



INAD 8069 D 0059

• Rodney R. Williams, MS
The University of Arizona
2601 E. Airport Drive
Tucson, AZ 85706-6985

AUG 15 2003

Dear Mr. Williams:

We refer to your submission dated March 8, 2003, concerning your investigational new animal drug (INAD) file for the use of oxytetracycline medicated feed for the control of mortality associated with necrotizing hepatopancreatitis in penaeid shrimp. You provided an annual report for activities under the INAD during 2002. Also, you requested an extension of the authorization to market treated animals.

We have considered your request to amend your authorization and have the following comments. We authorize you to market for human food use the edible tissues derived from shrimp treated in the following manner.

AMENDED AUTHORIZATION

DRUG	Oxytetracycline
Dosage Form	Type C medicated feed
Route of Administration	Oral
SPECIES	Shrimp
Class	All classes
Number of Animals	200 million
MAXIMUM DOSE (or Range) Frequency and Duration	4.5 g oxytetracycline/kg feed/day for 14 days
MINIMUM WITHDRAWAL PERIOD	2 days
RENDERING	Shrimp may be rendered at any time.
Other Restrictions	None

ENVIRONMENTAL CONSIDERATIONS

Your claim for the investigational use of oxytetracycline for control of mortality associated with necrotic hepatopancreatitis in shrimp falls within the categorical exclusion in 21 CFR 25.33(e). Your submission states that to your knowledge, no extraordinary circumstances exist which may significantly affect the human environment. Therefore, neither an environmental assessment (EA) nor an environmental impact statement is required. This categorical exclusion from preparation of an EA and an environmental impact statement does not relieve you of the

responsibility for determining and meeting all federal, state and local environmental and occupational laws and regulations that apply to the manufacturing, use, and disposal of the investigational drug.

You are responsible for complying with the Federal Clean Water Act as implemented under the National Pollutant Discharge Elimination System (NPDES), as well as any applicable ground-water pollution requirements, for all investigational sites covered under this INAD. You must contact the offices responsible for issuing NPDES permits, and other similar permits, to be certain they have no objection to the use and release of the investigational drug.

Please notify the Center for Veterinary Medicine (CVM) if the scope of your investigation changes (e.g., if additional facilities will treat fish, and/or if the protocol changes in ways which could result in increased environmental exposure, etc.).

GENERAL COMMENTS

Thank you for submitting the summary for your recently completed trials. The submitted information demonstrates your compliance in assisting CVM in compiling data which could contribute to a new animal drug application (NADA) approval for this drug. We have the following comments regarding your annual report.

1. The table containing the information regarding treatment at Southern Star indicates that eight treatments were 15-17 days in duration, exceeding the maximum permitted treatment duration of 14 days. Please inform all investigators not to exceed the 14-day maximum treatment duration.
2. You should contact Dr. Jeffrey M. Gilbert, Leader, Microbial Food Safety Team (HFV-157) at 301-827-0233, regarding the need to prepare a microbial food safety assessment as outlined in CVM's DRAFT Guidance for Industry #152 *Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern*, available at CVM's website (www.fda.gov/cvm). This assessment will outline the risk associated with using oxytetracycline in shrimp with respect to impact on human health therapy, especially regarding any impact on the ability to treat humans exposed to or infected with zoonotic pathogens (e.g., *Vibrio sp.*, *Salmonella sp.*, etc.) from shrimp treated with oxytetracycline under the proposed conditions of use.
3. In the future, three copies of all submitted information and data should be provided.
4. We remind you of the necessity to provide annual reports under the FDA CVM Aquaculture Workload Plan. Your annual report should comprise: a) a brief summary of the past year's activities and accomplishments in each of the technical

sections for the NADA; b) certification of accountability of all drugs shipped under the INAD, records maintenance for FDA inspection, compliance with the provisions of 21 CFR Part 511 and 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 for the next year's studies, indicating additions and deletions from the previous year; and d) any modification to the study protocol.

5. Clinical investigations for this INAD cover only the treatment regimen stated above. Your investigators should be made aware of their responsibilities under Section 511.1(b)(7)(ii) and Section 511.1(c)(1).

Future correspondence regarding this submission to the file for your INAD exemption should be identified by the date of this letter and our file number, INAD 8069 D 0059, and be submitted to the Document Control Unit, HFV-199. Please include only one request per submission, clearly stating the request in the first paragraph.

If you have any questions regarding this letter, please contact Dr. Donald Prater, Leader, Aquaculture Drugs Team, at 301-827-7567.

Sincerely yours,



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