



MAR 16 2010

I-009332-D-0121-OT

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

Re: Amended food-use authorization for fish treated with oxytetracycline dihydrate

Dear Dr. Erdahl:

You are authorized gilthead seabream (*Sparus aurata*) and European sea bass (*Dicentrarchus labrax*) 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 December 1, 2009 (D-0121). This amended authorization for the use of TERRAMYCIN 200 for Fish (oxytetracycline dihydrate) Type A medicated article in gilthead seabream (*Sparus aurata*) and European sea bass (*Dicentrarchus labrax*) is consistent with the public health.

AMENDED FOOD-USE AUTHORIZATION

DRUG IDENTITY	TERRAMYCIN 200 for Fish (oxytetracycline dihydrate)
Dosage Form	Type A medicated article
SPECIES	Marine and Freshwater Fish
Class	Salmonidae, Acipenseridae, Catostomidae, Centrarchidae, Cichlidae, Cyprinidae, Cyprinodontidae, Esocidae, Ictaluridae, Moronidae, Percidae, Poeciliidae, <i>Paralichthys</i> spp., <i>Seriola</i> spp. <i>Haliotis rufescens</i> (abalone), <i>Alosa sapidissima</i> (American shad), <i>Gadus morhua</i> (Atlantic cod), <i>Hippoglossus hippoglossus</i> (Atlantic halibut), <i>Centropristis striata</i> (black sea bass), <i>Scorpaenichthys marmoratus</i>

	(cabezon), <i>Semicossyphus pulcher</i> (California sheephead), <i>Rachycentron canadum</i> (cobia), <i>Dicentrarchus labrax</i> (European sea bass), <i>Sparus aurata</i> (gilthead seabream), <i>Alosa mediocris</i> (hickory shad), <i>Polyodon spathula</i> (paddlefish), <i>Atractoscion nobilis</i> (white sea bass)
Number of Animals	Up to 100 million (begin counting with D-0093 dated June 26, 2007)
PERMITTED DOSING REGIMEN Maximum Dose (or range) Frequency and Duration	<p>Objective A – Salmonids fed medicated feed containing 2.5 to 3.75 g oxytetracycline/ 100 lb of fish per day for 10 days.</p> <p>Objective B – Freshwater and marine fish fed medicated feed containing 10 g oxytetracycline per 100 lb of fish per day for 14 days in water temperatures not below 4 °C.</p> <p>Objective C – Non-salmonid freshwater and marine fish species fed medicated feed containing 2.5 to 3.75 g oxytetracycline/ 100 lb of fish per day for 10 days.</p> <p>Objective D – Abalone fed up to 6 g oxytetracycline per 100 lb body weight per day for 14 days.</p> <p>Objective E – Salmonid and non-salmonid fish fed at either the approved drug level (2.5 to 3.75 g OTC) or at 10.0 g oxytetracycline per 100 lb of fish per day for 14 days.</p>
Route of Administration	Oral
MINIMUM INVESTIGATIONAL WITHDRAWAL PERIOD	<p>Objective A – 21 days. No withdrawal period is required for fish that will not be catchable for 21 or more days after release, or are illegal for harvest.</p> <p>Objective B – 70 days. No withdrawal period is required for fish that will not be catchable for 70 or more days after release, or are illegal for harvest.</p>

	<p>Objective C – 40 days. No withdrawal period is required for fish that will not be catchable for 40 or more days after release, or are illegal for harvest.</p> <p>Objective D – 35 days. No withdrawal time is required for abalone that will not be harvestable for 35 or more days after release, or are illegal for harvest.</p> <p>Objective E –</p> <p>21 days for salmonids fed at the approved level. No withdrawal period is required for salmonids fed at the approved dose that will not be catchable for 21 or more days after release or are illegal for harvest.</p> <p>40 days for non-salmonids fed at the approved level. No withdrawal period is required for non-salmonids fed at the approved dose that will not be catchable for 40 or more days after release or are illegal for harvest.</p> <p>70 days for fish fed at the high dose (10 g OTC). No withdrawal period is required for fish that will not be catchable for 70 or more days after release or are illegal for harvest.</p>
MINIMUM INVESTIGATIONAL MILK DISCARD PERIOD	Not applicable
OTHER RESTRICTIONS OR CONDITIONS	The investigational withdrawal periods may be incorporated into grow-out periods for the treated fish.

This food-use authorization only applies to the treatment regimens 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)).

COUNTING NUMBERS OF FISH

This authorization replaces our authorization letter dated June 26, 2007 (D-0093). From here forward, please reference the current authorization (D-0121) and continue counting the number of fish used since June 26, 2007 (D-0093).

Please provide the total number of fish used towards the 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 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.

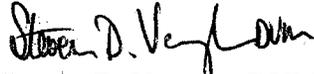
ADDITIONAL COMMENTS

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.

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 L. Burnsteel, Director, Division of Therapeutic Drugs for Food Animals at 240-276-8341.

Sincerely,



Steven D. Vaughn, DVM

Director

Office of New Animal Drug Evaluation

Center for Veterinary Medicine