

## **Channel Catfish Pituitary Clinical Field Trials - INAD 11-468**

### Year 2014 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 2014 (CY14), one INAD trial was conducted to evaluate the efficacy of CP to induce gamete maturation in channel catfish. This trial involved 3,763 treated fish and was conducted at one private fish hatchery. 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 this CP treatment 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 CY14 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 single trial was conducted at one private hatchery during CY14. Water temperature during treatments at the this testing facility was 80.0 °F.

### **2. CP used in trials**

All CP used in CY14 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 3,763 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 CY14.

### **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 CY14 CP efficacy results are listed in Table 1; and Table 2 describes the trial conducted, fish species and number of fish treated, and treatment regimen used.

#### **A. Efficacy at 10 mg/kg bw**

One trial was conducted in which female channel catfish were injected with CP at a dosage of 10 mg/kg bw (Table 1). Following treatment, there was 77.8% ovulation among all treated fish. Treatment appeared efficacious in this trial.

### **2. Observed Toxicity**

No toxicity or adverse effects relating to CP treatment were reported during CY14.

### **3. Observed Withdrawal Period**

All withdrawal times were either met or exceeded.

#### **Current Study Protocol for CP INAD #11-468**

No changes have occurred to the current study protocol for CP INAD #11-468.

#### **Facility Sign-up List**

Please see “Table 3. Facilities and Names of Investigators” for facilities that signed-up to participate in the CP INAD #11-468 during CY14.

#### **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 CY14.

#### **Number of Treated Fish under Treatment Use Authorization**

Total number of treated fish during CY14 was 3,763. The total number of treated fish to count against the treatment use authorization dated June 29, 2012 is 7,416 (which includes 355 fish that were over the previous authorization). The total number of treated fish to count against the treatment use authorization dated June 11, 2014 is zero.

## **Summary of Study Results**

The efficacy of CP was evaluated in one trial involving channel catfish at a dosage of 10 mg/kg bw. Treatments were administered as a series of 2 injections. A total of 3,763 adult fish were treated. Water temperature during treatments was 80.0°F. Results showed that this CP treatment appeared to be efficacious. The Investigator reported no evidence of toxicity or adverse effects related to CP treatments during CY14. 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 CY14 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
Wright Fish Farm	1	Channel Catfish	Injection	10	24	3,763	77.8	0	na

Table 2. Description of Number of Trials Conducted, Species and Number of Fish Treated, and Treatment Regimens Used in CY14 under CP INAD #11-468

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<b>Total Number of Trials Conducted:</b>	1
Number of Efficacious Trials:	1
<b>Total Number of Fish Treated:</b>	3,763
<b>Treatment Regimes Used:</b>	
10 mg/kg body weight (2 injections)	1 trial
<b>Treatment Water Temperature (°F):</b>	80.0
<b>Size of Treated Fish:</b>	Adult
<b>Species Treated:</b>	channel catfish <i>Ictalurus punctatus</i>

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