

## REVISED REPORT (JULY 10, 2006)

### TABULATION AND ANALYSIS OF RESULTS FROM 2005 SURVEY TO DETERMINE UNMET LABEL CLAIMS FOR THE IAFWA PROJECT DRUGS

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#### INTRODUCTION

On September 21, 2005, the International Association of Fish and Wildlife Agencies' (IAFWA), Fisheries and Water Resources Policy Committee, sent out the "Survey on Unmet Label Claim Needs for the IAFWA Project Exit Strategy" to the 38 states that financially supported the Federal-State Aquaculture Drug Approval Partnership Project (known as the IAFWA Project) from 1994 to 2002. Thirty-seven of the 38 state natural resources agencies responded by January 5, 2006 by filling out the surveys and only one state (Hawaii) responded by saying that they did not have any comments at this time. The states were offered the opportunity to let the IAFWA Drug Approval Working Group (DAWG) know if it has met or are meeting the states' needs for the legal use of drugs in hatchery or fish management operations. The DAWG wanted to be sure that each state has the tools needed to control mortality from diseases in or on cultured fish species and to sedate or anesthetize fish for immediate release or slaughter. The responses to this survey will help the DAWG assess progress to date and to determine what data need to be generated in the future to meet any of the states' unmet label claim needs. The DAWG pledged to not associate any specific comments from any state or individual but did compile the responses in a manner that protected their identity.

The IAFWA Project participants have helped gain approvals for five label claims for three drugs. It has also made tremendous progress in developing data that will support the ultimate approval of 19 more label claims for nine drugs. The IAFWA Project participants believe that the final submissions for 15 label claims for seven drugs will be completed by 2007 and those for an additional four label claims for three drugs by 2009 or beyond (see Table 1 for details).

Fish production data are important in prioritizing the unmet label claim needs of the states. In 2003, the IAFWA Project conducted a survey to determine the fish production of all 50 states so that pharmaceutical sponsors could determine the market potential for the various label claims that were unmet or were to be met through its partnerships with the sponsors and researchers. The Aquatic Animal Drug Approval Partnership Program (AADAP) placed the results in a Microsoft Access database entitled "Summary of Fish Production by Public Aquaculture Facilities in the U.S." Contact AADAP at <http://www.fws.gov/fisheries/aadap/index.htm> to obtain the data and details. Fish production data were extracted from the Microsoft Access database for most of the 38 states that contributed to the IAFWA Project; the rest of the data were provided by the remaining states during the survey response period.

#### ANALYSIS OF SURVEY RESULTS

Because all 38 contributing states responded to the survey and provided complete fish production data, the DAWG can gain a very accurate picture of their unmet label claim needs.

##### **Initial Label Claim Approvals for Meeting Medicinal Drug Needs**

The survey respondents were asked in general to indicate whether the initial label claims addressing just the disease or anesthetic/sedative claim without consideration to fish species or grouping would meet their medicinal drug needs. The results are as follows:

- The top five label claims that were considered to be met included (in order):
  - Zero withdrawal anesthetic for short-exposure handling (now sedative to handleable condition)
  - Saprolegniasis/fish eggs
  - Monogenetic trematodes
  - External protozoa
  - Coldwater disease.
- Three of the top five label claim needs (saprolegniasis/fish eggs, monogenetic trematodes, and external protozoa) that were considered met were covered in part by formalin, a drug approved under the IAFWA Project.
- The top five label claims for diseases and one for anesthesia/sedation needs that were considered **not** to be met included:
  - Anesthesia for long-exposure handling (now light sedation for transport)
  - Bacterial gill disease
  - External columnaris disease
  - Motile aeromonad septicemia
  - Systemic columnaris disease
  - Saprolegniasis/fish
- Only two label claims were considered to be **not applicable** in any significant number: *Streptococcus iniae* and enteric septicemia.

Then the survey respondents were asked to delineate whether the previously approved, approved under the IAFWA Project, or initial label claims to be approved that address disease or anesthetic claims **and** fish species or grouping would meet their medicinal drug needs. The results are listed in order of priority (with label claims to be approved depicted in **bold**):

1. Formalin—saprolegniasis/all fish eggs (approved under IAFWA Project)
2. Formalin—external protozoa/all fish (approved under IAFWA Project)
3. Formalin—ichthyophthiriasis/all fish (approved under IAFWA Project)
4. Formalin—monogenetic trematodes/all fish (approved under IAFWA Project)
5. **Formalin—saprolegniasis/all fish**
6. **Hydrogen peroxide—saprolegniasis/all fish eggs**
7. **AQUI-S®—short-exposure handling (now sedation to handleable condition)/warmwater fish**
8. **AQUI-S®—short-exposure handling (now sedation to handleable condition)/freshwater salmonids**
9. **AQUI-S®—short-exposure handling (now sedation to handleable condition)/coolwater fish**
10. Oral oxytetracycline—motile aeromonad septicemia/salmonids (previously approved)
11. **Florfenicol—furunculosis/salmonids**
12. Oral oxytetracycline—furunculosis/salmonids (previously approved)
13. **Oral oxytetracycline—coldwater disease/salmonids**
14. **Florfenicol—systemic columnaris disease/salmonids**
15. **Chloramine-T—bacterial gill disease/salmonids**
16. Romet-30® or TC®—furunculosis/salmonids (previously approved)
17. **Florfenicol—coldwater disease/salmonids**
18. **Hydrogen peroxide—bacterial gill disease/salmonids**
19. Oral oxytetracycline—motile aeromonad septicemia/catfish (previously approved)
20. **Florfenicol—systemic columnaris disease/catfish**
21. **Hydrogen peroxide—external columnaris disease/ coolwater fish**
22. **Hydrogen peroxide—external columnaris disease/catfish**
23. Romet-30® or TC®—enteric septicemia/catfish (previously approved)
24. **Immersion oxytetracycline—external columnaris disease/coolwater fish**
25. **Hydrogen peroxide—saprolegniasis/catfish**
26. **Immersion oxytetracycline—external columnaris disease/warmwater fish**
27. Florfenicol—enteric septicemia/catfish (approved October 2005)

