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 paragraph (e)(2) 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 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 freshwater-reared finfish, 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>
<thead>
<tr>
<th>Florfenicol in grams/ton of feed</th>
<th>Indications for use</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<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 <em>Bordetella bronchiseptica</em> 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 Feeds containing florfenicol must be withdrawn 13 days prior to slaughter.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—

<table>
<thead>
<tr>
<th>Florfenicol in grams/ton of feed</th>
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</thead>
<tbody>
<tr>
<td>(i) 182 to 2,724</td>
<td>Catfish: For the control of mortality due to enteric septicemia of catfish associated with <em>Edwardsiella ictaluri</em>.</td>
<td>Feed as a sole ration for 10 consecutive days to deliver 10 to 15 milligrams (mg) florfenicol per kilogram (kg) of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated 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 15 days prior to slaughter.</td>
</tr>
<tr>
<td>Florfenicol in grams/ton of feed</td>
<td>Indications for use</td>
<td>Limitations</td>
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<td>(ii) 182 to 1,816</td>
<td>Freshwater-reared salmonids: For the control of mortality due to coldwater disease associated with <em>Flavobacterium psychrophilum</em> and furunculosis associated with <em>Aeromonas salmonicida</em>.</td>
<td>Feed as a sole ration for 10 consecutive days to deliver 10 to 15 mg florfenicol per kg of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated 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>
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<tr>
<td>(iii) 182 to 2,724</td>
<td>Freshwater-reared finfish: For the control of mortality due to columnaris disease associated with <em>Flavobacterium columnare</em>.</td>
<td>Feed as a sole ration for 10 consecutive days to deliver 10 to 15 mg florfenicol per kg of fish for freshwater-reared warmwater finfish and other freshwater-reared finfish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. For catfish, 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 15 days prior to slaughter.</td>
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<tr>
<td>(iv) 273 to 2,724</td>
<td>Freshwater-reared warmwater finfish: For the control of mortality due to streptococcal septicaemia associated with <em>Streptococcus iniae</em>.</td>
<td>Feed as a sole ration for 10 consecutive days to deliver 15 mg florfenicol per kg of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. For catfish, 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 15 days prior to slaughter.</td>
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§ 558.265 Halofuginone.

(a) Specifications. Type A medicated articles containing 6 grams of halofuginone hydrobromide per kilogram.

(b) Approvals. See No. 016592 in §510.600(c) of this chapter.

(c) Related tolerances. See §556.308 of this chapter.

(d) Conditions of use. (1) It is used in feed for broiler chickens as follows:

(i) Amount. 2.72 grams per ton.

(A) Indications for use. For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.

(B) Limitations. Feed continuously as sole ration; withdraw 4 days before slaughter; do not feed to layers; avoid contact with skin, eyes, or clothing; keep out of lakes, ponds, or streams.

(ii) Amount per ton. Halofuginone 2.72 grams (0.0003 percent) plus bambermycins 1 to 2 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.

(iii) Amount per ton. Halofuginone 2.72 grams (0.0003 percent) plus virginiamycin 5 grams.