



I-012781-O-0002-OT

USDI Fish and Wildlife Service
AADAP Program
Attention: David Erdahl, Ph.D.
Branch Chief
4050 Bridger Canyon Road
Bozeman, MT 59715

Re: Food-use authorization for salmonids treated with erythromycin injection

Dear Dr. Erdahl:

You are authorized 250,000 salmonids 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 May 5, 2016, as amended July 15, 2016 (T-0004). This authorization for the use of ERYMICIN 200 Injection (erythromycin injection) in salmonids is consistent with the public health.

FOOD-USE AUTHORIZATION

DRUG IDENTITY	ERYMICIN 200 Injection (erythromycin injection)
Dosage Form	Solution
SPECIES	Salmonids
Class	Juvenile and Adult
Number of Animals	Up to 250,000
PERMITTED DOSING REGIMEN	10-25 mg erythromycin <i>per</i> kg/body weight (<i>per</i> injection), the total dosage will not exceed 75 mg/kg body weight over 3 injections
Maximum Dose (or range)	
Route of Administration	Injection (intramuscular or intraperitoneal)
Frequency and Duration of Dosing	1-3 injections; minimum injection interval 21 days
MINIMUM INVESTIGATIONAL WITHDRAWAL PERIOD	60 days following the cessation of treatment with erythromycin. Following the assigned investigational withdrawal period, treated fish can be (1) slaughtered for human consumption, or (2) released into public receiving waters for possible human consumption.
MINIMUM INVESTIGATIONAL MILK DISCARD TIME	Not applicable

Other Restrictions OR CONDITIONS	The progeny of any treated fish can be released into open waters zero days after the last injection of broodstock
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The New Animal Drug Regulations, 21 CFR 511.1(b)(4), require the sponsor to submit specific information prior to each shipment or other delivery of the drug for clinical investigation in animals. You may file the notice of the drug shipment electronically to the Center for Veterinary Medicine (CVM) using FDA's eSubmitter tool. Please refer to the Center's electronic submission information on the CVM website at <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ElectronicSubmissions/default.htm>. Alternatively, you can send one copy of the completed form to CVM.

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).

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

The appropriate investigational labeling required under 511.1(a) or (b) must be affixed to your investigational drug product before shipping your drug product for studies conducted under 21 CFR 511.1(a) or (b), respectively. Affix the investigational label 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.

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.

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 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 must be reported to this office. Please refer to this letter by date and INAD number when reporting the details of clinical investigations or the disposition of investigational animals.
2. Promptly report to this office any adverse reactions that may suggest significant safety hazards.
3. You should obtain a safety data sheet (SDS) for the investigational drug and follow the information in the SDS to protect all individuals who may be exposed to the investigational drug.
4. In your amendment dated July 15, 2016 (T-0004), you requested a food use authorization for 1 million fish. At this time, based on the use pattern described in your amendment and survey results presented by Doug Munson earlier this year¹ that suggest approximately 100,000 fish would be treated on an annual basis, we are authorizing treatment of 250,000 fish. An amended authorization may be requested in the future as additional fish are needed.

If you submit correspondence relating to this letter, you should reference the date and the principal submission identifier. If you have any questions or comments, please contact Dr. Cindy L. Burnsteel, Director, Division of Therapeutic Drugs for Food Animals at 240-402-0817.

Sincerely,

{see appended electronic signature page}
Steven D. Vaughn, DVM
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

¹ https://www.fws.gov/fisheries/aadap/22nd-AADAP-Coordination_meeting/3-Munson-treatments-for-BKD.pdf

**Electronic Signature
Addendum for Submission ID**

Signing Authority (Role)	Letter Date

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