28. Potassium permanganate—external columnaris disease/channel catfish
29. Copper sulfate—ichthyophthiriasis/channel catfish
30. Chloramine-T—external columnaris disease/walleye
31. Oral oxytetracycline—systemic columnaris disease/steelhead trout
32. Florfenicol—*Streptococcus iniae*/hybrid striped bass
33. Copper sulfate—saprolegniasis/channel catfish eggs
34. AQUI-S®—short-exposure handling (now sedation to handleable condition)/saltwater salmonids
35. Florfenicol—*Streptococcus iniae*/tilapia

### Prioritization of Unmet Label Claim Needs

Because not all states produce all fish species and certain states produce a majority of the fish species grouped by salmonids, coolwater, warmwater, and marine fish species, it was necessary to prioritize the unmet label claim needs to accurately reflect the needs of the states producing the majority of the fish in a particular group. For example, the percentage of the total fish production by fish grouping for the 38 states is as follows: (1) coolwater fish—47.8%, (2) warmwater fish—30.4%, (3) salmonids—19.9%, and (4) marine fish—1.9%. The number of states that produce fish from each fish grouping is as follows: (1) coolwater fish—26, (2) warmwater fish—30, (3) salmonids—36, and (4) marine fish—4. Thus, while 36 states produce salmonids, this fish grouping only represents 19.9% of the total fish produced. In comparison, only 26 states produced coolwater fish species but this fish grouping represents 47.8% of the total fish produced. In addition, the states that produce most of the fish needed to have a greater weighting in deciding which unmet label claims should be pursued to meet the needs of each fish grouping. States were selected as being a “Major Fish Grouping State” if they produced more than 7 million fish in that particular category.

These Major Fish Grouping States were then given a “Production Factor” number that was calculated by number of fish produced in a fish grouping divided by 2,380,473 billion total fish production for salmonids, coolwater, and warmwater fish and then multiplying this number by 100 (example: Pennsylvania produced 71.432 million coolwater fish; divide that by 2,380,473 billion total fish production for salmonids, coolwater, and warmwater fish to equal 030; multiply that by 100 to equal 3.0 as the Production Factor).

The prioritization of the unmet label claim needs was based on the total sum of four numbers: (1) number of “Yes” votes (drug, disease, and fish grouping) by all the states, (2) number of “Yes” votes (drug, disease, and fish grouping) by the Major Fish Grouping States, (3) number of “Top 4” votes from any state for unmet label claim needs (drug, disease, and fish grouping), and (4) number for “Production Factor” for Major Fish Grouping States voting on Top 4 (Tables 2, 3, and 4).

To gain the approval for the unmet label claims for all fish groupings noted in Tables 2, 3, and 4, only efficacy data are required except for those oral oxytetracycline label claims for coolwater and warmwater fish and any Romet or potassium permanganate label claim. In the case of oral oxytetracycline, a qualitative risk assessment will be needed to meet microbial food safety data requirements. In the case of Romet, a major effort would be needed to meet the current data requirements (environmental safety, human food safety, target animal safety, and efficacy) for controlling mortality due to motile aeromonad septicemia and systemic columnaris disease. For potassium permanganate requirements, see the next paragraph.

The same requirements listed above will apply except for those unmet label claims associated with copper sulfate and potassium permanganate. As stated in the introduction to the survey, “In the case of copper sulfate or potassium permanganate, their use after initial approvals will be limited to channel catfish in earthen ponds with no outflows until target animal safety [and efficacy] data are generated on other fish species and the environmental assessments are amended to cover culture systems with effluent discharges (e.g., in flow-through systems).”

Drug approval development for marine fish species was not addressed in the initial IAFWA Project efforts because of the extensive, additional requirements for environmental safety and human food safety.

Nevertheless, four states that contributed \$560,000 to the IAFWA Project have expressed their unmet label claim needs. The main label claims listed as unmet by this current effort include drugs that would control mortality due to (1) external protozoans on warmwater marine fish (especially sciaenids) and (2) Vibriosis in warmwater marine fish (especially sciaenids).

#### **Unmet Label Claim Needs Not Included in the Survey That States Wanted Addressed**

Table 5 lists the unmet label claim needs that were not addressed in the survey. The most cited label claim was for the control of mortality in salmonids due to bacterial kidney disease by erythromycin; that drug approval is being conducted by the University of Idaho under the National Research Support Program Number Seven. There were some label claims that the states wanted covered by injectable oxytetracycline and Epsom salts; those can be addressed through extra-label use or Low Regulatory Priority drug requests, respectively. Other states were interested in additional label claims for hydrogen peroxide or formalin and most of them can be covered by extra-label use. Diquat, Cutrine Plus®, Masoten®, ivermectin, anamectin, and chelated copper were mentioned for several disease indications but until company sponsors come forward to help in the approval process, no efforts will be made to work on these drugs.

