

Common Carp Pituitary Clinical Field Trials - INAD 8391

Year 2000 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 two U.S. Fish and Wildlife Service fish hatcheries, one state fish hatchery, and one private fish hatchery during Calendar Year 2000 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 26 trials and involved a total of 1,214 fish. Approximately 96% of the trials appeared efficacious, while 4% appeared ineffective.

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 (CY) 2000 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

Two U.S. Fish and Wildlife Service fish hatcheries, one state fish hatchery, and one private fish hatchery used CCP during CY 2000.

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 1 - 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

Five different fish species were treated during CY 2000. Species treated included channel catfish (*Ictalurus punctatus*), muskellunge (*Esox masquinongy*), river shiner (*Notropis girardi*), shortnose sturgeon (*Acipenser brevirostrum*), and walleye (*Stizostedion vitreum*).

2. Gender of fish treated

In CY 2000 trials, approximately 1009 female and approximately 205 male fish were administered CCP. A total of 340 river shiners were treated; however, there are no reliable means of determining sex of this species using external characteristics (170 are sexed as female and 170 are sexed as male for this report). 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 2000 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 were also collected.

Discussion of Study Results

- 1. Summary results on the efficacy of CCP to induce gamete maturation** (Note: efficacy data for all CY 2000 studies is presented in Table 1; summary data regarding all studies conducted is presented in Table 2; and a summary of all state and private individual CCP studies conducted is presented in Table 3.)

A. Efficacy at 1.0 mg/kg body weight

CCP was used at 1.0 mg/kg in 6 trials involving male shortnose sturgeon (Table 1). Percent spermiation in treated groups ranged from 80 - 100%. Treatment appeared to be efficacious in all trials

B. Efficacy at 4.0 mg/kg body weight

CCP was used at 4.0 mg/kg in 6 trials involving female shortnose sturgeon (Table 1). Percent ovulation in the treated groups ranged from 0 - 100%. Treatment appeared to be efficacious in 5 trials and non-efficacious in 1 trial.

C. Efficacy at 6.6 mg/kg body weight

CCP was used at 6.6 mg/kg in a single trial involving female muskellunge, and in a single trial involving female walleye (Table 1). These trials involved a non-treated control group. Percent ovulation in both of the treated groups was 80%, as compared to 0% ovulation in the control group of walleye and 50% ovulation in the control group of muskellunge. Both treatments were efficacious.

D. Efficacy at 10.0 mg/kg body weight

CCP was used at 10.0 mg/kg in 10 trials involving female channel catfish, 1 trial involving female river shiners, and 1 trial involving male river shiners (Table 1). Percent ovulation in treated female channel catfish groups ranged from 17 - 93%. Percent ovulation and percent spermiation in treated river shiners were unknown; however, eggs were recovered within 12 hours of injection and fry hatched approximately 16 hours later. 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 4.0 - 10.0 mg/kg body weight in female fish, and at 1.0 - 10.0 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 26 individual trials, 2 of which utilized non-treated control groups. A total of 1,214 adult fish were treated. Water temperature during treatment ranged from 52 - 82°F. CCP treatment appeared to be efficacious in 96% of the trials, and inefficacious in 4% of the 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 1. Summary of CY 2000 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	91	46	0	na	0	na	0	na
Gold Kist Inc.	Channel Catfish	Injection	10	36-40	100	44	0	na	0	na	0	na
Gold Kist Inc.	Channel Catfish	Injection	10	36-40	110	72	0	na	0	na	0	na
Gold Kist Inc.	Channel Catfish	Injection	10	36-40	88	17	0	na	0	na	0	na
Gold Kist Inc.	Channel Catfish	Injection	10	36-40	116	53	0	na	0	na	0	na
Gold Kist Inc.	Channel Catfish	Injection	10	36-40	94	35	0	na	0	na	0	na
Gold Kist Inc.	Channel Catfish	Injection	10	36-40	79	84	0	na	0	na	0	na
Gold Kist Inc.	Channel Catfish	Injection	10	36-40	50	18	0	na	0	na	0	na
Gold Kist Inc.	Channel Catfish	Injection	10	36-40	30	93	0	na	0	na	0	na
Gold Kist Inc.	Channel Catfish	Injection	10	36-40	42	62	0	na	0	na	0	na
Hackettstown SFH	Muskellunge	Injection	6.6	2 - 7 days	10	80	2	50	0	na	0	na

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Tishomingo NFH	River Shiner	Injection	10	12 - 24 hrs	170	unsure - eggs were collected & hatched	0	na	170	unsure - eggs were collected & hatched	0	na
Bears Bluff NFH	Shortnose Sturgeon	Injection	4.0 - F 1.0 - M	29 - 36 hrs	3	100	0	na	6	100	0	na
Bears Bluff NFH	Shortnose Sturgeon	Injection	4.0 - F 1.0 - M	29 - 36 hrs	4	100	0	na	7	100	0	na
Bears Bluff NFH	Shortnose Sturgeon	Injection	4.0 - F 1.0 - M	29 - 36 hrs	2	100	0	na	7	100	0	na
Bears Bluff NFH	Shortnose Sturgeon	Injection	4.0 - F 1.0 - M	29 - 36 hrs	3	100	0	na	6	83.3	0	na
Bears Bluff NFH	Shortnose Sturgeon	Injection	4.0 - F 1.0 - M	29 - 36 hrs	1	100	0	na	5	80	0	na
Bears Bluff NFH	Shortnose Sturgeon	Injection	4.0 - F 1.0 - M	29 - 36 hrs	1	0	0	na	4	100	0	na
Hackettstown SFH	Walleye	Injection	6.6	1 - 7 days	15	80	7	14	0	na	0	na

Table 2. Summary Data Regarding CY 2000 CCP Efficacy Studies

Total Number of Fish Treated: 1,214

Treatment Regimes Used:

1.0 mg/kg body weight (one injection)	6 trials
4.0 mg/kg body weight (two injections)	6 trials
6.6 mg/kg body weight (one injection)	2 trials
10.0 mg/kg body weight (one - two injections)	12 trials

Treatment Water Temperature (°C): 52.0 - 82.0

Size of Treated Fish: Adult

Species Treated: channel catfish (*Ictalurus punctatus*)
muskellunge (*Esox masquinongy*)
river shiner (*Notropis girardi*)
shortnose sturgeon (*Acipenser brevirostrum*)
walleye (*Stizostedion vitreum*).
