

Common Carp Pituitary Clinical Field Trials - INAD 8391

1998 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 1998 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 single trial and involved a total of 12 fish. Treatment results were inconclusive. Although spawning behavior was observed in treated fish (fish were left to spawn naturally in a pond), no fry were produced.

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 1998 (CY 98) 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 (Private John Allen NFH) used CCP during CY 98.

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 8 mg CCP/kg (both males and females). CCP was administered as a single intraperitoneal injection.

Fish Species and Gender Treated

1. Species of fish treated

A single fish species, alligator gar (*Lepisosteus spatula*) was treated with CCP during CY 98.

2. Gender of fish treated

In CY 98 trials, 5 female and 7 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 98 studies.

2. Primary response variables

The primary response variables for evaluating the effect of CCP were observed spawning behavior of fish in ponds and harvested fry collected 1-3 weeks post "spawning".

3. Spawning interval

Data with respect to the time period between CCP treatment and observed spawning behavior was also collected.

Discussion of Study Results

1. Summary results on the efficacy of CCP to induce spawning in alligator gar

CCP was administered to male and female alligator gar at a dosage of 8 mg/kg body weight (Table 1). Fish received a single intraperitoneal injection. Following injection, all fish were returned to a pond that had been prepared for "natural spawning". Fifty-four hours post-injection, fish were observed exhibiting known spawning behavior. However, seining of the pond at 1 and 2 weeks post-treatment did not result in the recovery of any fry. The pond was drained 21 days post-treatment, but once again, no fry were recovered. As a result, treatment efficacy was inconclusive.

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 8 mg/kg body weight. Treatment was administered as a single intraperitoneal injection. The single trial involved male and female alligator gar. A

total of 12 adult fish were treated. Water temperature during treatment was 22.2°C. Although fish were observed exhibiting known spawning behavior 54 hr post-treatment, no fry were produced. As a result, treatment efficacy was inconclusive. However, it should be noted that the Investigator 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 generation of higher quality data.

Table 1. Summary of 1998 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
Private John Allen NFH	Alligator Gar	Injection	8	54-76	5	unknown	0	na	7	unknown	0	na

Table 2. Summary Data Regarding 1998 CCP Efficacy Studies

Total Number of Fish Treated:	12
Treatment Regimes Used:	
8 mg/kg body weight (one injection)	1 trial
Treatment Water Temperature (°C):	22.2
Size of Treated Fish:	Adult
Species Treated:	Alligator gar (<i>Lepisosteus spatula</i>)
