



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

MAR 16 2010

I-009033-D-0113-OT

U.S. Fish and 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 hydrochloride

Dear Dr. Erdahl:

You are authorized gilthead seabream (*Sparus aurata*), European sea bass (*Dicentrarchus labrax*), black sea bass (*Centropristis striata*), white sea bass (*Atractoscion nobilis*), summer flounder (*Paralichthys dentatus*), and yellowtail (*Seriola lalandi*) 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 2, 2009 (D-0113). This amended authorization for the use of TERRAMYCIN 343 (oxytetracycline hydrochloride) soluble powder in 1) gilthead seabream (*Sparus aurata*), 2) European sea bass (*Dicentrarchus labrax*), 3) black sea bass (*Centropristis striata*), 4) white sea bass (*Atractoscion nobilis*), 5) summer flounder (*Paralichthys dentatus*), and 6) yellowtail (*Seriola lalandi*) is consistent with the public health.

AMENDED FOOD-USE AUTHORIZATION

|                      |  |
|----------------------|--|
| <b>DRUG IDENTITY</b> | TERRAMYCIN 343 (oxytetracycline hydrochloride)   |
| Dosage Form          | Soluble Powder   |
| <b>SPECIES</b>       | Marine and Freshwater Finfish  |
| Class                | Salmonidae, Acipenseridae, Catostomidae, Centrarchidae, Cyprinidae, Cyprinodontidae, Esocidae, Ictaluridae, Percidae, Poeciliidae, <i>Paralichthys</i> spp., <i>Seriola</i> spp. |

|  |   |
|--|---|
|  | <i>Centropristis striata</i> (black sea bass),<br><i>Scorpaenichthys marmoratus</i> (cabezon),<br><i>Dicentrarchus labrax</i> (European sea bass),<br><i>Sparus aurata</i> (gilthead seabream),<br><i>Polyodon spathula</i> (paddlefish),<br><i>Atractoscion nobilis</i> (white sea bass)   |
| Number of Animals                                  | 2 million (begin counting with D-0098 dated October 1, 2007)  |
| <b>PERMITTED DOSING REGIMEN</b>                    |   |
| Maximum Dose (or range)                            | 20 mg/L   |
| Route of Administration                            | Immersion   |
| Frequency and Duration of Dosing                   | Single treatment for 1 hour<br>or<br>Multiple treatment: One hour daily for 1 - 4 consecutive days  |
| <b>MINIMUM INVESTIGATIONAL WITHDRAWAL PERIOD</b>   | 21 days for single treatment. No withdrawal period is required for fish that will not be catchable for 21 or more days after release, or are illegal for harvest.<br><br>60 days for multiple treatments. No withdrawal period is required for fish that will not be catchable for 60 or more days after release, or are illegal for harvest. |
| <b>MINIMUM INVESTIGATIONAL MILK DISCARD PERIOD</b> | Not applicable  |
| <b>OTHER RESTRICTIONS OR CONDITIONS</b>            | None  |

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 October 1, 2007 (D-0098). From here forward, please reference the current authorization (D-0113) and continue counting the number of fish used since October 1, 2007 (D-0098).

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,

*Steve D. Vaughn 03-15-2010*

Steven D. Vaughn, DVM

Director

Office of New Animal Drug Evaluation

Center for Veterinary Medicine