U.S. Fish & Wildlife Service

The Aquatic Animal Drug Approval Partnership Program

Fact Sheet: Oxytetracycline Medicated Feed INAD 9332

INAD objective/purpose:	Collect supportive and pivotal data needed to establish the effectiveness of oxytetracycline (OTC) when fed as a feed additive to 1) control mortality caused by bacterial diseases in a variety of freshwater and marine fish, and abalone; and 2) mark skeletal tissue of finfish.
Drug name:	Oxytetracycline dihydrate (Terramycin 200® for Fish)
Source of drug:	Phibro Animal Health
Address:	65 Challenger Road; Ridgefield, NJ 07660
Contact:	Paul Duquette; Phone: 973-575-5255; Fax: 973-575-4354; email: paul.duquette@pahc.com
Target pathogen(s):	Bacterial pathogens susceptible to oxytetracycline.
Method of administration:	Medicated-feed treatment
Treatment dosage:	**Standard therapeutic finfish dose:** 2.5 - 3.75 g OTC per 100 pounds fish per day. **High therapeutic finfish dose:** 10 g OTC per 100 pounds fish body weight per day. **Standard abalone dose:** up to 6.0 g OTC per 100 pound abalone body weight per day. **Skeletal marking dose:** same as standard or high therapeutic finfish dose.
Treatment regimen:	**Option A**: standard therapeutic finfish dose; 10-day treatment duration (all salmonids). **Option B:** high therapeutic finfish dose; 14-day treatment duration; temp > 4°C (all finfish). **Option C:** standard therapeutic finfish dose; 10-day treatment duration (non-salmonid freshwater and marine fish). **Option D:** standard abalone dose; 14-day treatment duration. **Option E:** skeletal marking at standard therapeutic dose, 10-day treatment duration; skeletal marking at high therapeutic dose, 14-day treatment duration.
Withdrawal period:	**Option A:** 21 days. **Option B:** 70 days. **Option C:** 40 days. **Option D:** 35 days. **Option E (standard dose):** 21 days (salmonids); 40 days (non-salmonids). **Option E (high dose):** 70 days (all finfish). No withdrawal period is required for treated fish that will not be susceptible to legal harvest or slaughtered for market for the appropriate number of days as specified in the Options listed above.
Required test parameters:	Investigator must collect mortality data throughout the 5 day pre-treatment, treatment, and 21 day post-treatment periods. Investigator should also report general fish behavior and any possible adverse effects relating to treatment.
Limitations or restrictions on use of drug:	Investigator must follow all instructions in the Study Protocol for INAD 9332 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements. Drug discharge must be in compliance with local NPDES permitting requirements.
Required INAD fee:	$400.00/facility
AADAP Contact Information:	Ms. Bonnie Johnson, FWS-AADAP Phone: 406-994-9905 Fax: 406-582-0242 email: bonnie_johnson@fws.gov
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The Aquatic Animal Drug Approval Partnership Program

Fact Sheet: Oxytetracycline Injectable INAD 9027

INAD objective/purpose:	Collect supportive and pivotal data needed to establish the effectiveness of oxytetracycline (OTC) injectable therapy to control mortality caused by certain bacterial diseases.
Drug name:	Liquamycin® LA-200®
Source of drug:	Pfizer, Inc.
Address:	Pfizer Animal Health 700 Portage Road RIC-190-43 Kalamazoo, MI 49001-0199
Contact:	Dr. Mark Subramanyam Phone: 269-833-3388; Fax: 269-833-2707 Email: mark.subramanyam@pfizer.com
Target pathogen(s):	Bacterial pathogens susceptible to oxytetracycline.
Method of administration:	IP or IM injection
Treatment dosage:	20 milligrams per kilogram body weight
Treatment regimen:	***Option A:*** Single injection; all salmonids ***Option B:*** Single injection; all non-salmonids
Withdrawal period:	30 days No withdrawal period is required for treated fish that will not be susceptible to legal harvest for at least 30 days posttreatment.
Required test parameters:	Investigator must collect mortality data throughout the 5 day pretreatment, treatment, and 30 day posttreatment periods. Investigator should also report general fish behavior and any adverse effects relating to treatment.
Limitations or restrictions on use of drug:	Investigator must follow all instructions in the Study Protocol for INAD 9027 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements. Drug discharge must be in compliance with local NPDES permitting requirements.
Required INAD fee:	$400.00 per facility per year
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The Aquatic Animal Drug Approval Partnership Program