#### **Additional Comments for Consideration Related To the IAFWA Project Exit Strategy**

The main comments received from the states were that the IAFWA Project needed to concentrate on providing data so that more label claim approvals can be gained for coolwater and warmwater fish. Others indicated that state effluent requirements may preclude the use of chloramine-T thus making the approval of hydrogen peroxide even more important. Soft water hatcheries need a drug other than copper sulfate. Bath treatments are needed for non-feeding fish. To avoid drug resistance, additional treatments options are needed.

**TABLE 1. APPROVALS GAINED AND FINAL SUBMISSIONS PROJECTED FOR IAFWA PROJECT DRUGS (AS OF DECEMBER 27, 2005)**

<b>Label Claim Approvals Gained For IAFWA Project Drugs</b>		
Disease Indication or Function	Species	Drug
1. Enteric septicemia	Catfish	Florfenicol*
2. External protozoa	All fish	Formalin
3. Monogenetic trematodes	All fish	Formalin
4. Otolith marking	All fish	Immersion oxytetracycline**
5. Saprolegniasis	All freshwater-reared fish eggs	Formalin
<b>Label Claims For IAFWA Project Drugs With Final Submissions Projected For 2006-2007</b>		
Disease Indication or Function	Species	Drug
1. Bacterial gill disease	All freshwater-reared salmonids	Chloramine-T
2. Bacterial gill disease	All freshwater-reared salmonids	Hydrogen peroxide
3. External columnaris disease	Walleye	Chloramine-T
4. External columnaris disease	All coolwater fish and channel catfish	Hydrogen peroxide
5. External columnaris disease	All coolwater and warmwater fish	Immersion oxytetracycline
6. Furunculosis	All freshwater-reared salmonids	Florfenicol*
7. Ichthyophthiriasis	Channel catfish	Copper sulfate
8. Saprolegniasis	All freshwater-reared fish	Formalin
9. Saprolegniasis	Channel catfish (or all warmwater fish)	Hydrogen peroxide
10. Saprolegniasis	All freshwater-reared fish eggs	Hydrogen peroxide
11. <i>Streptococcus iniae</i>	Tilapia and hybrid striped bass	Florfenicol*
12. Systemic coldwater disease	All freshwater-reared salmonids	Florfenicol*
13. Systemic coldwater disease	All freshwater-reared salmonids	Oral oxytetracycline
14. Systemic columnaris disease	All freshwater-reared salmonids and catfish	Florfenicol*
15. Systemic columnaris disease	Steelhead trout	Oral oxytetracycline
<b>Label Claims For IAFWA Project Drugs With Final Submissions Projected For 2008-2009</b>		
Disease Indication or Function	Species	Drug
1. External columnaris disease	Channel catfish	Potassium permanganate***
2. Saprolegniasis	Channel catfish eggs	Copper sulfate
3. Zero withdrawal anesthetic for short-exposure handling****	All freshwater fish	AQUI-S®
4. Zero withdrawal anesthetic for short-exposure handling****	All saltwater salmonids	AQUI-S®***

\*Florfenicol data generation supported mainly by the sponsor, Schering-Plough Animal Health.

\*\*Immersion oxytetracycline data generation supported mainly by the National Research Support Program Number Seven

\*\*\*As of July 10, 2006, final submissions projected for 2009+

\*\*\*\*Anesthetic to short-exposure handling is now sedation to handleable condition

**TABLE 2. 20 HIGH PRIORITY UNMET LABEL CLAIMS FOR COOLWATER FISH PRODUCTION**

Drug—Disease	Total Yes + Major Coolwater State Yes Votes	Top 4 Votes	Top 4 Major State Production Factor	Total points
1. Chloramine-T—bacterial gill disease	22+16	8	35.3	81.3
2. Oral oxytetracycline—systemic columnaris disease	25+15	6	8.0	54.0
3. Hydrogen peroxide—saprolegniasis/fish	25+15	3	4.3	47.3
4. Chloramine-T—external columnaris disease	18+12	7	9.4	46.4
5. Immersion oxytetracycline—systemic columnaris disease	18+12	2	13.8	45.8
6. Florfenicol—systemic columnaris disease	24+16	2	2.6	44.6
7. Oral oxytetracycline—motile aeromonad septicemia	25+16	1	1.5	43.5
8. Hydrogen peroxide—bacterial gill disease	19+12	1	10.8	42.8
9. AQUI-S®—Long-exposure handling (now light sedation for transport)	24+11	2	2.2	39.2
10. Romet—motile aeromonad septicemia	23+16	0	0	39.0
11. Hydrogen peroxide—external protozoa	20+13	2	3.5	38.5
12. Florfenicol— motile aeromonad septicemia	19+13	1	2.9	35.9
13. Florfenicol—furunculosis	17+11	2	5.7	35.7
14. Hydrogen peroxide— ichthyophthiriasis	21+13	1	0.4	35.4
15. Hydrogen peroxide—monogenetic trematodes	18+10	3	3.4	34.4
16. Romet—systemic columnaris disease	21+13	0	0	34.0
17. Immersion oxytetracycline—bacterial gill disease	19+13	0	0	32.0
18. Romet—furunculosis	19+12	0	0	31.0
19. Potassium permanganate—external columnaris disease	18+9	3	0	30.0
20. Oral oxytetracycline—furunculosis	16+10	0	0	26.0

