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21 CFR Ch. I (4–1–03 Edition)

handling methods to reduce the incidence of downer pigs should be thoroughly evaluated prior to initiating use of PAYLEAN.”

(ii) “Not for use in breeding swine.”
 (2) Tylosin in combinations as tylosin phosphate.
 (e) *Conditions of use.* (1) *Swine*—

| Ractopamine in grams/ton | Combination in grams/ton | Indications for use | Limitations | Sponsor |
|--------------------------|--------------------------|---|---|------------------|
| (i) 4.5 | | For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine fed a complete ration containing at least 16 percent crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight. | Feed continuously as sole ration. | 000986 |
| (ii) 4.5 | Tylosin 40 | Finishing swine: As in paragraph (e)(1)(i) of this section; and for prevention of swine dysentery (vibronic). | Feed continuously as sole ration until market weight following the use of tylosin at 100 grams per ton (g/t) for at least 3 weeks. | 000986 |
| (iii) 4.5 | Tylosin 100 | 1. Finishing swine: As in paragraph (e)(1)(i) of this section; and for prevention and/or control of porcine proliferative enteropathies (ileitis) associated with <i>Lawsonia intracellularis</i> . 2. Finishing swine: As in paragraph (e)(1)(i) of this section; and for prevention of swine dysentery (vibronic). | Feed continuously as sole ration for 21 days. Feed continuously as sole ration for at least 3 weeks followed by tylosin at 40 g/t until market weight. | 000986 000986 |
| (iv) 4.5 to 18 | | For improved feed efficiency and increased carcass leanness in finishing swine fed a complete ration containing at least 16 percent crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight. | Feed continuously as sole ration. | 000986 |
| (v) 4.5 to 18 | Tylosin 40 | Finishing swine: As in paragraph (e)(1)(iv) of this section; and for prevention of swine dysentery (vibronic). | Feed continuously as sole ration until market weight following the use of tylosin at 100 g/t for at least 3 weeks. | 000986 |
| (vi) 4.5 to 18 | Tylosin 100 | 1. Finishing swine: As in paragraph (e)(1)(iv) of this section; and for prevention and/or control of porcine proliferative enteropathies (ileitis) associated with <i>Lawsonia intracellularis</i> . 2. Finishing swine: As in paragraph (e)(1)(iv) of this section; and for prevention of swine dysentery (vibronic). | Feed continuously as sole ration for 21 days. Feed continuously as sole ration for at least 3 weeks followed by tylosin at 40 g/t until market weight. | 000986 000986 |

(2) [Reserved]

[67 FR 71820, Dec. 3, 2002]

§ 558.515 **Robenidine hydrochloride.**

(a) *Approvals.* Type A medicated articles: 30 grams per pound to 046573 in § 510.600(c) of this chapter.

(b) *Special considerations.* Type C feed containing robenidine hydrochloride

must be fed within 50 days from the date of manufacture. Do not use in Type B or Type C medicated feeds containing bentonite.

(c) *Related tolerances.* See § 556.580 of this chapter.

(d) *Conditions of use.* It is used in feed for chickens as follows:

| Robenidine hydrochloride in grams/ton | Combination in grams/ton | Indications for use | Limitations | Sponsor |
|---------------------------------------|--------------------------|---|--|---------|
| 30 (0.0033 pct) | | For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by <i>E. mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> . | Feed continuously as sole ration. Do not feed to layers. Withdraw 5 days prior to slaughter. | 046573 |

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| Robenidine hydrochloride in grams/ton | Combination in grams/ton | Indications for use | Limitations | Sponsor |
|---------------------------------------|---|--|--|---------|
| | Bacitracin (as bacitracin methylene disalicylate) 4 to 30 | For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by <i>E. mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> . For increased rate of weight gain. | Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter. | 046573 |
| | Bacitracin (as bacitracin methylene disalicylate) 27 to 50 | For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by <i>E. mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> . For improved feed efficiency. | Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter. | 046573 |
| | Bacitracin (as bacitracin methylene disalicylate) 50 | For broiler and fryer chickens: As an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin. | Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter. | 046573 |
| | Bacitracin (as bacitracin methylene disalicylate) 100 to 200 | For broiler and fryer chickens: As an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin. | To control a necrotic enteritis outbreak, start medication at first clinical signs of disease; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin methylene disalicylate to prevention level (50 g/ton). Do not feed to laying hens. Withdraw 5 days before slaughter. | 046573 |
| | Bacitracin (as bacitracin methylene disalicylate) 50 and roxarsone 22.7 to 45.4 | For broiler chickens: As an aid in the prevention of coccidiosis caused by <i>E. mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> . As an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin. For increased rate of weight gain, improved feed efficiency, and improved pigmentation. | Feed continuously as sole ration. Use as the sole source of organic arsenic; poultry should have access to water at all times; drug overdose or lack of water intake may result in leg weakness or paralysis. Do not feed to laying chickens. Withdraw 5 days prior to slaughter. | 046573 |

