National INAD Program

Sign-up and Information Sheet
For Calendar Year 2016

Note: *This is a non-binding preliminary sign-up form to accelerate the preparation of FDA submittals and permanent files at the National INAD Office/AADAP. Final confirmation of this information will be obtained prior to invoicing and submission of enrollment data to FDA.*

Agency/Company: _____

Facility: _____

Mailing Address: _____

FedEx Address: _____

Investigator: _____ **e-mail:** _____

Phone: _____ **Fax:** _____

Current NPDES Permit Number: _____

Monitor: _____ **e-mail:** _____

Phone: _____ **Fax:** _____

Mailing Address: _____

FedEx Address: _____

Billing Information: By submitting this form for approval I verify that the above-described facility would like to sign-up to participate in the National INAD Program. Further by submitting this form, I understand that if this is a non-USFWS facility, then a sign-up charge of $700 per INAD will be invoiced for this facility.

General Information:

1. The Investigator and Monitor can not be the same person. Investigators are responsible for conduct of studies and complete and accurate data collection. Study Monitors are responsible for supervision of the trials, adherence of the Investigator to the Study Protocol, and inspection of the site.

2. FDA and the appropriate drug sponsors will be notified of your facility's participation.

3. INAD study protocols, forms, and general INAD information can be found on the AADAP website located at https://www.fws.gov/fisheries/aadap/inads-available/injectable/Erythromycin/index.html.

INAD Compounds that this Facility is Interested in Participating under in 2016, Including Fish Species and Number of Fish to be Treated for Each INAD: (Instructions: please list the species to be treated and the maximum number of each species to be treated in the appropriate columns).

INAD Compound	Yes	Fish Species (common/scientific name)	Max. Number Treated
1. ERYMICIN 200 Injection (Erythromycin injection) INAD #12-781			

Please email the completed Sign-up Forms to:

Ms. Bonnie Johnson
AADAP Office
4050 Bridger Canyon Road
Bozeman, MT 59715

Email: bonnie_johnson@fws.gov
Ph: (406) 994-9905
Fax: (406) 582-0242

Form ERYMICIN-W: Worksheet for Designing Individual Field Trials Under Erymicin 200 Injection INAD 12-781

INSTRUCTIONS

1. Investigator must fill out Form ERYMICIN-W for each proposed treatment under this INAD **before** actual use of Erymicin 200 Injection.

2. Investigator should forward a copy of ERYMICIN Form-W to the Study Monitor for review.

3. After review, the Study Monitor should forward a copy to the AADAP Office for review and assignment of a Study Number.

SITE INFORMATION

Facility			
Address			
Investigator			
Reporting Individual (if not Investigator)			
Phone		Email	

FISH CULTURE AND DRUG TREATMENT INFORMATION

Fish species to be treated			
Disease/pathogen to be treated		**BKD / *Renibacterium salmoninarum***	
Treatment Objective A (control of mortality)			
Treatment Objective B (control/prevent vertical transmission via eggs)			
Average fish weight (gm)		Average fish length (in)	
Number of fish per rearing unit		Number of rearing units to be treated	
Total number of fish to be treated		Approximate water temperature	
Intended erythromycin dosage (10-25 mg/kg bw) per injection			
Number of injections		Injection interval (days)	
Anticipated date treatment will be initiated			
Anticipated treatment evaluation date			

STUDY DESIGN: Describe in detail the purpose of the clinical trial. Study design must be carefully focused and lend itself to rigorous evaluation. If more space is required to describe study details, title additional page(s) "Study Design" and attach them to this Worksheet.

Study designed by _____

DISPOSITION OF TREATED FISH (Human Food Safety Considerations):

☐ Investigator should initial here to indicate awareness that fish disposition must be in compliance with FDA-mandated withdrawal times as described in the Study Protocol.

USE AND DISPOSITION OF ERYMICIN 200 Injection (Environmental Safety Considerations):

☐ Investigator should initial here to indicate awareness that Erymicin 200 Injection usage and disposition must be in compliance with requirements described in the Study Protocol.

WORKER SAFETY CONSIDERATIONS:

☐ Investigator should initial here to indicate that all personnel handling Erymicin 200 Injection have read the Material Safety Data Sheet for Erymicin 200 Injection and have been provided personal protective equipment, in good working condition, as described in the Study Protocol.

