



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

JUL 31 2009

I-010697-D-0096-OT

U.S. Department of the Interior  
Fish and Wildlife Service  
Aquatic Animal Drug Approval Partnership Program  
Attention: David Erdahl, Ph.D.  
Branch Chief  
4050 Bridger Canyon Road  
Bozeman, MT 59715

Re: Amended food-use authorization for finfish treated with florfenicol-medicated feed

Dear Dr. Erdahl:

You are authorized 16 million finfish for human and animal food use. Edible tissues derived from experimental animals treated under the conditions described in this letter may be marketed for human consumption, for use in animal feeds, or released into public waters for possible human consumption. This authorization is in response to your submission dated April 30, 2009. This amended authorization for the use of florfenicol-medicated feed in finfish is consistent with the public health. Previous authorizations are superseded.

AMENDED FOOD-USE AUTHORIZATION

<b>DRUG IDENTITY</b>	Florfenicol
Dosage Form	Type A medicated article
<b>SPECIES</b>	Food Fish
Class	Salmonidae, Ictaluridae, <i>Micropterus</i> spp., <i>Morone</i> spp., <i>Oreochromis</i> spp, <i>Paralichthys</i> spp. Paddlefish, Black sea bass, Atlantic cod, Cabezon, Cobia
Number of Animals	16 million
<b>PERMITTED DOSING REGIMEN</b>	
Maximum Dose (or range)	10 to 15 mg/kg of fish/day
Route of Administration	Medicated feed
Frequency and Duration of Dosing	Daily for 10 consecutive days

<b>MINIMUM INVESTIGATIONAL WITHDRAWAL PERIOD</b>	21 days for salmonids 28 days for nonsalmonids
<b>MINIMUM INVESTIGATIONAL MILK DISCARD PERIOD</b>	Not applicable
<b>OTHER RESTRICTIONS OR CONDITIONS</b>	Not for the use of florfenicol for indications for which AQUAFLOL or AQUAFLOL-CA1 are approved or conditionally approved.

This food-use authorization only applies to the treatment regimen stated above. Any change in the dosage regimen or the combining of this treatment with any other drug will require a separate food-use authorization. Drugs given to control animals must be administered in full compliance with the currently approved use. Your investigators should be made aware of their responsibilities under 21 CFR 511.1(b)(7)(ii) and (c)(1).

In addition, we remind you that a sponsor must submit specific information prior to each shipment or other delivery of the drug for clinical investigation in animals (see 21 CFR 511.1(b)(4)). You may file the notice of the drug shipment electronically to the Center for Veterinary Medicine (CVM). Please refer to the Center's electronic submission information on the CVM website at <http://www.fda.gov/cvm/esubstoc.html>. Alternatively, you can send three copies of the completed form to CVM. Furthermore, we note that clinical tests conducted under the provisions of this letter do not exempt investigational animals and their products from compliance with any other applicable inspection requirements (see 21 CFR 511.1(b)(5)(iii)).

#### INVESTIGATIONAL LABELING

You provided intended investigational labeling language to be included in the file (D-0073). This labeling is consistent with the requirements set forth in 21 CFR 511.1(b)(1). The investigational labeling should be affixed to your investigational drug product prior to shipment and this investigational label should be affixed to each individual drug container.

#### COUNTING NUMBERS OF FISH

You should note that this authorization is for a specific number of fish. You should begin counting the number of fish used from the date you receive our letter starting at zero. Previous authorizations are superseded.

Please provide the total number of fish used towards this authorization in your annual reports. We remind you that a fish treated more than once still only counts as a single fish toward the authorization.

Additional numbers of fish may be requested in the future. A request for additional fish should be made with sufficient lead time to allow us to process an amended authorization.

## ANNUAL REPORTS

We remind you of the continued necessity to provide annual reports under the FDA/CVM Aquaculture Workload Plan. Your annual report should include: a) a brief summary of the past year's activities and accomplishments in each of the investigational new animal drug (INAD) technical sections; b) certification of accountability of all drugs shipped under the INAD, records maintenance for FDA inspection, and compliance with the provisions of 21 CFR Part 511, including notification of adverse effects relative to humans, target animals, or the environment resulting from the use of the investigational drug; c) a list of all investigators, facilities, and species treated; and d) a copy of the current study protocol(s) noting any modification or revision. We recommend that any changes to pivotal study protocols be reviewed by CVM prior to initiating further investigations.

## ADDITIONAL COMMENTS

1. In order for us to complete our files, the disposition of all investigational animals and unused drugs should be reported to this office, as well as adverse reactions observed. Please refer to this letter by date and INAD number when reporting the details of clinical investigations or the disposition of investigational animals.
2. We remind you that the investigational new animal drug must be manufactured, processed, packaged, and labeled in such a way as to maintain appropriate standards of identity, strength, quality, and purity as needed for safety and to give significance to investigations made with the drug (21 CFR Parts 210 and 211).
3. You should obtain a material safety data sheet (MSDS) for the investigational drug and follow the information in the MSDS to protect all individuals who may be exposed to the investigational drug.
4. We recommend that you request a meeting to further discuss your product development plan with us.
5. We note that your submission included a request for a categorical exclusion from the requirement to prepare an environmental assessment. Please note that this letter only addresses the food use authorization request. Your request for a categorical exclusion will be addressed in a separate letter (X-0098). In the future, please make one request per submission.

If you submit correspondence relating to this letter, your correspondence should reference the date and the principal submission identifier found at the top of this letter. If you have any questions or comments, please contact Dr. Cindy Burnsteel, Director, Division of Therapeutic Drugs for Food Animals, at 240-276-8341.

Sincerely,

*Elizabeth Luddy*  
for Steven D. Vaughn, DVM  
Office of New Animal Drug Evaluation  
Center for Veterinary Medicine