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 only one U.S. Fish and Wildlife Service fish hatchery 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 a 12 trials and involved a total of 72 fish. Treatment results appeared to be effective in all 12 trials.

Introduction

The use of hormones to induce spawning in fish is critical to the success of many U.S. Fish and Wildlife Service (Service) 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. It has also been used for research purposes in a number of Service and USGS/BRD fisheries and technology development programs. CCP has had a significant, positive impact on Service fisheries 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

A single U.S. Fish and Wildlife Service National Fish Hatchery (Bears Bluff NFH) used CCP during CY 99.

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 dosage used in this study was 1.8 mg CCP/kg for females and 0.45 mg CCP/kg for males. CCP was administered by an intramuscular injection (1-2 injections/fish).

Fish Species and Gender Treated

1. Species of fish treated

A single fish species, shortnose sturgeon (*Acipenser brevirostrum*) was treated with CCP during CY 99.

2. Gender of fish treated

In CY 99 trials, 23 female and 49 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 HCG were observed ovulation in female and spermiation in male treated fish.

3. Spawning interval

Data with respect to the time period between CCP treatment and observed final gamete maturation was also collected.

Discussion of Study Results

1. Summary results on the efficacy of CCP to induce gamete maturation

CCP was administered to male and female shortnose sturgeon at a dosage of 1.8 mg CCP/kg for females and 0.45 mg CCP/kg for males (Table 1). Fish received 1 - 2 intramuscular injections. CCP treatment resulted in 60 - 80% spermiation in 6 trials of male shortnose sturgeon, and 50 - 100% ovulation in 6 trials of female shortnose sturgeon. CCP treatment appeared to be efficacious.

2. Observed Toxicity

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

Summary of Study Results

CCP was used at a dosage of 1.8 mg CCP/kg for female shortnose sturgeon and 0.45 mg CCP/kg for male shortnose sturgeon. Treatment was administered as an intramuscular injection (1 - 2 injections/fish). HCG was used in 12 individual trials involving 1 fish species (Table 1). Water temperature during treatment was 13^{o}C. HCG treatment appeared to be effective in 100% of the trials. Overall, HCG treatment appeared to be efficacious in inducing final gamete maturation. Furthermore,

Investigators reported no evidence of toxicity or adverse effects related to HCG 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 generation of higher quality data.

Table 1. 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
Bears Bluff NFH	Shortnose sturgeon	Injection	0.45	30 - 36	0	0	0	na	10	60	0	na
Bears Bluff NFH	Shortnose sturgeon	Injection	0.45	30 - 36	0	0	0	na	10	40	0	na
Bears Bluff NFH	Shortnose sturgeon	Injection	0.45	30 - 36	0	0	0	na	5	60	0	na
Bears Bluff NFH	Shortnose sturgeon	Injection	0.45	30 - 36	0	0	0	na	9	78	0	na
Bears Bluff NFH	Shortnose sturgeon	Injection	0.45	30 - 36	0	0	0	na	5	80	0	na
Bears Bluff NFH	Shortnose sturgeon	Injection	0.45	30 - 36	0	0	0	na	10	40	0	na
Bears Bluff NFH	Shortnose sturgeon	Injection	1.8	30 - 36	3	100	0	na	0	0	0	na
Bears Bluff NFH	Shortnose sturgeon	Injection	1.8	30 - 36	6	67	0	na	0	0	0	na
Bears Bluff NFH	Shortnose sturgeon	Injection	1.8	30 - 36	2	100	0	na	0	0	0	na
Bears Bluff NFH	Shortnose sturgeon	Injection	1.8	30 - 36	5	80	0	na	0	0	0	na
Bears Bluff NFH	Shortnose sturgeon	Injection	1.8	30 - 36	3	100	0	na	0	0	0	na
Bears Bluff NFH	Shortnose sturgeon	Injection	1.8	30 - 36	4	50	0	na	0	0	0	na

Table 2. Summary Data Regarding 1999 CCP Efficacy Studies

Total Number of Fish Treated:	72
Treatment Regimes Used:	
0.45 mg/kg body weight (one injection)	6 trials
1.80 mg/kg body weight (two injections)	6 trials
Treatment Water Temperature (°C):	13.0
Size of Treated Fish:	Adult
Species Treated:	shortnose sturgeon (*Acipenser brevirostrum*)