Fact Sheet: Oxytetracycline Immersion INAD 9033

INAD objective/purpose:	Collect supportive and pivotal data needed to establish the effectiveness of oxytetracycline (OTC) immersion therapy to control mortality caused by certain bacterial diseases.
Drug name:	Terramycin-343®
Source of drug:	Pfizer, Inc.
Address:	Pfizer Animal Health 700 Portage Road RIC-190-43 Kalamazoo, MI 49001-0199
Contact:	Dr. Mark Subramanyam Phone: 269-833-3388; Fax: 269-833-2707; Email: mark.subramanyam@pfizer.com
Target pathogen(s):	Bacterial pathogens susceptible to oxytetracycline.
Method of administration:	Immersion treatment
Treatment dosage:	***Options A & B:*** single treatment of 20 milligrams OTC per liter. ***Options C & D:*** up to multiple treatments at 20 milligrams OTC per liter.
Treatment regimen:	***Option A:*** 1-hour treatment for salmonids. ***Option B:*** 1-hour treatment for various cool and warmwater fish. ***Option C:*** 1-hour treatment on 1 to 4 consecutive days for salmonids. ***Option D:*** 1-hour treatment on 1 to 4 consecutive days for various cool and warmwater fish.
Withdrawal period:	***Options A & B:*** 21 days. No withdrawal period is required for fish that will not be catchable for 21 or more days after release, or are illegal for harvest. ***Options C & D:*** 60 days. No withdrawal period is required for fish that will not be catchable for 60 or more days after release, or are illegal for harvest.
Required test parameters:	Investigator must collect mortality data throughout the 5 day pretreatment, treatment, and 30 day posttreatment periods. Investigator should also report general fish behavior and any adverse effects relating to treatment.
Limitations or restrictions on use of drug:	Investigator must follow all instructions in the Study Protocol for INAD 9033 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements. Drug discharge must be in compliance with local NPDES permitting requirements.
Required INAD fee:	$400.00 per facility per year
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The Aquatic Animal Drug Approval Partnership Program

Fact Sheet: 17-α Methyltestosterone INAD 11-236

[For detailed information see INAD Study Protocol]

INAD objective/purpose:	Collect supportive and pivotal data needed to establish the effectiveness of 17-α methyltestosterone when fed as a feed additive to larval tilapia to produce populations comprising over 90% male fish.
Drug name:	17-α methyltestosterone (MT)
Source of drug/feed:	Rangen Inc.
Address:	P.O. Box 706 Buhl, ID 83316
Contact:	Attention: David Brock Phone: 1-800-657-6446 x 3332 Fax: 208-543-8037 email: dbrock@rangen.com
Target pathogen(s):	Not Applicable
Method of administration:	Medicated-feed treatment
Treatment dosage:	9 milligrams (mg) MT per kilogram (kg) fish per day Note: MT will typically be incorporated into standard tilapia feed at a rate of 60 mg MT per kg feed
Treatment regimen:	28 consecutive days
Withdrawal period:	Batch Culture: 120 days (from last day of treatment) Note: Batch culture is defined as when all fish in a group/lot enter and leave the lot at the same time. Partial Harvest/Restock Culture: individual minimum weight of 350 grams per fish Note: Partial harvest/restock culture is defined as the mixing of different lots of fish during the grow-out period and selective harvest from the production unit at various times.
Required test parameters:	A minimum of once per calendar year, a minimum of 60 fish must be sampled from a specific treatment lot to determine the sex ration of the population. Investigator should also report general fish behavior and any adverse effects relating to treatment.
Limitations or restrictions on use of drug:	No re-treatment of fish is allowed. Investigator must follow all instructions in the Study Protocol for INAD 11-236 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements. Drug discharge must be in compliance with local NPDES permitting requirements.
Required INAD fee:	$600.00 per facility per year
AADAP Contact Information:	Ms. Bonnie Johnson, FWS-AADAP Phone: 406-587-9265 ext 136 Fax: 406-582-0242 email: bonnie_johnson@fws.gov
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The Aquatic Animal Drug Approval Partnership Program

