



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 12 2011

I-011741-D-0016-OT

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

Re: Amended food-use authorization request for Florida pompano treated with eugenol

Dear Dr. Erdahl:

You are authorized to treat all saltwater-reared 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 February 14, 2011. This amended authorization for the use of AQUI-S E (eugenol) in fish and prawn is consistent with the public health. Previous authorizations are superseded.

AMENDED FOOD-USE AUTHORIZATION

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| DRUG IDENTITY/FEED INGREDIENT IDENTITY | AQUI-S E (50% eugenol) |
| Dosage Form | Liquid |
| SPECIES | Fish |
| Class | All freshwater-reared finfish Freshwater prawn All saltwater-reared finfish |
| Number of Animals | 15 million (begin counting with O-0005 dated September 9, 2009) |
| PERMITTED DOSING REGIMEN | |
| Maximum Dose (or range) | 10 to 100 mg eugenol/L |
| Route of Administration | Immersion |
| Frequency and Duration of Dosing | Up to 15 minutes exposure |
| MINIMUM INVESTIGATIONAL WITHDRAWAL PERIOD | 72 hours |
| MINIMUM INVESTIGATIONAL MILK DISCARD TIME | not applicable |
| OTHER RESTRICTIONS OR CONDITIONS | Fish that are illegal for harvest during that 72 hour period can be released immediately after treatment. Euthanized fish must not be sent to slaughter or be otherwise available for food. |

We will be able to consider a request for a shorter investigational withdrawal period following submission and review of additional human food safety information concerning your product.

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

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

This authorization replaces our authorization letter dated September 9, 2010 (O-0005). From here forward, please reference the current authorization (D-0016) and continue counting the number of fish used since September 9, 2009 (O-0005).

Please provide the total number of fish used towards O-0005 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 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 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. The current authorization is specifically for AQUI-S E (50% eugenol). We have received and are currently reviewing your amended authorization request dated April 19, 2011, and your categorical exclusion request dated April 21, 2011, for the use of AQUI-S 20E (10% eugenol) under this INAD. Separate letters regarding AQUI-S 20E will follow once the reviews of these submissions have been completed.
5. The current authorization is granted for sedation to handleable. If you choose to pursue an additional claim besides sedation to handleable such as sedation for transport or harvest or euthanasia, you will need to submit a new food use authorization request and request a new categorical exclusion.

If you submit correspondence relating to this letter, you 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