

Common Carp Pituitary Clinical Field Trials - INAD 8391

1999 Annual Summary Report on the Use of Common Carp Pituitary in Field Efficacy Trials

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Summary

Common Carp Pituitary (CCP) was used at one state fish hatchery and two private fish hatcheries during 1999 to evaluate the efficacy of this drug (hormone) to induce gamete maturation in a variety of fish species. The U.S. Food and Drug Administration has authorized the use of this compound under Compassionate Investigational New Animal Drug Exemption #8391 for the purpose of collecting pivotal and ancillary efficacy data to support a new animal drug approval for Common Carp Pituitary. Common Carp Pituitary was administered in 12 trials and involved a total of 492 fish. Treatment results appeared efficacious in all trials.

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. In many cases, especially with respect to captured wildstock species, final gamete maturation will not occur without hormone treatment.

Final gamete maturation in fish can be induced by the administration of a variety of hormones. Common Carp Pituitary (CCP) has been shown to induce gamete maturation in a number of fish species, including certain threatened and endangered species. CCP has been shown to be particularly effective when used in cool and warm water species. CCP has had a significant, positive impact on federal, state, private, and tribal programs nationwide.

Purpose

The primary purpose of this report is to summarize the results of calendar year 1999 (CY 99) supplemental CCP field efficacy studies. However, it is also expected that these data will be used to enhance the existing CCP database that has been established from previous years studies for the purpose of supporting a new animal drug approval for the use of CCP in aquaculture.

Facilities, Materials, and Methods

1. Facilities

One state fish hatchery and two private fish hatcheries used CCP during CY99.

2. CCP used in trials

All CCP used in trials was supplied by Stoller Fisheries, Spirit Lake IA.

3. Drug dosages

As described in the Study Protocol, Investigators were allowed to use CCP at dosages between 4 - 10 mg CCP/kg body weight. The drug dosages used in these studies ranged from 2 - 10 mg CCP/kg (in both males and females). CCP was administered as either a single intraperitoneal injection, or as a series of two injections.

Fish Species and Gender Treated

1. Species of fish treated

Four different fish species were treated during CY 99. Species treated included channel catfish (*Ictalurus punctatus*), goldfish (*Carassius auratus*), koi (*Cyprinus sp.*), and muskellunge (*Esox masquinongy*).

2. Gender of fish treated

In CY 99 trials, 382 female and 110 male fish were administered CCP. Typically, females are treated with spawning hormones to shorten the egg maturation period or synchronize ovulation. Males are treated to ensure that sufficient milt is available for egg fertilization.

Data Collected

1. Pathologists Reports

Fish health pathology reports provide essential information with respect to disease confirmation and general fish health. However, no pathology reports were submitted during CY 99 studies.

2. Primary response variables

The primary response variables for evaluating the effect of CCP were observed ovulation in female and spermiation in male treated fish. With respect to the treatment of females, in some cases, percent hatch and percent eyed eggs was also determined.

3. Spawning interval

Data with respect to the time period between CCP treatment and observed ovulation or spermiation was also collected.

Discussion of Study Results

- 1. Summary results on the efficacy of CCP to induce gamete maturation** (Note: A summary of all individual CCP studies conducted during CY 99 under INAD 8391 is presented in Table 1; and summary data regarding all studies conducted is presented in Table 3)

A. Efficacy at 2.0 mg/kg body weight

CCP was used at 2.0 mg/kg in 3 trials involving male goldfish (Table 2). Non-treated control groups were used in all trials. Percent spermiation in treated groups ranged from 80 - 100%, as compared to 0 - 40% spermiation in control groups. Treatment was efficacious in all trials

B. Efficacy at 6.6 mg/kg body weight

CCP was used at 6.6 mg/kg in a single trial involving female muskellunge (Table 2). This trial involved a non-treated control group. Percent ovulation in the treated group was 83%, as compared to 0% ovulation in the control group. Treatment was efficacious.

C. Efficacy at 7.0 mg/kg body weight

CCP was used at 7.0 mg/kg in 3 trials involving female koi (Table 2). Non-treated control groups were used in all trials. Percent ovulation in the treated groups ranged from 75 - 93%, as compared to 0 - 7% ovulation in control groups. Treatment was efficacious.

D. Efficacy at 10.0 mg/kg body weight

CCP was used at 10.0 mg/kg in 5 trials involving female channel catfish (Table 2). Percent ovulation in treated groups ranged from 20 - 84%. Treatment appeared to be efficacious in all trials

2. Observed Toxicity

No toxicity or adverse effects relating to CCP treatment were reported.

Summary of Study Results

CCP was used at dosages ranging from 6.6 - 10.0 mg/kg body weight in female fish, and at 2.0 mg/kg body weight in male fish. Treatment was administered as either a single intraperitoneal injection, or as a series of two injections. CCP was used in 12 individual trials, 7 of which utilized non-treated control groups. A total of 492 adult fish were treated. Water temperature during treatment ranged from 52 - 82°F. CCP treatment appeared to be efficacious in all trials. Furthermore, investigators reported no evidence of toxicity or adverse effects related to CCP treatment. It is understood that these data 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 CCP. It is anticipated that additional ancillary efficacy data will continue to be collected under INAD #8391. In future trials conducted under INAD #8391, efforts will be directed towards the continued generation of high quality data.

Table 2. Summary of 1999 CCP Efficacy Results

					Females				Males			
					Treated		Control		Treated		Control	
Facility	Species	Treatment Method	Dose (mg/kg)	Spawning Interval (hr)	Number Treated	% Ovulate	Number Controls	% Ovulate	Number Treated	% Spermiate	Number Controls	% Spermiate
Gold Kist Inc.	Channel Catfish	Injection	10	36-40	50	20	0	na	0	na	0	na
Gold Kist Inc.	Channel Catfish	Injection	10	36-40	49	84	0	na	0	na	0	na
Gold Kist Inc.	Channel Catfish	Injection	10	36-40	47	83	0	na	0	na	0	na
Gold Kist Inc.	Channel Catfish	Injection	10	36-40	47	45	0	na	0	na	0	na
Gold Kist Inc.	Channel Catfish	Injection	10	36-40	49	61	0	na	0	na	0	na
Dutchman Creek Fish Farm	Goldfish	Injection	2	12	0	na	0	na	50	80	25	40
Dutchman Creek Fish Farm	Goldfish	Injection	2	12	0	na	0	na	53	75	25	36
Dutchman Creek Fish Farm	Goldfish	Injection	2	12	0	na	0	na	7	100	5	0
Dutchman Creek Fish Farm	Koi	Injection	7	12	25	75	25	0	0	na	0	na
Dutchman Creek Fish Farm	Koi	Injection	7	12	29	83	29	0	0	na	0	na
Dutchman Creek Fish Farm	Koi	Injection	7	12	68	93	30	7	0	na	0	na
Hackettstown SFH	Muskellunge	Injection	6.6	48-144	18	83.3	5	0	0	na	0	na

Table 3. Summary Data Regarding 1999 CCP Efficacy Studies

Total Number of Fish Treated:	492
Treatment Regimes Used:	
2.0 mg/kg body weight (two injections)	3 trials
6.6 mg/kg body weight (one injection)	1 trial
7.0 mg/kg body weight (two injections)	3 trials
10.0 mg/kg body weight (two injections)	5 trials
Treatment Water Temperature (°C):	52.0 - 82.0
Size of Treated Fish:	Adult
Species Treated:	channel catfish (<i>Ictalurus punctatus</i>) goldfish (<i>Carassius auratus</i>) koi (<i>Cyprinus sp.</i>) muskellunge (<i>Esox masquinongy</i>)