**TABLE 3. 20 HIGH PRIORITY UNMET LABEL CLAIMS FOR WARMWATER FISH PRODUCTION**

Drug—Disease	Total Yes + Major Warmwater State Yes Votes	Top 4 Votes	Top 4 Major State Production Factor	Total points
1. Oral oxytetracycline—systemic columnaris disease	25+8	4	24.5	61.5
2. Hydrogen peroxide—external columnaris disease	24+10	2	24.0	60.0
3. Oral oxytetracycline—motile aeromonad septicemia	24+10	2	24.0	60.0
4. Chloramine-T—external columnaris disease	21+10	4	24.9	59.9
5. Romet—motile aeromonad septicemia	25+10	1	23.0	59.0
6. Romet—systemic columnaris disease	22+9	1	23.0	55.0
7. Potassium permanganate—external columnaris disease	22+7	2	23.7	54.7
8. AQUI-S®—Long-exposure handling (now light sedation for transport)	29+9	1	1.2	40.2
9. Florfenicol—systemic columnaris disease	24+10	1	0.8	35.8
10. Chloramine-T—bacterial gill disease	22+9	3	1.8	35.8
11. Hydrogen peroxide—saprolegniasis/fish	25+10	0	0	35.0
12. Potassium permanganate—external protozoa	22+9	2	1.2	34.2
13. Hydrogen peroxide—external protozoa	22+9	2	1.1	34.1
14. Hydrogen peroxide—ichthyophthiriasis	23+9	1	0.8	33.8
15. Copper sulfate—external protozoa	20+7	3	2.4	32.4
16. Hydrogen peroxide—monogenetic trematodes	19+8	2	1.1	30.1
17. Florfenicol—motile aeromonad septicemia	20+9	0	0	29.0
18. Potassium permanganate—ichthyophthiriasis	19+9	0	0	28.0
19. Copper sulfate—external columnaris disease	19+7	1	0.7	27.7
20. Immersion oxytetracycline—systemic columnaris disease	18+8	1	0.3	27.3

**TABLE 4. 20 HIGH PRIORITY UNMET LABEL CLAIMS FOR SALMONID PRODUCTION**

Drug—Disease	Total Yes + Major Salmonid State Yes Votes	Top 4 Votes	Top 4 Major State Production Factor	Total points
1. Oral oxytetracycline—systemic columnaris disease	29+10	8	4.0	51.0
2. Hydrogen peroxide—saprolegniasis/fish	30+11	5	3.1	49.1
3. Chloramine-T—external columnaris disease	26+9	6	6.1	47.1
4. Hydrogen peroxide—external columnaris disease	25+9	4	6.6	44.6
5. Hydrogen peroxide—external protozoa	26+10	5	1.4	42.4
6. Florfenicol— motile aeromonad septicemia	27+9	5	0.5	41.5
7. Hydrogen peroxide—ichthyophthiriasis	26+10	4	0	40.0
8. Romet—motile aeromonad septicemia	28+9	3	0	40.0
9. AQUI-S®—Long-exposure handling (now light sedation for transport)	27+9	3	0.4	39.4
10. Immersion oxytetracycline—systemic columnaris disease	26+8	2	3.4	39.4
11. Immersion oxytetracycline—external columnaris disease	20+7	4	6.3	37.3
12. Hydrogen peroxide—monogenetic trematodes	22+8	3	3.4	36.4
13. Romet—systemic columnaris disease	26+7	2	0	35.0
14. Romet—coldwater disease	22+7	4	0.8	33.8
15. Potassium permanganate—external columnaris disease	18+3	4	4.3	29.3
16. Immersion oxytetracycline—bacterial gill disease	17+9	2	0	28.0
17. Potassium permanganate—bacterial gill disease	18+6	2	2.0	28.0
18. Potassium permanganate—ichthyophthiriasis	15+4	4	2.2	25.2
19. Potassium permanganate—external protozoa	19+6	0	0	25.0
20. Copper sulfate—ichthyophthiriasis	13+4	3	2.2	22.2

**TABLE 5. LABEL CLAIMS NOT ADDRESSED IN SURVEY**

Disease—Fish Grouping—Drug	Total States Requesting
Bacterial kidney disease—salmonids--erythromycin	5
Enteric Redmouth Disease—salmonids—oral oxytetracycline and Romet	2
Motile aeromonad septicemia—warmwater fish—injectable oxytetracycline	1
Furunculosis—esocids—Injectable oxytetracycline	1
Vibriosis—warmwater marine fish—injectable oxytetracycline	1
External coldwater disease—salmonids—hydrogen peroxide	1
External columnaris disease—coolwater and warmwater fish—diquat	3
External columnaris disease—coolwater and warmwater fish—chelated copper	1
Bacterial gill disease—all fish—diquat	1
External copepods—salmonids—ivermectin, anamectin	1
External copepods—all species-Slice®	1
Ichthyophthiriasis—coolwater and warmwater fish—chelated copper	1
All external protozoa—all fish—formalin and hydrogen peroxide	1
External protozoa—warmwater marine fish—Cutrine Plus®	1
Gill amoeba—sturgeon--formalin	1
Anchor parasites and trematodes—coolwater and warmwater fish—Masoten®	1
Trematodes in ponds—coolwater and warmwater fish—other than formalin	1
Internal protozoa—salmonids—Epsom salts	1
Hexamitiasis—salmonids—Epsom salts	1
Intestinal helminths—all fish—Ivermectin, anamectin	1
Saprolegniasis/fish eggs—percids—hydrogen peroxide (higher doses)	1

