



United States Department of the Interior

U.S. FISH & WILDLIFE SERVICE
AQUATIC ANIMAL DRUG APPROVAL PARTNERSHIP PROGRAM
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BOZEMAN, MT 59715
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October 1, 2008

Dr. Burnsteel
Director, Division of Therapeutic Drugs
for Food Animals
Document Control Unit, HFV-199
Center for Veterinary Medicine
7500 Standish Place, MPN-2
Rockville, MD 20855

Dear Dr. Burnsteel:

The purpose of this letter is to request that CVM, on behalf of the U. S. Fish and Wildlife Service (Service), establish a Public Master File (PMF) for the use of florfenicol as a medicated feed treatment to control mortality caused by pathogens susceptible to florfenicol in a variety of fish species. We also request that the attached information be placed in the PMF. The purpose of the Service's PMF will be to serve as a repository for efficacy information and data required to support a sponsor's New Animal Drug Application (NADA) for florfenicol as a medicated feed. All information and data, including Freedom of Information (FOI) Summaries, that are being submitted to the PMF have been reviewed by CVM and issued Technical Section Complete letters.

This submission includes three copies each of (1) the efficacy study protocols (n = 4) under which effectiveness studies were conducted, (2) abstracts from nine effectiveness final study reports summarizing the use of 10 mg florfenicol per kg of fish per day for 10 consecutive days to control mortality in freshwater-reared salmonids and hybrid striped bass, (3) CVM correspondence related to completion of Technical Sections from the Service's INAD file # 010697, and (4) Freedom of Information (FOI) Summaries of these data. Also included is a Table of Contents for the PMF. An electronic copy of all attachments is provided for your convenience.

We request that the availability of this information and these data be announced in the FEDERAL REGISTER so that a commercial sponsor may use them by reference to support these components of an NADA.

The information in this PMF supports the following label claims:

For use to control mortality caused by furunculosis associated with Aeromonas salmonicida in freshwater-reared salmonids;

For use to control mortality caused by coldwater disease associated with Flavobacterium psychrophilum in freshwater-reared salmonids; and

For use to control mortality caused by streptococcal septicemia associated with Streptococcus iniae in hybrid striped bass.

Treat fish one time per day at 10 mg/kg of fish for 10 consecutive days.

If you have questions regarding the above-described request, please contact Dr. David Erdahl, Branch Chief, U. S. Fish and Wildlife Service, AADAP Program at (406)-994-9904. We would like to thank you in advance for your time and consideration with respect to our request.

Sincerely,



Dr. David Erdahl
Branch Chief, AADAP Program

Attachments (3 copies of each)

1. PMF Table of Contents
2. Protocols
 - a. The Efficacy of florfenicol medicated feed to control mortality caused by pathogens susceptible to florfenicol in a variety of fish species (Protocol Number FLOR-01-EFF)
 - b. The Efficacy of florfenicol medicated feed to control mortality caused by pathogens susceptible to florfenicol in a variety of fish species (Protocol Number FLOR-01-EFF First Revision)
 - c. The Efficacy of florfenicol medicated feed to control mortality caused by pathogens susceptible to florfenicol in a variety of fish species (Protocol Number FLOR-01-EFF Second Revision)
 - d. The Efficacy of florfenicol medicated feed to control mortality caused by pathogens susceptible to florfenicol in a variety of fish species (Protocol Number FLOR-01-EFF.3)

3. Efficacy Final Study Reports

- a. Abstract- Efficacy of florfenicol-medicated feed to control mortality of fingerling Westslope cutthroat trout *Oncorhynchus clarki* caused by bacterial coldwater disease, causative agent *Flavobacterium psychrophilum* (Study Number FLOR-01-EFF-03)
- b. Abstract- Efficacy of florfenicol-medicated feed to control mortality of fingerling Westslope cutthroat trout *Oncorhynchus clarki* caused by bacterial coldwater disease, causative agent *Flavobacterium psychrophilum* (Study Number FLOR-01-EFF-04)
- c. Abstract- Efficacy of florfenicol-medicated feed to control mortality of fingerling steelhead trout *Oncorhynchus mykiss* caused by bacterial coldwater disease, causative agent *Flavobacterium psychrophilum* (Study Number FLOR-01-EFF-06)
- d. Abstract- Efficacy of florfenicol-medicated feed to control mortality of Westslope cutthroat trout fry *Oncorhynchus clarki lewisi* caused by bacterial coldwater disease, causative agent *Flavobacterium psychrophilum* (Study Number FLOR-01-EFF-12)
- e. Abstract- Efficacy of florfenicol-medicated feed to control mortality of fingerling coho salmon *Oncorhynchus kisutch* caused by furunculosis, causative agent *Aeromonas salmonicida* (Study Number FLOR-01-EFF-01)
- f. Abstract- Efficacy of florfenicol-medicated feed to control mortality of fall chinook salmon *Oncorhynchus tshawytscha* caused by furunculosis, causative agent *Aeromonas salmonicida* (Study Number FLOR-01-EFF.3-22)
- g. Abstract- Efficacy of florfenicol-medicated feed to control mortality of coho salmon *Oncorhynchus kisutch* caused by furunculosis, causative agent *Aeromonas salmonicida* (Study Number FLOR-01-EFF.3-27)
- h. Abstract- Efficacy of florfenicol-medicated feed to control mortality of fingerling hybrid striped bass caused by bacterial streptococcal septicemia, causative agent *Streptococcus iniae* (Study Number FLOR-01-EFF-02.b)
- i. Abstract- Efficacy of florfenicol-medicated feed to control mortality of hybrid striped bass *Morone chrysops* x *M. saxatilis* caused by bacterial streptococcal septicemia, causative agent *Streptococcus iniae* (Study Number FLOR-01-EFF.3-19)

4. CVM Correspondence related to Technical Section completion

5. Freedom of Information (FOI) Summaries