I-010536-P-0024-TS

USDA Minor Use Animal Drug Program
Attention: Amy L. Omer, DVM
FDA Liaison to USDA's Minor Use Animal Drug Program
FDA/CVM/HFV-50
7500 Standish Place
Rockville, MD 20855

Re: Target Animal Safety technical section complete

Dear Dr. Omer:

Based upon the information you submitted on behalf of the USDA Minor Use Animal Drug Program on December 20, 2018, and the information contained in INAD 010536, we consider the Target Animal Safety technical section to be complete. The technical section is complete for the use of strontium powder for immersion for the skeletal marking of freshwater salmonid fry and fingerlings.

TARGET ANIMAL SAFETY

This technical section complete letter represents our finding that the studies and other information essential to determining target animal safety are complete and accepted. We also evaluate target animal safety in our review of other technical sections, particularly the Effectiveness and All Other Information (AOI) technical sections.

The submitted study included fry. The indication may be limited to fry and fingerling stages if reproductive safety is not evaluated via a reproductive safety study on broodstock fish. Any label limitation with regard to life stage will also be considered within the EFFECTIVENESS technical section. Please consider this in the development of the product.

DRAFT LABELING

We reviewed the draft label language and provide the following comments. These statements should be incorporated in the labeling for the product.

The directions for use should state:

- "Flush tanks to remove excess strontium at the end of the exposure."
- "This product may interfere with chemical test methods in commonly used water quality test kits. Do not rely on water quality measures from exposure waters."

The label should include the following caution: "Use of drugs or chemicals, particularly those administered via immersion, that may effect or are known to effect the gills should be avoided immediately after strontium exposure."

The label should include the following reproductive safety statement as a precaution: "Not for use in animals intended for breeding purposes. The effect of strontium on reproductive performance has not been determined."

FREEDOM OF INFORMATION (FOI) SUMMARY

We appreciate your cooperation in including the relevant portions of the FOI Summary with this submission. The Target Animal Safety section of the FOI Summary has been revised, and a copy is enclosed. Please review the FOI Summary for accuracy and notify us if you find errors. CVM will prepare the final version of the FOI Summary and will provide a copy when the last technical section is complete.

ALL FURTHER TARGET ANIMAL SAFETY INFORMATION

The information provided in this submission is acceptable. The information does not need to be re-submitted when the AOI technical section is submitted. Any additional information pertaining to the target animal safety of strontium in freshwater salmonids should be submitted when the AOI technical section is submitted.

In accordance with section 502(w)(3) of the Federal Food, Drug, and Cosmetic Act (which was added by section 303 of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018), the following statement must be added to labeling (except representative [Blue Bird] labeling) of approved new animal drugs by September 30, 2023:

Approved by FDA under NADA # XXX-XXX

All currently approved and marketed labeling components for this new animal drug must bear the required statement. We recommend that you add the statement to your labeling. See below for recommendations on appropriate placement or contact us.

When formatting the statement on your labeling:

- Present the statement on a single straight line using the exact format and spacing as presented above. If there is insufficient space to present the statement on a single line, two straight lines is acceptable.
- When you are adding the statement:
  - For single panel labeling components, including a single-sided package insert, place the statement near the end of the labeling component.
  - For a package insert that is multi-page, place the statement near the end of the last page.
  - For labeling components, other than a package insert, with several panels (e.g., front, sides, and/or back), place the statement at the bottom of the front panel.

Include a copy of this technical section complete letter when you submit your new animal drug application. Please contact us if there are changes in the product development plan (e.g., indication, dosage regimen, product formulation) or you become aware of any issues that may impact the status of this technical section or your application. We will make a final decision on whether we can approve your application after we have reviewed all of the data for all applicable technical sections and any other information available to us, as a whole, and determined whether the requirements for approval described in the Federal Food, Drug, and Cosmetic Act have been met.

In accordance with the reauthorization of the Animal Drug User Fee Act (ADUFA) and Animal Generic Drug User Fee Act (AGDUFA), effective October 1, 2018, all applications and submissions, addressed to the Office of New Animal Drug Evaluation (ONADE), need to be submitted to the Center for Veterinary Medicine (CVM) electronically using the eSubmitter tool. Paper submissions are no longer accepted by ONADE/CVM. For information about submitting electronically to CVM, please see our website:

https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ElectronicSubmissions/default.htm. If you have any questions regarding electronic submissions, email CVM's Electronic Submissions Support Team at cvmesubmitter@fda.hhs.gov.

If you submit correspondence relating to this letter, your correspondence should reference the date and the principal submission identifier at the top of this letter. If you have any questions or comments, please contact me at 240-402-0817 or at cindy.burnsteel@fda.hhs.gov. You may also contact Dr. Jennifer Matysczak, Leader, Aquaculture Drugs Team, at 240-402-0588 or at jennifer.matysczak@fda.hhs.gov.

Sincerely,

{see appended electronic signature page}
Cindy L. Burnsteel, DVM
Director, Division of Therapeutic
Drugs for Food Animals
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

Enclosure:
Draft Section of Freedom of Information (FOI) Summary

Electronic Signature Addendum for Submission ID

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Signing Authority (Role)	Letter Date
Cindy Burnsteel (Division Director)	5/31/2019

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