# TABULATION OF THE 2005 SURVEY ON UNMET LABEL CLAIM NEEDS FOR THE IAFWA PROJECT EXIT STRATEGY

## INTRODUCTION

The exit strategy for the Federal-State Aquaculture Drug Approval Partnership Project (known as the IAFWA Project) stipulates that a survey be made of the stakeholders for their recommendations for what unmet label claims should be pursued beyond the initial new animal drug application (NADA) approvals that are anticipated for the nine IAFWA Project drugs. Your answers to this survey will not obligate your state to any additional financial burdens during the remaining period before the IAFWA Project ends; you will get the initial approved NADAs indicated in the survey and in Table 1 as part of your original contribution to the IAFWA Project. This survey is intended only as a guide to help IAFWA Project collaborators focus in the remaining time before the IAFWA Project ends on generating data to address any unmet label claims that the states feel are critical to their fish production effort.

A label claim indicates a disease to be controlled or condition to be managed in a particular species or group of species by a specific drug produced by a specific NADA sponsor. This means that unless both the disease and the species to be treated are on the label, a particular drug cannot be used unless a veterinarian prescribes its use under extra label provisions and it is allowed under a National Pollutant Discharge Elimination System (NPDES) permit. As an example, when oral oxytetracycline is approved to control mortalities associated with systemic columnaris disease in freshwater-reared salmonids, a veterinarian would have to prescribe it under extra label use if oxytetracycline were to be used to control the same disease in either coolwater or warmwater fish species. Since this use is not on the approved label, the facility would need to contact their NPDES permit writer to request authorization to release oxytetracycline-medicated feed. Thus, veterinarian extra-label use could be restricted based on the facility's NPDES permit. In the case of florfenicol, the current regulatory policy would not allow extra label use because florfenicol will be classified as a Veterinary Feed Directive drug when it is approved.

Most of the initial NADA approvals will be limited to freshwater-reared salmonids or channel catfish. However, all the data (except efficacy) have been or will have been generated to extend the label claims to all freshwater-reared fish for seven of the nine IAFWA Project drugs—AQUI-S®, chloramine-T, florfenicol, formalin, hydrogen peroxide, oral oxytetracycline, and immersion oxytetracycline. In the case of copper sulfate or potassium permanganate, their use after initial approvals will be limited to channel catfish in earthen ponds with no outflows until target animal safety data are generated on other fish species and the environmental assessments are amended to cover culture systems with effluent discharges (e.g., in flow-through systems). In addition, veterinarians will not be able to prescribe extra label use for either copper sulfate or potassium permanganate for fish reared in flow-through systems or ponds of any kind that have effluent discharges.

The purpose of this survey is to ensure that you, the stakeholder, have the opportunity to indicate what additional label claims will be needed to meet your needs for a basic medicine chest for the fish species you culture, the diseases you need to control, and the procedures for which you need a zero withdrawal anesthetic or sedative so that you can release or slaughter the fish immediately after treatment.

This survey will not be associated with any specific comments from you either by name or by state but instead will be compiled in a manner to protect your identity.

Please complete the attached survey by marking each question with an "X" under either "Yes", "No", or "NA" for not applicable. Please note that the questions start with "will" for initial label claims and "would" for unmet label claims. Please return the survey **by October 28, 2005** to Rosalie (Roz) Schnick via e-mail ([RozSchnick@centurytel.net](mailto:RozSchnick@centurytel.net)) or regular mail (National Coordinator for Aquaculture New Animal Drug Applications, Michigan State University, 3039 Edgewater Lane, La Crosse, WI 54603-1088).

**CONFIDENTIAL INFORMATION FROM THE SURVEY RESPONDENT**

Name \_\_\_\_\_

Position \_\_\_\_\_

State agency \_\_\_\_\_

E-mail address \_\_\_\_\_

Telephone number \_\_\_\_\_

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**A. EXTERNAL BACTERIAL DISEASES**

**A1. Initial Label Claims for Control of Mortalities Associated with Bacterial Gill Disease**

Drug	Species	Projected Dates for Final Submissions
Chloramine-T	All freshwater-reared salmonids	2006-2007
Hydrogen peroxide	All freshwater-reared salmonids	Early 2006

**A1. Survey for Label Claim Needs for Bacterial Gill Disease**

Questions Related to Initial Label Claims After They are Approved	Yes	No	NA
A1.1. Will these initial label claims meet your medicinal drug needs regarding bacterial gill disease?	24	12	1
A1.2. Will you use chloramine-T for bacterial gill disease on any freshwater-reared salmonid species?	29	4	4
A1.3. Will you use hydrogen peroxide for bacterial gill disease on any freshwater-reared salmonid species?	24	9	4
Questions Related to UNMET Label Claims That Would be Pursued for Approval If Requested	Yes	No	NA
A1.4. Would you use chloramine-T for bacterial gill disease on any coolwater fish species?	22	6	9
A1.5. Would you use chloramine-T for bacterial gill disease on any warmwater fish species?	22	7	8
A1.6. Would you use copper sulfate for bacterial gill disease on any freshwater-reared salmonid species?	10	21	6
A1.7. Would you use copper sulfate for bacterial gill disease on any coolwater fish species?	11	19	7
A1.8. Would you use copper sulfate for bacterial gill disease on any warmwater fish species?	15	14	8
A1.9. Would you use hydrogen peroxide for bacterial gill disease on any coolwater fish species?	19	10	8
A1.10. Would you use hydrogen peroxide for bacterial gill disease on any warmwater fish species?	19	9	9
A1.11. Would you use immersion oxytetracycline for bacterial gill disease on any freshwater-reared salmonid species?	17	16	4
A1.12. Would you use immersion oxytetracycline for bacterial gill disease on any coolwater fish species?	19	11	7
A1.13. Would you use immersion oxytetracycline for bacterial gill disease on any warmwater fish species?	17	11	9
A1.14. Would you use potassium permanganate for bacterial gill disease on any freshwater-reared salmonid species?	18	15	4
A1.15. Would you use potassium permanganate for bacterial gill disease on any coolwater fish species?	16	14	7
A1.16. Would you use potassium permanganate for bacterial gill disease on any warmwater fish species?	18	10	9

