

Channel Catfish Pituitary Clinical Field Trials - INAD 11-468

Year 2010 Annual Summary Report on the Use of Channel Catfish Pituitary in Field Efficacy Trials

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Summary

Spawning aids such as channel catfish pituitary (CP), common carp pituitary (CCP), luteinizing hormone-releasing hormone analogue, and human chorionic gonadotropin are used in fisheries programs to induce gamete maturation in fish to enhance fish propagation programs. The U.S. Food and Drug Administration has authorized the use of CP under the Compassionate Investigational New Animal Drug (INAD) Exemption #11-468 for the purpose of gathering efficacy data to support a new animal drug approval for CP. In calendar year 2010 (CY10), two INAD trials were conducted to evaluate the efficacy of CP to induce gamete maturation in channel catfish. Trials involved 2,148 treated fish and were conducted at two private fish hatcheries. Efficacy was determined by whether or not treated fish (1) produced or yielded eggs or milt, or (2) produced or yielded more eggs or milt than untreated fish. Overall, results showed that these CP treatments appeared to be efficacious.

Introduction

The use of hormones to induce spawning in fish is critical to the success of many federal, state, private, and tribal fisheries programs. A wide variety of programs, including several that involve the restoration of threatened/endangered species are dependent upon hormone treatment to complete final gamete maturation and ensure successful spawning.

The time of spawning is by its own nature a stressful period for all fish species. The handling required during the artificial spawning of fish complicates an already delicate situation. In order to maintain the health of both wild and domestic brood fish, it is beneficial to minimize overall fish handling. Successful hormone treatment can reduce handling requirements to a single hormone administration event followed by actual gamete collection, thereby greatly reducing overall fish handling.

Studies have shown that final gamete maturation in fish can be induced by the administration of a variety of hormones (Donaldson and Hunter 1983; Goetz 1983). The first reported studies investigating the hormonal control of reproduction in fish utilized intraperitoneal injection of freshly dissected pituitary glands (Houssay, 1931; von Ihering, 1937). The use of CCP was first reported in the United States by Hasler et al., (1939, 1940). These and many other early studies investigating the use of fish pituitaries to induce gamete maturation in a variety of fish species were thoroughly

reviewed by Pickford and Atz (1957) in their comprehensive treatise on the fish pituitary gland.

The efficacy of CCP to induce ovulation and spermiation in fish is well documented (Chaudhuri, 1976), CCP has been shown to induce gamete maturation in a wide variety of species, including certain threatened and endangered species. Common carp pituitary, which has been shown to be particularly effective when used in cool and warm water species, has had a significant, positive impact on federal, state, private, and tribal programs nationwide.

Channel catfish (*Ictalurus punctatus*) pituitary (CP) has also been found to be similarly effective in inducing ovulation and spermiation (Sneed and Clemens, 1960; and Clemens and Sneed, 1968). Although CP has not been widely used to date, it is easily obtainable, and may in fact offer some advantages as compared to CCP with respect to specific use in catfish species.

Purpose

The purpose of this report is to summarize the results of CY10 supplemental CP field efficacy trials. Furthermore, it is expected that these data will be used to enhance the existing CP database that has been established from previous years trials for the purpose of supporting a new animal drug approval for the use of CP in aquaculture.

Facilities, Materials, and Methods

1. Participating Facilities

A total of two trials were conducted at two private hatcheries during CY10. Water temperature during treatments at these testing facilities ranged from 77.0 - 80.0 °F. Overall mean treatment temperature from all trials was 78.5 °F.

2. CP used in trials

All CP used in CY10 trials was supplied by Hybrid Catfish Company, Inverness, MS.

3. Drug dosages

As described in the current authorization, Investigators were allowed to use CP at doses ranging up to 25 mg CP/kg body weight (bw). During this reporting period, the drug dosage used was 10 mg CP/kg bw. CP was administered as a series of two injections.

Fish Species and Gender Treated

1. Species of fish treated

Channel catfish (*Ictalurus punctatus*) was the only fish species that was treated with CP during the reporting period.

2. Gender of fish treated

A total of 2,148 females were injected with CP during the reporting period.