Fact Sheet: LHRHa INAD 8061

INAD objective/purpose:	Collect supportive and pivotal data needed to establish the effectiveness of LHRHa to induce gamete maturation in a variety of fish species.
Drug name:	Luteinizing-Hormone - Releasing Hormone analogue (des-Gly^{10}, [D-Ala^{6}] LH-RH Ethylamide) - LHRHa
Source of drug:	Western Chemical, Inc.
Address:	1269 Lattimore Road Ferndale, WA 98248 USA
Contact:	Attention: Jim Brackett Toll Free: 800-283-5292 Tel: 360-384-5898 email: brackett@wchemical.com
Target pathogen(s):	Not Applicable
Method of administration:	Injectable only, implants not permitted
Treatment dosage:	5 - 100 micrograms LHRHa per kilogram body weight
Treatment regimen:	Single or multiple treatment. Multiple treatment will generally consist of a single "priming dose," followed by a single "resolving dose." Administered IP or IM.
Withdrawal period:	14 days for all fish; no withdrawal period is required for injected fish that will not be susceptible to legal harvest for at least 14 days posttreatment.
Required test parameters:	Investigator must collect data reporting percent ovulation and/or percent spermiation in treated fish. Investigator should also report general fish behavior and any adverse effects relating to treatment.
Limitations or restrictions on use of drug:	Investigator must follow all instructions in the Study Protocol for INAD 8061 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements. Use of LHRHa implants is not authorized
Required INAD fee:	$400.00 per facility per year
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The Aquatic Animal Drug Approval Partnership Program

Fact Sheet: Potassium Permanganate INAD 9246

[For detailed information see INAD Study Protocol]

INAD objective/purpose:	Collect supportive and pivotal data needed to establish the effectiveness of potassium permanganate to control external protozoan and metazoan parasites, and bacterial and fungal infections in a variety of warmwater fish species.
Drug name:	Potassium permanganate (Cairox)
Source of drug:	Carus Chemical Company
Address:	315 5th Street Peru, IL 61354-0599
Contact:	Brenda Veronda Phone: 815-224-6557; Fax: 815-224-6697; email: brenda.veronda@caruschem.com
Target pathogen(s):	external parasites, bacteria, and fungi
Method of administration:	Immersion: standing-bath or flow-through treatment
Treatment dosage:	1 - 10 milligrams potassium permanganate per liter
Treatment regimen:	Treatment duration is 1 hour. Although a single treatment event is generally efficacious, repeated treatments may be used.
Withdrawal period:	7 days No withdrawal period is required for fish that are not susceptible to legal harvest for a period of 7 days posttreatment.
Required test parameters:	Investigator must collect data indicating pretreatment pathogen level, and pathogen level at 1, 4, and 18 hours posttreatment. Investigator should also report general fish behavior and any adverse effects relating to treatment.
Limitations or restrictions on use of drug:	Investigator must follow all instructions in the Study Protocol for INAD 9246 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements. Drug discharge must be in compliance with local NPDES permitting requirements.
Required INAD fee:	None
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The Aquatic Animal Drug Approval Partnership Program