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____

Form ERYMICIN-1: Report on Receipt of Drug - Guide for Reporting Investigational New Animal Drug Shipments for Poikilothermic Food Animals

INSTRUCTIONS

1. Investigator must fill out Form ERYMICIN-1 **immediately** upon receipt of Erymicin 200 Injection.
2. Investigator should forward a copy of Form ERYMICIN-1 to the Study Director at the AADAP Office

The sponsor, U.S. Fish and Wildlife Service, submits a notice of claimed investigational exemption for the shipment or delivery of a new animal drug under the provisions of Section 512 of the Federal Food, Drug, and Cosmetics Act. The following information is submitted to FDA:

Name of Drug	**Erymicin 200 Injection**	INAD Number	12-781
Proposed Use of Drug	Objective A: To control mortality caused by bacterial kidney disease in a variety of salmonid species Objective B: To control (prevent) the vertical transmission of Renibacterium salmoninarum via salmonid eggs		
Date of CVM Authorization Letter	08/11/2016		
Source of Drug	Western Chemical, Inc.		
Date of Drug Receipt		**Amount of Drug Received**	
Drug Lot Number			
Name of Investigator			
Address of Investigator			
Location of Trial			
Approximate Number of Treated Animals			
Study Protocol Number	12-781		
Approximate dates of trial (start/end)			
Species, Size, and Type of Animals			
Maximum daily dose and duration	25mg/Kg body weight		
Methods of Administration	Injection (up to 3 injections)		
Withdrawal Period	60 days following completion of treatment		

[1] **To be filled out by the AADAP Office**

Investigator: _____ **Study Monitor:**_____

Signature and Date Signature and Date

Form ERYMICIN-2. Chemical Use Log for Clinical Field Trials Using Erymicin 200 Injection Under INAD 12-781

Instructions: 1. Initiate Form ERYMICIN-2 immediately upon receipt of Erymicin 200 Injection.

2. Each lot number of Erymicin 200 Injection may be used for multiple treatment regimes.

.

Quantity on Hand From Previous Page (ml): _____ **Facility:** _____ **Reporting Individual:** _____

Erymicin 200 Injection Lot Number	Date Received	Amount Received (ml)	Date Used	Study Number	Erymicin 200 Injection Used for Teatment (ml)	Erymicin 200 Injection Transferred[1] (ml)	Erymicin 200 Injection Disposal[2] (ml)	Erymicin 200 Injection On-hand (ml)	Inventoried by (initials)

[1] **Unused Erymicin 200 Injection that is shipped to another facility participating in Erymicin 200 Injection INAD 12-781 (Note: Erymicin 200 Injection can only be transferred to another facility with prior authorization by the AADAP Office).**

[2] **Unused Erymicin 200 Injection that is past expiry date or has been compromised should be disposed of in a lined-landfill.**

Investigator: _____ **Study Monitor:** _____

Signature and Date **Signature and Date**

Form ERYMICIN-3: Results Report Form for Clinical Field Trials Using Erymicin 200 Injection Under INAD 12-781

INSTRUCTIONS

1. Investigator must fill out Form ERYMICIN-3 no later than 10 days after completion of treatment. Attach lab reports and other pertinent study information.
2. If Erymicin 200 Injection was not used under the assigned Study Number, contact the Study Director at the AADAP Office to close-out the study.
3. Investigator should forward a copy of Form ERYMICIN-3 to the Study Monitor. Within 10 days of receipt, the Study Monitor should forward a copy to the Study Director at the AADAP Office.