## A2. Initial Label Claims for Control of Mortalities Associated with External Columnaris Disease

Drug	Species	Projected Dates for Final Submissions
Chloramine-T	Walleye	2006-2007
Hydrogen peroxide	All coolwater fish & catfish	Early 2006
Immersion oxytetracycline	All coolwater & warmwater fish	2006-2007
Potassium permanganate	Channel catfish	2008-2009

## A2. Survey for Label Claim Needs for External Columnaris Disease

Questions Related to Initial Label Claims After They are Approved	Yes	No	NA
A2.1. Will these initial label claims meet your medicinal drug needs regarding external columnaris disease?	18	17	2
A2.2. Will you use chloramine-T for external columnaris disease on walleye?	13	13	11
A2.3. Will you use hydrogen peroxide for external columnaris disease on any coolwater fish species?	21	8	8
A2.4. Will you use hydrogen peroxide for external columnaris disease on catfish?	21	3	13
A2.5. Will you use immersion oxytetracycline for external columnaris disease on any coolwater fish species?	19	10	8
A2.6. Will you use immersion oxytetracycline for external columnaris disease on any warmwater fish species?	18	9	10
A2.7. Will you use potassium permanganate for external columnaris disease on channel catfish?	16	7	14
Questions Related to UNMET Label Claims That Would be Pursued for Approval If Requested	Yes	No	NA
A2.8. Would you use chloramine-T for external columnaris disease on any freshwater-reared salmonid species?	26	6	5
A2.9. Would you use chloramine-T for external columnaris disease on any coolwater fish species other than walleye?	18	9	10
A2.10. Would you use chloramine-T for external columnaris disease on any warmwater fish species?	21	6	9
A2.11. Would you use copper sulfate for external columnaris disease on any freshwater-reared salmonid species?	8	23	6
A2.12. Would you use copper sulfate for external columnaris disease on any coolwater fish species?	10	18	9
A2.13. Would you use copper sulfate for external columnaris disease on any warmwater fish species?	19	9	9
A2.14. Would you use hydrogen peroxide for external columnaris disease on any freshwater-reared salmonid species?	25	8	4
A2.15. Would you use hydrogen peroxide for external columnaris disease on any scaled warmwater fish species?	24	4	9
A2.16. Would you use immersion oxytetracycline for external columnaris disease on any freshwater-reared salmonid species?	20	13	4
A2.17. Would you use potassium permanganate for external columnaris disease on any freshwater-reared salmonid species?	18	14	5
A2.18. Would you use potassium permanganate for external columnaris disease on any coolwater fish species?	18	11	8
A2.19. Would you use potassium permanganate for external columnaris disease on any warmwater fish species other than channel catfish?	22	6	9

## B. SYSTEMIC BACTERIAL DISEASES

### B1. Initial Label Claims for Control of Mortalities Associated with *Aeromonas hydrophila* (Hemorrhagic Septicemia or Motile Aeromonad Septicemia)

Drug	Species	Projected Dates for Final Submissions
Oral oxytetracycline	Salmonids & catfish	PREVIOUSLY APPROVED

### B1. Survey for Label Claim Needs for Motile Aeromonad Septicemia

Questions Related to Initial Label Claims After They are Approved	Yes	No	NA
B1.1. Will this previously approved label claim meet your medicinal drug needs regarding motile aeromonad septicemia?	23	14	0
B1.2. Will you use oral oxytetracycline for motile aeromonad septicemia in any salmonid species?	30	2	5
B1.3. Will you use oral oxytetracycline for motile aeromonad septicemia in any catfish species?	23	1	13
Questions Related to UNMET Label Claims That Would be Pursued for Approval If Requested	Yes	No	NA
B1.4. Would you use florfenicol for motile aeromonad septicemia in any freshwater-reared salmonid species?	27	6	4
B1.5. Would you use florfenicol for motile aeromonad septicemia in any coolwater fish species?	19	9	9
B1.6. Would you use florfenicol for motile aeromonad septicemia in any warmwater fish species?	20	7	10
B1.7. Would you use oral oxytetracycline for motile aeromonad septicemia in any coolwater fish species?	25	4	8
B1.8. Would you use oral oxytetracycline for motile aeromonad septicemia in any scaled warmwater fish species?	24	4	9
B1.9. Would you use Romet-30® or Romet-TC® for motile aeromonad septicemia in any freshwater-reared salmonid species?	28	5	4
B1.10. Would you use Romet-30® or Romet-TC® for motile aeromonad septicemia in any coolwater fish species?	23	6	8
B1.11. Would you use Romet-30® or Romet-TC® for motile aeromonad septicemia in any warmwater fish species?	25	3	9