Fact Sheet: 35% PEROX-AID® INAD 11-669

INAD objective/purpose:	Collect supportive and pivotal data needed to establish the effectiveness and safety of hydrogen peroxide to control mortality caused by ectoparasites in a variety of fish species.
Drug name:	35% PEROX-AID® (hydrogen peroxide)
Source of drug:	Eka Chemical Inc.
Address:	1269 Lattimore Road Ferndale, WA 98248 USA
Contact:	Attention: Ron Malnor Toll Free: 800.283.5292 Tel: 360.384.5898 email: ronm@wchemical.com
Target pathogen(s):	Ectoparasites of the genera *Ambiphrya, Chilodonella, Dactylogyrus, Epistylis, Gyrodactylus, Ichthyobodo, Ichthyophthirius, Trichodina, Trichophrya, Argulus*, *Salmincola*, *Lernaea,* and *Ergasilus* in freshwater fish species; and of the genera *Neobenedenia*, *Amyloodinium*, *Cryptocaryon*, and *Uronema* in marine fish species.
Method of administration:	Immersion bath
Treatment dosage:	***Option A***: 100 or 150 milligrams per liter ***Option B:*** 50, 75 or 100 milligrams per liter ***Option C:*** 200 milligrams per liter
Treatment regimen:	***Option A:*** Treatment duration is 30 min; 3 consecutive or alternate days ***Option B:*** Treatment duration is 60 min; 3 consecutive or alternate days ***Option C:*** Treatment duration is 30 min; 3 consecutive or alternate days
Withdrawal period:	None. Fish may be allowed to enter the food chain immediately after treatment.
Required test parameters:	Investigator must collect mortality data throughout the 5 day pretreatment, treatment, and 10 day posttreatment periods. Investigator should also report general fish behavior and any adverse effects relating to treatment.
Limitations or restrictions on use of drug:	Investigator must follow all instructions in the Study Protocol for INAD 11-669 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements.
Required INAD fee:	$400.00 per facility per year
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The Aquatic Animal Drug Approval Partnership Program

Fact Sheet: Formalin (fungicide) INAD 9013

[For detailed information see INAD Study Protocol]

INAD objective/purpose:	Collect supportive and pivotal data needed to establish the effectiveness of formalin to control mortality caused by external fungal infections on a variety of fish species and their eggs.
Drug name:	Formalin (formaldehyde solution)
Source of drug:	Natchez Animal Supply Co., 201 John R. Junkin Dr., Natchez, MS 39120 Phone: 800-647-6760 Western Chemical Inc., 1269 Lattimore Road, Ferndale, WA 98248 Phone: 206-384-5898 Argent Chemical Laboratories, 8702 152nd Ave. NE, Redmond, WA 98052 Phone: 800-426-6258
Target pathogen(s):	external fungi
Method of administration:	Immersion: standing-bath or flow-through treatment
Treatment dosage:	15 - 2000 milligrams formalin per liter
Treatment regimen:	Treatment duration is variable. See Study Protocol for details. Treatments may be repeated at various intervals.
Withdrawal period:	5 days No withdrawal period is required for fish that are not susceptible to legal harvest for a period of 5 days post-treatment.
Required test parameters:	Investigator must collect mortality data throughout the 10-day pretreatment, treatment, and 14day post-treatment period. Investigator should also report general fish behavior and any adverse effects relating to treatment.
Limitations or restrictions on use of drug:	Investigator must follow all instructions in the Study Protocol for INAD 9013 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements. Drug discharge must be in compliance with local NPDES permitting requirements.
Required INAD fee:	None
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The Aquatic Animal Drug Approval Partnership Program

Fact Sheet: Florfenicol INAD 10-697

INAD objective/purpose:	Collect supportive and/or pivotal data needed to establish the effectiveness of florfenicol to control mortality caused by certain bacterial diseases.
Drug name:	Florfenicol (Aquaflor®)
Source of drug:	Schering-Plough Animal Health
Address:	1095 Morris Avenue Union, NJ 07083-1982
Contact:	Dr. Richard Endris Phone: 908-473-3133; Fax: 908-629-3654; email: richard.endris@spcorp.com
Target pathogen(s):	Bacterial pathogens susceptible to florfenicol, exclusive of already approved claims (i.e., *Edwardsiella ictaluri* and *Flavobacterium columnare* in catfish, and *Aeromonas salmonicida* and *Flavobacterium psychrophilum* in freshwater-reared salmonids).
Method of administration:	Medicated feed treatment
Treatment dosage:	10 milligrams florfenicol per kilogram fish body weight per day
Treatment regimen:	10 days (consecutive)
Withdrawal period:	21 days all salmonids 28 days all non-salmonids No withdrawal period is required for fish that are not susceptible to legal harvest for a period posttreatment equal to the withdrawal periods noted above or are illegal for harvest during those same periods.
Required test parameters:	Investigator must collect mortality data throughout the 10 day pretreatment, treatment, and 21-day posttreatment period. Investigator should also report general fish behavior and any adverse effects relating to treatment.
Limitations or restrictions on use of drug:	Investigator must follow all instructions in the Study Protocol for INAD 10-697 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements. Drug discharge must be in compliance with local NPDES permitting requirements.
Required INAD fee:	$400/facility
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The Aquatic Animal Drug Approval Partnership Program

