I-013345-P-0037-EF

USDI Fish and Wildlife Service
AADAP Program
Attention: Marilyn Blair, DVM
Branch Manager
4050 Bridger Canyon Road
Bozeman, MT 59715

Re: Effectiveness technical section complete

Dear Dr. Blair:

We consider the Effectiveness technical section to be complete, based upon your submission and the information contained in the investigational new animal drug (INAD) file I-013345. The technical section is complete for the use of chicken gonadotropin releasing hormone II analog (cGnRH IIa) powder for injectable solution for use as a spawning aid in female ictalurids. We received the submission on August 27, 2025.

DRAFT LABELING

Thank you for submitting draft labeling sections related to Effectiveness in this submission. CVM would like to continue working with you and the manufacturing sponsor on the reconstitution and mixing instructions for the product labeling.

ALL FURTHER INFORMATION

The information provided in this submission is acceptable. You do not need to re-submit the information when you submit the All Other Information (AOI) technical section. Please submit any additional information that you become aware of pertaining to Effectiveness of cGnRH IIa when you submit your AOI technical section.

FREEDOM OF INFORMATION (FOI) SUMMARY

We appreciate your cooperation in including the relevant portion of the FOI Summary with this submission. The Effectiveness 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 you a copy when the last technical section is complete.

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.

If you submit correspondence relating to this letter, your correspondence should reference the date and the principal submission identified in this letter. If you have any questions or comments, please contact Suzanne J. Sechen, Ph.D., Branch Chief, Food Animal Branch 2, at 240-402-0814 or at Suzanne.Sechen@fda.hhs.gov.

If you have questions or need assistance with the drug development process or project updates, contact your project manager. If you do not know who your project manager is, send an email to askonapepm@fda.hhs.gov.

Sincerely,

{see appended electronic signature page}
Crystal Groesbeck, Ph.D.
Director, Division of Food Animal Drugs
Office of New Animal Product Evaluation
Center for Veterinary Medicine

Enclosure
Draft section of the FOI Summary

Electronic Signature Addendum for Submission ID

I-013345-P-0037-EF

Signing Authority (Role)	Letter Date
Crystal Groesbeck (Division Director)	2/19/2026

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.