Food and Drug Administration, HHS

§ 558.261 Florfenicol.

(a) Specifications. Type A medicated articles containing florfenicol in the following concentrations:

(1) 40 grams per kilogram for use as in paragraph (e)(1) of this section.

(2) 500 grams per kilogram for use as in paragraphs (e)(2) and (e)(3) of this section.

(b) Sponsor. See No. 000061 in §510.600(c) of this chapter.

(c) Special considerations—(1) Federal law limits this drug to use under the professional supervision of a licensed.
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veterinarian. See §558.6 of this chapter for additional requirements.

(2) The expiration date of veterinary feed directives (VFDs) for florfenicol medicated feeds:

(i) For catfish and freshwater-reared salmonids, must not exceed 15 days from the date of issuance;

(ii) For swine must not exceed 90 days from the date of issuance.

(3) VFDs for florfenicol shall not be refilled.

(d) Related tolerances. See §556.283 of this chapter.

(e) Conditions of use—(1) Swine—

<table>
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<th>Florfenicol in grams/ton of feed</th>
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<td>182</td>
<td>For the control of swine respiratory disease (SRD) associated with <em>Actinobacillus pleuropneumoniae</em>, <em>Pasteurella multocida</em>, <em>Streptococcus suis</em>, and * Bordetella bronchiseptica* in groups of swine in buildings experiencing an outbreak of SRD.</td>
<td>Feed continuously as a sole ration for 5 consecutive days. The safety of florfenicol on swine reproductive performance, pregnancy, and lactation have not been determined. Feeds containing florfenicol must be withdrawn 13 days prior to slaughter.</td>
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(2) Fish—

Catfish: For the control of mortality due to enteric septicemia of catfish associated with *Edwardsiella ictaluri*.

Feed as a sole ration for 10 consecutive days to deliver 10 milligrams florfenicol per kilogram of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be re-evaluated by a licensed veterinarian before initiating a further course of therapy. A dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 12 days prior to slaughter.
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<td>(ii) 182 to 1,816 Freshwater-reared salmonids: For the control of mortality due to coldwater disease associated with Flavobacterium psychrophilum and furunculosis associated with Aeromonas salmonicida.</td>
<td>Feed as a sole ration for 10 consecutive days to deliver 10 milligrams florfenicol per kilogram of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be re-evaluated by a licensed veterinarian before initiating a further course of therapy. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.</td>
<td>(A) Indications for use. For the prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati, and E. maxima; for increased rate of weight gain and improved feed efficiency. (B) Limitations. Feed continuously as sole ration; withdraw 5 days before slaughter; do not feed to layers. (ii) Amount per ton. Florfenicol 2.72 grams (0.0003 percent) plus virginiamycin 5 grams. (A) Indications for use. For the prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati, and E. maxima; for increased rate of weight gain and improved feed efficiency. (B) Limitations. Feed continuously as sole ration; withdraw 5 days before slaughter; do not feed to layers. (iv) Amount per ton. Florfenicol 2.72 grams (0.0003 percent) plus virginiamycin 5 to 15 grams. (A) Indications for use. For the prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati, E. maxima; for increased rate of weight gain. (B) Limitations. Feed continuously as sole ration; withdraw 6 days before slaughter; do not feed to layers. (v) Amount per ton. Florfenicol hydrobromide 2.72 grams (0.0003 percent) plus bacitracin methylene disalicylate 10 to 50 grams and roxarsone 22.7 to 45.4 grams. (A) Indications for use. For the prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati, and E. maxima; for increased rate of weight gain; and for improved feed efficiency. (B) Limitations. Feed continuously as sole ration; withdraw 5 days before slaughter; use as sole source of organic arsenic; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams. (vi) Amount per ton. Florfenicol 2.72 grams (0.0003 percent) plus bacitracin methylene disalicylate 10 to 50 grams. (A) Indications for use. For the prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati, E. maxima and for improved feed efficiency. (B) Limitations. Feed continuously as sole ration; withdraw 5 days before slaughter; do not feed to layers.</td>
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