SITE INFORMATION

Facility	
Reporting Individual	

FISH CULTURE AND DRUG TREATMENT INFORMATION

Erymicin 200 Injection Lot Number		Total amount of drug used (ml)	
Treatment **Objective A**		Treatment **Objective B**	
Fish species treated		Disease treated	**BKD/R. sal**
Average fish weight (gm)		Average fish length (in)	
Number of rearing units treated		Number of fish per treated rearing unit	
ID of all treated rearing units (e.g. Tank 5, Pond 6B)			
Total number of treated fish			
Number of control rearing units		Number of fish per control rearing unit	
ID of all control rearing units (e.g. Tank 5, Pond 6B)			
Total number of control fish			
Treatment dosage (mg/kg)		Treatment date(s)	
Injection method (IM or IP)			
Number of injections		Injection interval (days)	
Evaluation date(s)		Evaluation interval (time from treatment until evaluation; days)	

Daily Mortality Record (use for treatments under both Objective A and Objective B)

1. Investigator should fill out the Daily Mortality Record as completely as possible.
2. Prior to initiation of the trial, fill out Rearing Unit ID, whether a rearing unit is **T**reated or **C**ontrol, and the number of fish in each rearing unit.
3. Use additional copies of this form if more than 6 rearing units are involved in the trial and/or the post-treatment period exceeds 21 days

Facility										
	Rearing Unit ID									
	Treated or **C**ontrol									
	Number of fish									
	Day	Date	Water Temp (^{o}F)	Mortality (# of fish)	Mortality (# of fish)	Mortality (# of fish)	Mortality (# of fish)	Mortality (# of fish)	Mortality (# of fish)	Observer Initials
Pre-Treatment Period	5									
	4									
	3									
	2									
	1									
Treatment Day(s)[1]										
	0									
Post-Treatment Period	1									
	2									
	3									
	4									
	5									
	6									
	7									
	8									
	9									
	10									
	11									
	12									
	13									
	14									
	15									
	16									
	17									
	18									
	19									
	20									
	21									

[1] If more than 1 treatment (injection) is used under Objective B, please note additional treatment date(s) on form

Renibacterium salmoninarum dectection in adult females at time of spawning

(use only for treatments under Objective B)

1. Investigator should fill out this form as completely as possible.
2. Prior to initiation of the trial, fill out Rearing Unit ID, whether a rearing unit is **T**reated or **C**ontrol, and the number of fish in each rearing unit.
3. Use additional copies of this form if more than 6 rearing units are involved in the trial and/or in order to include (report) data for all fish sampled.

Facility									
	Rearing Unit ID								
	Treated or **C**ontrol								
	Number of fish								
Fish #	Date sampled	**E**LISA or RT-**PCR**	**P**ositive or **N**egative and OD or CT[1]	**P**ositive or **N**egative and OD or CT	**P**ositive or **N**egative and OD or CT	**P**ositive or **N**egative and OD or CT	**P**ositive or **N**egative and OD or CT	**P**ositive or **N**egative and OD or CT	Observer Initials

[1] OD = optical density from ELISA; CT = cycle threshold for RT=PCR

WATER QUALITY PARAMETERS

Mean treatment water temperature (^{o}F)		Dissolved Oxygen (mg/L)	
Hardness - $CaCO_3$ (mg/L)		pH	

RESULTS: Please describe treatment results in as much detail as possible. Was treatment successful? If treatment did not appear to be successful, explain why not? Describe general fish behavior, including feeding behavior. Were there any mitigating environmental conditions that may have impacted treatment results? Were there any deviations from the Study Protocol?

Pathology Report: Attach pathology report to this form. Report should include: 1) a description of how the pathogen(s) was identified; 2) disease identification records that confirm the presence of the pathogen; and 3) the name and title of the individual performing the diagnosis.

Pathology Report included: ☐ pre-treatment ☐ post-treatment

Toxicity observations: Report **<u>any</u>** apparent drug toxicity that was observed during the study period, including a detailed description of unusual or abnormal fish behavior.

OBSERVED WITHDRAWAL PERIOD:

Observed withdrawal period: ☐ **60 days** Investigator should initial here to indicate compliance with established withdrawal period

Estimated number of days between last treatment and first availability of fish for human consumption (ensure this time period meets the withdrawal period). _____

DISPOSITION OF Erymicn 200 Injection

☐ Use and disposition of all Erymicin 200 Injection followed Study Protocol guidelines and has been clearly identified on Form ERYTHRO-2 (Investigator should initial)

☐ **NEGATIVE REPORT:** Erymicin 200 Injection was not used at this facility under this Study Number during the reporting period (Investigator should initial for negative reports as soon as the Study Number is known to be no longer needed or valid

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____