications for use.* Prevention of *Strongylus vulgaris* larval infections; control of adult large strongyles (*S. vulgaris*, and *S. edentatus*), adult and 4th stage larvae small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp., and *Triodontophorus* spp.), adult and 4th stage larvae pinworms (*Oxyuris equi*), and adult and 4th stage larvae ascarids (*Parascaris equorum*).

(B) *Limitations.* Administer either as a top-dress (not to exceed 20,000 grams per ton) or mixed in the horse's daily grain ration (not to exceed 1,200 grams per ton) during the time that the animal is at risk of exposure to internal parasites. Not for use in horses intended for food. Consult your veterinarian before using in severely debilitated animals and for assistance in the

diagnosis, treatment, and control of parasitism.

(ii) [Reserved]

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.485, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 558.500 Ractopamine.

(a) *Specifications.* Type A medicated articles containing 9 or 45 grams of ractopamine hydrochloride per pound.

(b) *Approvals.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.570 of this chapter.

(d) *Special considerations.* (1) Labeling of Type B and Type C feeds shall bear the following: "Not for animals intended for breeding."

(2) Labeling of Type B and Type C swine feeds shall bear the following:

(i) "No increased benefit has been shown when ractopamine concentrations in the diet are greater than 4.5 g/ton."

(ii) "Ractopamine may increase the number of injured and/or fatigued pigs during marketing."

(3) Labeling of Type B and Type C tom turkey feeds shall bear the following: "No increased benefit has been shown when ractopamine concentrations in the diet are greater than 4.6 g/ton."

(4) Tylosin in combinations as tylosin phosphate.

(5) Ractopamine liquid Type B cattle feeds may be manufactured from dry ractopamine Type A articles. The liquid Type B feeds must be maintained at a pH of 4.5 to 7.5 or, if in combination with monensin and/or tylosin, at a pH of 4.5 to 6.0. Mixing directions for liquid Type B feeds requiring recirculation or agitation: Recirculate immediately prior to use for not 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.

(e) *Conditions of use*—(1) *Swine*—