

# Form LA200 -W. Worksheet for Designing Individual Field Trials under LIQUAMYCIN® LA-200® INAD #9027

## INSTRUCTIONS

1. Investigator must fill out Form LA200-W for each trial conducted under this INAD **before** actual use of LIQUAMYCIN® LA-200®. The Investigator is responsible that Form LA200-W is completed accurately.
2. Investigator should keep the original on file, and fax a copy to the Study Monitor for review.
3. After review, the Study Monitor will fax a copy to the AADAP Office for assignment of the Study Number.
4. The AADAP Office will review the worksheet, and then fax the assigned trial Study Number to both the Investigator and Study Monitor, at which time the trial may be initiated.
5. **Note:** Both Investigator and Study Monitor should sign and date Form LA200-W.

## **SITE INFORMATION**

Facility	Fish Hatchery A		
Address	123 Hatchery Rd		
	Anywhere, USA 55555		
Investigator	John Doe		
Reporting Individual (if not Investigator)			
Phone	555-555-5555	Fax	555-555-5556

## **FISH CULTURE AND DRUG TREATMENT INFORMATION**

Fish species to be treated	Largemouth bass	Disease to be treated	columnaris
Average fish weight (gm)	320	Average fish length (in)	11.7
No. of fish per unit (e.g. 100 fish/raceway)			200
Number of treated units	1	Number of treated fish	200
Number of untreated control units	0	Number of control fish	0
Anticipated date treatment will be initiated			4/14/08
Estimated total weight of fish treated (lbs)	141	OTC target dosage (mg OTC/Kg body weight)	20
Estimated total amount of drug needed for proposed treatment (mg)	1300	Number of injections/fish	1
Drug manufacturer	Pfizer, Inc.	Drug lot number	111000

**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.

Treatment is to prevent the loss of valuable largemouth bass broodstock that are being transferred to a pond. Past history has shown that these fish will break with columnaris without treatment.

Study designed by John Doe

**DISPOSITION OF TREATED FISH (Human Food Safety Considerations):**

>30 days Estimated time (days, months) from last treatment day to first possible harvest for human consumption

Check applicable box(es):

<input type="checkbox"/>
jd

Study Objective A - Withdrawal period of 30 days for variety of salmonid fish. Single injection at 20 mg OTC/Kg body weight.

Study Objective B - Withdrawal period of 30 days for non-salmonid fish. Single injection at 20 mg OTC/Kg body weight.

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

**WORKER SAFETY CONSIDERATIONS:**

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Investigator should initial here to indicate that all personnel handling drug have read Material Safety Data Sheet for LIQUAMYCIN<sup>®</sup> LA-200<sup>®</sup> and have been provided protective equipment, in good working condition, as described in the MSDS.

Date Prepared: 4/10/08

Investigator: Sign here

Date Reviewed: 4/10/08

Study Monitor: Sign here