

# **FINDING OF NO SIGNIFICANT IMPACT**

**for**

**Aquaflor<sup>®</sup> (Florfenicol) Type A Medicated Article**

**for**

**Freshwater-Reared Salmonids  
For Furunculosis Disease**

**Supplemental NADA 141-246**

**Schering-Plough Animal Health  
Summit, NJ**

**FOR PUBLIC DISPLAY  
(HFA-305)**

FINDING OF NO SIGNIFICANT IMPACT

for

Aquaflor<sup>®</sup> Type A Medicated Article

for

Control of Mortality in Freshwater-reared Salmonids

Due to Furunculosis Disease

Supplemental NADA 141-246

Schering-Plough Animal Health  
Summit, NJ

The Center for Veterinary Medicine has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment. Therefore, an environmental impact statement will not be prepared.

Schering-Plough Animal Health is requesting approval of a supplemental new animal drug application (NADA) for the use of Aquaflor<sup>®</sup> (florfenicol) Type A Medicated Article in freshwater-reared salmonids. Aquaflor<sup>®</sup> is used to control mortality caused by furunculosis disease associated with *Aeromonas salmonicida* and will be fed as the sole ration for 10 consecutive days at a dose rate of 10 mg florfenicol/kg body weight of fish.

Florfenicol is approved for use in freshwater-reared salmonids for control of mortality in freshwater-reared salmonids due to coldwater disease associated with *Flavobacterium psychrophilium* as codified in 21 CFR 558.261. Florfenicol is also approved for use in catfish and swine as codified under 21 CFR 558.261 and for use in swine and cattle as codified under 21 CFR 520.955 and 522.955.

In support of their application, Schering-Plough Animal Health has provided the attached supplement to the Environmental Assessment (EA) for Aquaflor for Freshwater-reared Salmonids (dated January 31, 2007). The January 2007 EA ("original EA") addressed the use of Aquaflor for treatment of coldwater disease in freshwater-reared salmonids under flow-through conditions. The supplement to the EA addresses expected changes to the use and exposure profile for florfenicol based on approval of the use of Aquaflor for control of furunculosis in freshwater-reared salmonids.

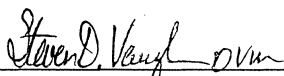
The supplement to the EA contains a summary of responses from 10 fishery management professionals throughout the United States who were contacted by telephone. These professionals were questioned on the occurrence of furunculosis and coldwater disease at their facilities, and about likely treatment conditions for these diseases. There was general agreement by the group that typically no more than 20% of a facility would be treated even if concurrent treatments were to occur for both diseases.

Based on quantitative data presented in the supplement to the EA, it appears that overall use of Aquaflor in freshwater-reared salmonids might increase by approximately 50% in terms of number of treatments with the addition of furunculosis to the Aquaflor label, while the number of individual fish treated might increase by about 35%. However, because of the pattern of disease occurrence<sup>1</sup>, except in rare cases, end-of-pipe effluent concentrations of florfenicol would not be expected to increase above those previously presented in the original EA for the use of Aquaflor in freshwater-reared salmonids for control of coldwater disease. The initial predicted environmental concentrations (PECs) and risk quotients presented in the original EA for both the worst-case and typical case scenarios (Tables 18a and 18c) would be valid in all cases. Furthermore, it should be kept in mind that these risk characterizations are conservative in nature because the risk quotients were based on predicted effluent-end-of-pipe concentrations which did not account for potential dilution in receiving waters for either the worst-case or typical case scenarios.

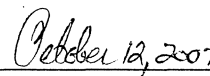
Several of the fishery management professionals agreed that antibiotic treatment of a whole facility for furunculosis and/or coldwater disease might be necessary on rare occasions. However, based on data presented in the original EA for freshwater-reared salmonids (Table 18a), risk quotients for the initial "worst-case scenario" would still be acceptable for sensitive aquatic invertebrates and fish for even if one assumes that 100% of the facility is treated concurrently with Aquaflor<sup>2</sup>. For the "typical case scenario" based on more typical assumptions, the refined risk quotients assuming 100% treatment of a facility would be well below one for all aquatic species except the most sensitive species of algae (*Skeletonema costatum*)<sup>3</sup>. Therefore, it is concluded that the risk characterizations presented in the original EA can continue to be relied upon for evaluating the supplemental claim for furunculosis.

Risk analyses for florfenicol and its metabolites indicate that there is a potential for short-term inhibitory effects on sensitive algae and bacteria downstream of a very small percentage (<5%) of locations where Aquaflor<sup>®</sup> is used. Mitigating factors have been discussed in the FONSI for the original EA for freshwater-reared salmonids and in the original EA itself. Adverse effects on fish, aquatic invertebrates and terrestrial organisms are not expected under any conditions.

The supplemental information relating to the occurrence and use for furunculosis, in conjunction with the original EA for use to control coldwater disease, is adequate to conclude that the use of Aquaflor<sup>®</sup> in intensive aquaculture of freshwater-reared salmonids and its disposal are not expected to have a significant impact on the environment.



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Director, Office of New Animal Drug Evaluation, HFV-100  
FDA, Center for Veterinary Medicine



\_\_\_\_\_  
Date

<sup>1</sup> Coldwater disease usually occurs during the high flow periods (i.e., late spring and early summer) while furunculosis occurs primarily during times of low water flow (i.e., July through September).

<sup>2</sup> The initial risk characterization for the worst-case scenario presented in Table 18a assumed 100% treatment of a facility and other conservative assumptions for the fish density and internal flow rates.

<sup>3</sup> In this case, the refined PECs and risk quotients in Table 18d of the original EA were multiplied by a factor of five to account for 100% treatment of a facility.

Attachment: Supplement to the Environmental Assessment for Aquaflor for Freshwater-reared Salmonids