Fact Sheet: Diquat INAD 10-969

INAD objective/purpose:	Collect supportive and/or pivotal data needed to establish the effectiveness of diquat to control mortality caused by certain bacterial diseases.
Drug name:	Diquat (Reward®)
Source of drug:	Syngenta Crop Protection, Inc
Address:	P.O. Box 18300 Greensboro, NC 27419-8300
Contact:	Attn: Dennis Tierney Phone: 800-334-9481 ext 2850
Target pathogen(s):	External flavobacteriosis (e.g. bacteria responsible for bacterial gill disease and external columnaris)
Method of administration:	Immersion: flow-through or standing bath treatment
Treatment dosage:	***Option A:*** 2-18 milligrams Diquat per liter ***Options B:*** 19-28 milligrams Diquat per liter
Treatment regimen:	***Option A:*** 1-4 hour treatment; 1-4 treatments on alternate or consecutive days ***Options B:*** 30-60 minute treatment; 1-3 treatments on alternate days
Withdrawal period:	5 days for channel catfish, musky, tiger musky, and northern pike. 30 days for all other fish species. No withdrawal period is required for treated fish that will not be susceptible to legal harvest for at least 30 days posttreatment.
Required test parameters:	Investigator must collect mortality data throughout the 5 day pretreatment, treatment, and 14 day posttreatment periods. Investigator should also report general fish behavior and any adverse effects relating to treatment.
Limitations or restrictions on use of drug:	Prophylactic (preventive) treatment of fish will not be allowed. Investigator must follow all instructions in the Study Protocol for INAD 10-969 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements. Drug discharge must be in compliance with local NPDES permitting requirements.
Required INAD fee:	None
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Fact Sheet: Copper Sulfate INAD 9101

[For detailed information see INAD Study Protocol]

INAD objective/purpose:	Collect supportive and pivotal data needed to establish the effectiveness of copper sulfate to control external protozoan and metazoan parasites, and bacterial and fungal infections in a variety of warmwater fish species.
Drug name:	Copper sulfate
Source of drug:	Phelps Dodge Refining Corporation
Address:	P.O Box 20001 El Paso, TX 79998
Contact:	David Fisher Phone: 915-775-8853; Fax: 915-775-8350; email: dfisher@phelpsdodge.com
Target pathogen(s):	external parasites, bacteria, and fungi
Method of administration:	Immersion: standing-bath or flow-through treatment
Treatment dosage:	Variable (dependent upon total alkalinity). See Study Protocol for calculations.
Treatment regimen:	Treatment duration is 1 hour. Although a single treatment event is generally efficacious, repeated treatments may be used.
Withdrawal period:	7 days No withdrawal period is required for fish that are not susceptible to legal harvest for a period of 7 days posttreatment.
Required test parameters:	Investigator must collect data indicating pretreatment pathogen level, and pathogen level at 1, 4, and 18 hours posttreatment. Investigator should also report general fish behavior and any adverse effects relating to treatment.
Limitations or restrictions on use of drug:	Investigator must follow all instructions in the Study Protocol for INAD 9101 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements. Drug discharge must be in compliance with local NPDES permitting requirements.
Required INAD fee:	None
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Fact Sheet: CP INAD 11-468