### B2. Initial Label Claims for Control of Mortalities Associated with Enteric Septicemia

Drug	Species	Projected Dates for Final Submissions
Florfenicol	Catfish	2005
Romet-30®, Romet-TC®	Catfish	PREVIOUSLY APPROVED

### B2. Survey for Label Claim Needs for Enteric Septicemia

Questions Related to Initial Label Claims After They are Approved	Yes	No	NA
B2.1. Will these initial and previously approved label claims meet your medicinal drug needs regarding enteric septicemia?	21	4	12
B2.2. Will you use florfenicol for enteric septicemia in any catfish species?	17	6	14
B2.3. Will you use Romet-30® or Romet-TC® for enteric septicemia in any catfish species?	20	2	15
Questions Related to UNMET Label Claims That Would be Pursued for Approval If Requested	Yes	No	NA
B2.4. Would you use oral oxytetracycline for enteric septicemia in any catfish species?	17	5	15

### B3. Initial Label Claims for Control of Mortalities Associated with Furunculosis

Drug	Species	Projected Dates for Final Submissions
Florfenicol	All freshwater-reared salmonids	2006-2007
Oral oxytetracycline	All salmonids	PREVIOUSLY APPROVED
Romet-30®, Romet-TC®	All salmonids	PREVIOUSLY APPROVED

### B3. Survey for Label Claim Needs for Furunculosis

Questions Related to Initial Label Claims After They are Approved	Yes	No	NA
B3.1. Will these initial and previously approved label claims meet your medicinal drug needs regarding furunculosis?	26	8	3
B3.2. Will you use florfenicol for furunculosis in any freshwater-reared salmonid species?	30	2	5
B3.3. Will you use oral oxytetracycline for furunculosis in any salmonid species?	30	2	5
B3.4. Will you use Romet-30® or Romet-TC® for furunculosis in any salmonid species?	29	3	5
Questions Related to UNMET Label Claims That Would be Pursued for Approval If Requested	Yes	No	NA
B3.5. Would you use florfenicol for furunculosis in any saltwater-reared salmonid species?	4	6	27
B3.6. Would you use florfenicol for furunculosis in any coolwater fish species?	17	7	13
B3.7. Would you use florfenicol for furunculosis in any warmwater fish species?	19	5	13
B3.8. Would you use oral oxytetracycline for furunculosis in any coolwater fish species?	16	10	11
B3.9. Would you use oral oxytetracycline for furunculosis in any warmwater fish species?	15	10	12
B3.10. Would you use Romet-30® or Romet-TC® for furunculosis in any coolwater fish species?	19	7	11
B3.11. Would you use Romet-30® or Romet-TC® for furunculosis in any warmwater fish species?	19	6	12

### B4. Initial Label Claims for Control of Mortalities Associated with *Streptococcus iniae*

Drug	Species	Projected Dates for Final Submissions
Florfenicol	Tilapia & hybrid striped bass	2006-2007

### B4. Survey for Label Claim Needs for *Streptococcus iniae*

Questions Related to Initial Label Claims After They are Approved	Yes	No	NA
B4.1. Will this initial label claim meet your medicinal drug needs regarding <i>Streptococcus iniae</i> ?	9	5	23
B4.2. Will you use florfenicol for <i>Streptococcus iniae</i> in tilapia?	4	2	31
B4.3. Will you use florfenicol for <i>Streptococcus iniae</i> in hybrid striped bass?	10	3	24
Questions Related to UNMET Label Claims That Would be Pursued for Approval If Requested	Yes	No	NA
B4.4. Would you use amoxicillin for <i>Streptococcus iniae</i> in tilapia?	3	2	32
B4.5. Would you use amoxicillin for <i>Streptococcus iniae</i> in hybrid striped bass?	9	5	23
B4.6. Would you use amoxicillin for <i>Streptococcus iniae</i> in any warmwater fish species other than tilapia & hybrid striped bass?	9	5	23
B4.7. Would you use florfenicol for <i>Streptococcus iniae</i> in any warmwater fish species other than tilapia & hybrid striped bass?	11	3	23
B4.8. Would you use oral oxytetracycline for <i>Streptococcus iniae</i> in tilapia?	3	2	32
B4.9. Would you use oral oxytetracycline for <i>Streptococcus iniae</i> in hybrid striped bass?	11	4	22
B4.10. Would you use oral oxytetracycline for <i>Streptococcus iniae</i> in any warmwater fish species other than tilapia & hybrid striped bass?	10	6	21
B4.11. Would you use Romet-30® or Romet-TC® for <i>Streptococcus iniae</i> in tilapia?	3	3	31
B4.12. Would you use Romet-30® or Romet-TC® for <i>Streptococcus iniae</i> in hybrid striped bass?	12	3	22
B4.13. Would you use Romet-30® or Romet-TC® for <i>Streptococcus iniae</i> in any warmwater fish species other than tilapia or hybrid striped bass?	12	4	21

### B5. Initial Label Claims for Control of Mortalities Associated with Systemic Coldwater Disease

Drug	Species	Projected Dates for Final Submissions
Florfenicol	All freshwater-reared salmonids	2006-2007
Oral oxytetracycline	All freshwater-reared salmonids	2006-2007

### B5. Survey for Label Claim Needs for Systemic Coldwater Disease

Questions Related to Initial Label Claims After They are Approved	Yes	No	NA
B5.1. Will these initial label claims meet your medicinal drug needs regarding systemic coldwater disease?	28	4	5
B5.2. Will you use florfenicol for systemic coldwater disease in any freshwater-reared salmonid species?	29	3	5
B5.3. Will you use oral oxytetracycline for systemic coldwater disease in any freshwater-reared salmonid species?	30	2	5
Questions Related to UNMET Label Claims That Would be Pursued for Approval If Requested	Yes	No	NA
B5.4. Would you use Romet-30® or Romet-TC® for systemic coldwater disease in any freshwater-reared salmonid species?	22	9	6