Typically, females are treated with spawning hormones to shorten the egg maturation period or synchronize ovulation. No males were treated with CP during the reporting period.

Data Collected

1. Necropsy Reports

Necropsy reports provide essential information with respect to fish that die or are euthanized during the study period; no necropsy reports were submitted for CY10.

2. Primary response variables

The primary response variables for evaluating the effect of CP were (1) the relative number of female fish that ovulated following treatment, or (2) the number of male fish that reached active spermiation following treatment. With respect to the treatment of females, in some cases, percent hatch and percent eyed eggs were also determined.

3. Spawning interval

The spawning interval is the period of time between the final CP treatment and when treated fish were evaluated for gamete maturation. Where appropriate, the spawning interval was documented.

Discussion of Study Results

1. Summary results on the efficacy of CP to induce gamete maturation (Note:

Summary of CY10 CP efficacy results are listed in Table 1; Table 2 describes the number of trials conducted, fish species and number of fish treated, and treatment regimens used; and Table 3 describes individual CP trials conducted at each facility under this INAD).

A. Efficacy at 10 mg/kg bw

Two trials were conducted in which female channel catfish were injected with CP at a dosage of 10 mg/kg bw (Table 1). Following treatment, there was 65 - 100% ovulation among all treated fish; average ovulation was 83.5%. Overall, treatment appeared efficacious in both trials.

2. Observed Toxicity

No toxicity or adverse effects relating to CP treatment were reported during CY10.

3. Observed Withdrawal Period

All withdrawal times were either met or exceeded.

Current Study Protocol for CP INAD #11-468

Please see the attached current study protocol for CP INAD #11-468. Please note no changes have occurred to this study protocol.

Facility Sign-up List

Please see “Table 4. Facilities and Names of Investigators” for facilities that signed-up to participate in the CP INAD #11-468 during CY10. Facilities not listed in Appendix III-a of the current CP INAD #11-468 study protocol have been highlighted.

Correspondence sent to CP Participants

Please see the attached correspondence that was sent to all CP participants after the AADAP Office received their sign-up form for CY10.

Number of Treated Fish under Treatment Use Authorization

Total number of treated fish during CY10 was 2,148. The total number of treated fish to count against the treatment use authorization dated December 6, 2006 is 5,951.

Summary of Study Results

The efficacy of CP was evaluated in two trials involving channel catfish at a dosage of 10 mg/kg bw. Treatments were administered as a series of 2 injections. A total of 2,148 adult fish were treated. Water temperature during treatments ranged from 77.0 to 80.0°F. Overall, results showed that all CP treatment appeared to be efficacious. The Investigator reported no evidence of toxicity or adverse effects related to CP treatments during CY10. Because of the lack of pivotal field efficacy trials, it is understood that data summarized in this report can only be considered as ancillary data. None-the-less, the ancillary data described above should provide useful corroborative data to support a new animal drug approval for CP. It is anticipated that additional ancillary efficacy data will continue to be collected under INAD #11-468. In future trials conducted under INAD #11-468, efforts will continue to be directed towards the generation of high quality data.

References

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Table 1. Summary of CY10 CP Efficacious Results						Females			
						Treated		Control	
Facility	Number of Trials	Species	Treatment Method	Dose (mg/kg)	Spawning Interval (hr)	Number Treated	% Ovulate	Number Controls	% Ovulate
Baxter Land Co.	1	Channel Catfish	Injection	10	24 - 36	967	66 - 100 (ave 84)	0	na
NeedMore Fisheries	1	Channel Catfish	Injection	10	38	1181	65 - 98 (ave 83)	0	na

Table 2. Description of Number of Trials Conducted, Species and Number of Fish Treated, and Treatment Regimens Used in CY10 under CP INAD #11-468

Total Number of Trials Conducted:	2
Number of Efficacious Trials:	2
Total Number of Fish Treated:	2,148
Treatment Regimes Used:	
10 mg/kg body weight (2 injections)	2 trials
Treatment Water Temperature (°F):	77.0 - 80.0
Size of Treated Fish:	Adult
Species Treated:	channel catfish <i>Ictalurus punctatus</i>