INAD objective/purpose:	Collect scientific data necessary to establish the efficacy of Channel Catfish Pituitary (CP) on gamete maturation in a variety of catfish species.
Drug name:	Channel Catfish Pituitary
Source of drug:	Hybrid Catfish Company
Address:	1233 Montgomery Dr Inverness, MS 38753
Contact:	Attn: Roger Yant Phone: 662-265-5308 FAX: 662-207-0461 email: yant@technoinfo.com
Target pathogen(s):	Not applicable
Method of administration:	IP or IM injection in sterile saline
Treatment dosage:	Up to 25 mg per kg body weight within a 12 hour period. Although certain situations may require a higher dosage rate, dosage will never exceed 25 mg CP/kg body weight.
Treatment regimen:	1 or 2 treatments total within a 12 hour period. A dual treatment will generally consist of a single “priming dose”, followed by a single “resolving dose."
Withdrawal period:	3 days. No withdrawal period is required for treated fish that will not be susceptible to legal harvest for 3 days posttreatment. No withdrawal period is required for offspring of fish receiving channel catfish pituitary.
Required test parameters:	Investigator must collect data reporting percent ovulation and/or percent spermiation in treated fish. Investigator should also report general fish behavior and any adverse effects relating to treatment.
Limitations or restrictions on use of drug:	Investigator must follow all instructions in the Study Protocol for INAD 11-468 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements.
Required INAD fee:	$400.00 per facility per year
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Fact Sheet: Chloramine-T INAD 9321

INAD objective/purpose:	Collect supportive and pivotal data needed to establish the effectiveness of chloramine-T to control mortality caused by certain bacterial diseases.	
Drug name:	Chloramine-T (Halamid®)	Chloramine-T (Actamide)
Source of drug:	Axcentive SARL/International Specialty Chemicals, Inc.	B.L. Mitchell, Inc.
Address:	303 South Broadway Suite 425 Tarrytown, NY 10591	1774 E Azalea Dr. Greenville, MS 38701-7505
Contact:	Larry Holzman Telephone: 914-333-0606 Telefax: 914-333-0333 email: lbh@ischem.com	Betty Mitchell Phone: 662-686-9002 Fax: 662-686-9020 email: blmitchell@bellsouth.net
Target pathogen(s):	External flavobacteriosis (e.g. bacteria responsible for BGD and external columnaris)	
Method of administration:	Immersion: flow-through or standing bath treatment	
Treatment dosage:	10, 15 or 20 mg/L for BGD & external columnaris in cold, cool & warmwater fish.	
Treatment regimen:	60 minutes per day for up to 3 days.	
Withdrawal period:	None. Fish may be released or harvested for market immediately following treatment.	
Required test parameters:	Investigator must collect mortality data throughout the 5 day pre-treatment, treatment, and 14 day post-treatment periods. Investigator should also report general fish behavior and any adverse effects relating to treatment.	
Limitations or restrictions on use of drug:	Not for use on fish in culture systems with no outflows . Investigator must follow all instructions in the Study Protocol for INAD 9321 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements.	
Required INAD fee:	$400.00/facility	
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The Aquatic Animal Drug Approval Partnership Program

Fact Sheet: CCP INAD 8391

INAD objective/purpose:	Collect supportive and pivotal data needed to establish the effectiveness of CCP to induce gamete maturation in a variety of fish species.	
Drug name:	Common Carp Pituitary	
Source of drug:	Stoller Fisheries	Argent Laboratories
Address:	1301 18th St; P.O. Box B Spirit Lake, IA 51360	8702 152nd Avenue, N.E. Redmond, WA 98052
Contact:	Phone: 800-831-5174 email: stollerfisheries@mchsi.com	Phone: 800-426-6258 email: email@argent-labs.com
Target pathogen(s):	Not applicable	
Method of administration:	IP or IM injection	
Treatment dosage:	up to 25 milligrams (mg) CCP per kilogram (kg) body weight. Although certain situations may require a higher dose rate, dosage should never exceed 25 mg CCP per kg body weight	
Treatment regimen:	Single or multiple treatment. Multiple treatment will generally consist of a single "priming dose," followed by a single "resolving dose."	
Withdrawal period:	No withdrawal period is required for treated fish.	
Required test parameters:	Investigator must collect data reporting percent ovulation and/or percent spermiation in treated fish. Investigator should also report general fish behavior and any adverse effects relating to treatment.	
Limitations or restrictions on use of drug:	Investigator must follow all instructions in the Study Protocol for INAD 8391 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements. Drug discharge must be in compliance with local NPDES permitting requirements.	
Required INAD fee:	$400.00 per facility per year	
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The Aquatic Animal Drug Approval Partnership Program

