

INAD 9757 P-0006 & T-0009

July 12, 2002

Meg R. Oeller, DVM  
FDA Liaison to NRSP-7  
Center for Veterinary Medicine  
7519 Standish Place, MPN-4  
Rockville, MD 20855

Dear Dr. Oeller:

We refer to your submission dated September 20, 2001, as amended April 10, 2002, to your investigational new animal drug (INAD) file for the use of crude carp pituitary (CCP) as a spawning aid in fish. The submission provided data to support the effectiveness technical section.

Based on information in this submission, the Division of Therapeutic Drugs for Food Animals considers the EFFECTIVENESS technical section complete for the purpose of recommending approval of a New Animal Drug Application for the use of CCP as a spawning aid in female finfish raised in freshwater. Please provide a copy of this letter in Section 8 (FDA form 356V), EVIDENCE TO ESTABLISH SAFETY AND EFFECTIVENESS, of your administrative NADA.

A final decision on the approval of the application will be made when all the data for all technical sections are viewed as a whole and it is determined that:

- 1) the information contained in and referenced by the application supports approval;
- 2) the GMP status of each manufacturing facility is current and satisfactory;
- 3) if a claim for categorical exclusion was made, conditions for the categorical exclusion are still applicable.
- 4) there is no new information that would preclude the approval of the application.

The data demonstrate that the effective dose range of common CCP is 2.5-10 mg/kg administered as one or two intraperitoneal injections to female fish. The quantity and quality of the data provided is inadequate to support effectiveness for the use of CCP in male fish. The following specific doses and dose ranges can be included on the label.

<b>Species</b>	<b>Family</b>	<b>Dose (mg/kg)</b>
Muskellunge ( <i>Esox masquinongy</i> )	Esocidae	2.75-10
Northern pike ( <i>Esox lucius</i> )	Esocidae	2.5-10
Channel catfish ( <i>Ictalurus punctatus</i> )	Ictaluridae	10
Walleye ( <i>Stizostedion vitreum</i> )	Percidae	6.6
Koi ( <i>Cyprinus</i> sp.)	Cyprinidae	7
Shortnose sturgeon ( <i>Acipenser brevirostrum</i> )	Acipenseridae	4
Bonytail chub ( <i>Gila elegans</i> )	Leuciscinae	4

The FOI summary as written needs revision. The effectiveness section should be modified to include data from INAD 8105 during years 1992-2001 and from INAD 8391 during years 1996, 1999 and 2000. Also, data from INAD 8770 may be included. Only data from the treatment of female fish should be included.

Future correspondence regarding this letter should be identified by the date of this correspondence and our file number, INAD 9757 P-0006, and be addressed to the Document Control Unit, HFV-199. Please include only one request per submission, clearly stating the request in the first paragraph of the submission.

If you have any questions or comments regarding this correspondence, please telephone Dr. Joan Gotthardt at 301-827-7571.

Sincerely yours,

Thomas Letonja, D.V.M., M.S., Ph.D.  
Acting Director, Division of Therapeutic  
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