

**FINDING OF NO SIGNIFICANT  
IMPACT**

for

**AQUAFLO® (FLORFENICOL) 50% Type A  
Medicated Article for Catfish**

**SCHERING-PLOUGH ANIMAL HEALTH  
KENILWORTH, NJ**

**FOR PUBLIC DISPLAY**

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SCHERING-PLOUGH ANIMAL HEALTH  
KENILWORTH, 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 their new animal drug application (NADA) for the use of AQUAFLO<sup>®</sup> (florfenicol) 50% Type A Medicated Article for Catfish. AQUAFLO<sup>®</sup> is used to control mortality in channel catfish associated with infection by *Edwardsiella ictaluri*, the etiologic agent of enteric septicemia.

Florfenicol is also approved, for use in swine and cattle as codified under 21 CFR 520.955 and 522.955.

In support of their application, Schering-Plough has provided the attached environmental assessment (EA), dated January 15, 2004.

The EA addresses risk from short-term exposure for aquatic organisms, microorganisms, terrestrial plants, and earthworms. Risks to sediment-dwelling and most terrestrial organisms were not considered in the EA because florfenicol and its metabolites are not likely to adsorb with sediment or be transported to a terrestrial environment. Additionally, the EA does not address potential risks to avian species because no significant bioaccumulation of florfenicol is expected and direct exposure is unlikely.

Risk characterization data for freshwater organisms are presented in the EA. The EA does not differentiate between acute and chronic exposures or risks. This is appropriate because releases of water from catfish ponds will occur over relatively short periods of time (i.e., a week or so). Data in the EA indicates that impacts on invertebrate and vertebrate aquatic organisms are not expected. There is some data to indicate possible effects on *Skeletonema costatum*. These data indicates there is some risk of short-term effects on the growth of sensitive algae species. However, the risk was generated using worst-case assumptions that are highly unlikely at most locations. Even if effects on algae occur, these effects are not likely to be ecologically significant in receiving waters for several reasons. First, florfenicol is algistatic but does not actually kill algae so a rapid recovery in population growth is expected shortly after the release of florfenicol is

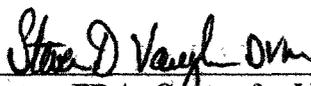
completed. Second, although algal toxicity data are limited, it is apparent from the existing data that there is a wide range of sensitivity to florfenicol. *S. costatum* appears to be at one extreme. Many, and perhaps most, algal species will likely not be affected by florfenicol under the expected exposure conditions. Third, because there is functional redundancy in algal communities, even if sensitive species are affected, the overall productivity of the phytoplankton is likely to remain relatively constant.

As with algae, under the worst-case scenario, the EA indicate that inhibition of sensitive bacteria in the water column is possible. This is not unexpected because florfenicol is an antibacterial. Most, if not all, of the effects on bacteria are expected to be confined to catfish ponds themselves. Ecologically significant effects on bacteria in receiving waters are not expected because releases of florfenicol from catfish ponds will be short-lived and relatively rare. In addition, bacterial population growth is rapid, resulting in a short recovery time.

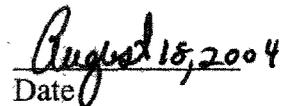
None of the four primary individual metabolites would be expected on an individual basis to contribute significantly to the overall cumulative risk. Even if each of the metabolites were just as toxic as the parent compound, which generally does not appear to be the case, this would not significantly increase the risk associated with AQUAFLO<sup>®</sup>.

Based on data submitted in the EA, 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 catfish ponds where Aquaflor<sup>®</sup> is used. However, none of these effects, if they occur, is expected to be widespread, ecologically significant or long lasting, and a rapid recovery in population growth should occur shortly after the release of florfenicol is completed. Adverse effects on fish and aquatic invertebrates and terrestrial organisms including birds are not expected under any conditions.

The information provided in the EA is adequate to conclude that the use and disposal of AQUAFLO<sup>®</sup> (florfenicol) are not expected to have a significant impact on the environment.



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

  
Date

**Attachment:** January 15, 2004 EA