Fact Sheet: Calcein INAD 10-987

INAD objective/purpose:	Collect supportive and/or pivotal data needed to establish the effectiveness of calcein to mark fin rays, scales, otoliths, and other calcified fish or selected mussel tissues, via immersion bath.
Drug name:	Calcein (SE-MARK®)
Source of drug:	Western Chemical, Inc.
Address:	1269 Lattimore Road Ferndale, WA 98248
Contact:	Attention: Ron Malnor Phone: 1-800-283-5292; Fax: 360-384-0270; email: ronm@wchemical.com
Target pathogen(s):	Not applicable
Method of administration:	Immersion: standing-bath treatment only
Treatment dosage:	***Option A:*** 125 - 250milligrams calcein per liter ***Option B:*** 2.5 - 5.0 grams calcein per liter (finfish only)
Treatment regimen:	***Option A:*** Treatment duration is 1 - 6 hr ***Option B:*** Treatment duration is 1 - 7 min (Note: Treatment may include a pretreatment with a 1 -5% salt solution for ~3.5 min.) Calcein may be applied as a single treatment, or repeated treatments.
Withdrawal period:	None for fish; they may be released immediately following treatment for those treated at less than 2 grams and for Federally Threatened and Endangered species. None for mussels; due to their treatment at an early life stage and the limited human consumption
Required test parameters:	Investigator must collect mark retention and mortality data. Investigator should also report general fish behavior and any adverse effects relating to treatment.
Limitations or restrictions on use of drug:	Treatment is restricted to finfish having a body weight of 2 grams or less. Treatment of mussels is restricted to the following species: Higgins eye, hickory nut, black sandshell, pocketbook, fat mucket, sheepnose and maple leaf. Repeated treatments may be conducted to establish mutltiple marks. However, an interval of at least 2 days should be observed between treatment events. No discharge of calcein marking solution is allowed. Although used calcein marking solution may be stored on station in a secure, leak-proof container, it must ultimately be disposed of according to procedures detailed in a general Waste-stream profile (see INAD Study Protocol for specific instructions). Investigator must follow all instructions in the Study Protocol for INAD 10-987 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements.
Required INAD fee:	$400.00 per facility per year
AADAP Contact Information:	Ms. Bonnie Johnson, FWS-AADAP Phone: 406-994-9905 Fax: 406-582-0242 email: bonnie_johnson@fws.gov
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The Aquatic Animal Drug Approval Partnership Program

Fact Sheet: sGnRHa/Ovaplant INAD 11-375

[For detailed information see INAD Study Protocol]

INAD objective/purpose:	Collect supportive and pivotal data needed to establish the effectiveness of sGnRHa/Ovaplant® to induce gamete maturation in a variety of fish species.
Drug name:	Ovaplant®; salmon Gonadotropin - Releasing Hormone analogue (des-Gly^{10}, [D-Arg^{6}, Trp^{7}, Leu^{8}]- LHRH, ethyl amide)
Source of drug:	Western Chemical, Inc.
Address:	1269 Lattimore Road Ferndale, WA 98248 USA
Contact:	Attention: Jim Brackett Toll Free: 800-283-5292; Tel: 360-384-5898 email: brackett@wchemical.com
Target pathogen(s):	Not Applicable
Method of administration:	Pellet-implant treatment
Treatment dosage:	10 - 75 micrograms sGnRHa per kilogram body weight
Treatment regimen:	Implant:: Single treatment
Withdrawal period:	Implant:: No Release. All treated broodfish must be maintained indefinitely or destroyed.
Required test parameters:	Investigator must collect data reporting percent ovulation and/or percent spermiation in treated fish. Investigator should also report general fish behavior and any adverse effects relating to treatment.
Limitations or restrictions on use of drug:	Investigator must follow all instructions in the Study Protocol for INAD 11-375 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements. Drug discharge must be in compliance with local NPDES permitting requirements.
Required INAD fee:	$400.00 per facility per year
AADAP Contact Information:	Ms. Bonnie Johnson, FWS-AADAP Phone: 406-994-9905 Fax: 406-582-0242 email: bonnie_johnson@fws.gov
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