| Robenidine hydrochloride in grams/ton | Combination in grams/ton | Indications for use | Limitations | Sponsor |
|---------------------------------------|---|---|---|------------------|
| | Bacitracin (as bacitracin methylene disalicylate) 100 to 200 and roxarsone 22.7 to 45.4 | For broiler chickens: As an aid in the prevention of coccidiosis caused by <i>E. mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> . As an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin. For increased rate of weight gain, improved feed efficiency, and improved pigmentation. | To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Use as the sole source of organic arsenic; poultry should have access to water at all times; drug overdose or lack of water intake may result in leg weakness or paralysis. Do not feed to laying chickens. Withdraw 5 days prior to slaughter. | 046573 |
| | Bacitracin (as bacitracin zinc) 4 to 30 | For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by <i>E. mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> . For increased rate of weight gain. | Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter. | 046573 046573 |
| | Bacitracin (as bacitracin zinc) 27 to 50 | For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by <i>E. mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> . For improved feed efficiency. | Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter. | 046573 046573 |
| | Chlortetracycline 100 to 200 | For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by <i>E. mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> . For control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline. | Feed continuously as sole ration up to 14 days. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days prior to slaughter. | |
| | Chlortetracycline 200 to 400 | For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by <i>E. mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> . For control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to chlortetracycline. | Feed continuously as sole ration up to 14 days. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days prior to slaughter. | |
| | Chlortetracycline 500 | For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by <i>E. mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> . As an aid in the reduction of mortality due to <i>E. coli</i> susceptible to chlortetracycline. | Feed continuously as sole ration up to 5 days. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days prior to slaughter. | 046573 |

| Robenidine hydrochloride in grams/ton | Combination in grams/ton | Indications for use | Limitations | Sponsor |
|---------------------------------------|--|---|---|---------|
| | Lincomycin 2 | For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by <i>E. mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> . For increase in rate of weight gain and improved feed efficiency. | Feed continuously as the sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter. | 000009 |
| | Oxytetracycline 400 | For broiler chickens: As an aid in the prevention of coccidiosis caused by <i>E. mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> . For control of CRD and air sac infection caused by <i>Mycoplasma gallisepticum</i> and <i>E. coli</i> susceptible to oxytetracycline. | Feed continuously for 7 to 14 days. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days before slaughter. | 066104 |
| | Roxarsone 22.5 to 45.4 (0.005 percent) | For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by <i>E. mivati</i> , <i>E. brunetti</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. maxima</i> , and <i>E. necatrix</i> . For increased rate of weight gain. | Feed continuously as the sole ration. Use as sole source of organic arsenic. Do not feed to layers. Withdraw 5 days prior to slaughter. | 046573 |

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.515, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 558.530 Roxarsone.

(a) *Approvals.* Type A medicated articles: 10, 20, 50, and 80 percent to 046573 in § 510.600(c) of this chapter for use as in paragraphs (d)(1) through (d)(4) of this section.

(b) *Related tolerances.* See § 556.60 of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Growing chickens and growing turkeys*—(i) *Grams per ton.* Roxarsone 22.7 and 45.4 (0.0025 to 0.005 percent).

(ii) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(iii) *Limitations.* Withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; feed continuously throughout growing period.

(2) *Growing chickens*—(i) *Grams per ton.* Roxarsone, 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 10 to 50.

(A) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations.* Do not feed to chickens producing eggs for human consumption; withdraw 5 days before slaughter; as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness; feed continuously throughout growing period.

(ii) *Grams per ton.* Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 100 to 200.

(A) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(2)(i)(B) of this section except feed continuously for 7 to 14 days.

(iii) *Grams per ton.* Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 200 to 400.

(A) *Indications for use.* For increased rate of weight gain, improved feed efficiency, and improved pigmentation; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.

(B) *Limitations.* See paragraph (d)(2)(i)(B) of this section except feed continuously for 7 to 14 days.

(iv) *Grams per ton.* Roxarsone 22.7 to 45.4 (0.0025 to 0.005 percent) plus chlortetracycline, 500.