### B6. Initial Label Claims for Control of Mortalities Associated with Systemic Columnaris Disease

Drug	Species	Projected Dates for Final Submissions
Florfenicol	All freshwater-reared salmonids & catfish	2006-2007
Oral oxytetracycline	Steelhead trout	2006-2007

### B6. Survey for Label Claim Needs for Systemic Columnaris Disease

Questions Related to Initial Label Claims After They are Approved	Yes	No	NA
B6.1. Will these initial label claims meet your medicinal drug needs regarding systemic columnaris disease?	22	15	0
B6.2. Will you use florfenicol for systemic columnaris disease in any freshwater-reared salmonid species?	30	3	4
B6.3. Will you use florfenicol for systemic columnaris disease in any catfish species?	22	2	13
B6.4. Will you use oral oxytetracycline for systemic columnaris disease in steelhead trout?	13	3	21
Questions Related to UNMET Label Claims That Would be Pursued for Approval If Requested	Yes	No	NA
B6.5. Would you use florfenicol for systemic columnaris disease in any coolwater fish species?	24	4	9
B6.6. Would you use florfenicol for systemic columnaris disease in any scaled warmwater fish species?	24	4	9
B6.7. Would you use oral oxytetracycline for systemic columnaris disease in any freshwater-reared salmonid species other than steelhead trout?	29	3	5
B6.8. Would you use oral oxytetracycline for systemic columnaris disease in any coolwater fish species?	25	3	9
B6.9. Would you use oral oxytetracycline for systemic columnaris disease in any warmwater fish species?	25	3	9
B6.10. Would you use immersion oxytetracycline for systemic columnaris disease in any freshwater-reared salmonid species?	26	7	4
B6.11. Would you use immersion oxytetracycline for systemic columnaris disease in any coolwater fish species?	18	10	9
B6.12. Would you use immersion oxytetracycline for systemic columnaris disease in any warmwater fish species?	18	9	10
B6.13. Would you use Romet-30® or Romet-TC® for systemic columnaris disease in any freshwater-reared salmonid species?	26	6	5
B6.14. Would you use Romet-30® or Romet-TC® for systemic columnaris disease in any coolwater fish species?	21	6	10
B6.15. Would you use Romet-30® or Romet-TC® for systemic columnaris disease in any warmwater fish species?	22	5	10

## C. FUNGAL DISEASES

### C1. Initial Label Claims for Control of Mortalities Associated with Saprolegniasis on Fish

Drug	Species	Projected Dates for Final Submissions
Formalin	All freshwater-reared fish	2006-2007
Hydrogen peroxide	Channel catfish	2006-2007

### C1. Survey for Label Claim Needs for Saprolegniasis on Fish

Questions Related to Initial Label Claims After They are Approved	Yes	No	NA
C1.1. Will these initial label claims meet your medicinal drug needs regarding saprolegniasis on fish?	25	12	0
C1.2. Will you use formalin for saprolegniasis on any freshwater-reared fish species?	34	2	1
C1.3. Will you use hydrogen peroxide for saprolegniasis on channel catfish?	19	4	14
Questions Related to UNMET Label Claims That Would be Pursued for Approval If Requested	Yes	No	NA
C1.4. Would you use copper sulfate for saprolegniasis on any freshwater-reared salmonid species?	11	21	5
C1.5. Would you use copper sulfate for saprolegniasis on any coolwater fish species?	11	18	8
C1.6. Would you use copper sulfate for saprolegniasis on any warmwater fish species?	14	15	8
C1.7. Would you use hydrogen peroxide for saprolegniasis on any freshwater-reared salmonid species?	30	3	4
C1.8. Would you use hydrogen peroxide for saprolegniasis on any coolwater fish species?	25	4	8
C1.9. Would you use hydrogen peroxide for saprolegniasis on any warmwater fish species other than channel catfish?	25	2	10

### C2. Initial Label Claims for Control of Mortalities Associated with Saprolegniasis on Fish Eggs

Drug	Species	Projected Dates for Final Submissions
Copper sulfate	Channel catfish eggs	2008-2009
Formalin	All freshwater-reared fish eggs	APPROVED
Hydrogen peroxide	All freshwater-reared fish eggs	Early 2006

### C2. Survey for Label Claim Needs for Saprolegniasis on Fish Eggs

Questions Related to Initial Label Claims After They are Approved	Yes	No	NA
C2.1. Will these approved and initial label claims meet your medicinal drug needs regarding saprolegniasis on fish eggs?	35	2	0
C2.2. Will you use copper sulfate for saprolegniasis on eggs of channel catfish?	8	16	13
C2.3. Will you use formalin for saprolegniasis on eggs of any freshwater-reared fish species?	37	0	0
C2.4. Will you use hydrogen peroxide for saprolegniasis on eggs of any freshwater-reared fish species?	34	2	0
Questions Related to UNMET Label Claims That Would be Pursued for Approval If Requested	Yes	No	NA
C2.5. Would you use copper sulfate for saprolegniasis on eggs of any freshwater-reared salmonid species?	7	26	4
C2.6. Would you use copper sulfate for saprolegniasis on eggs of any coolwater fish species?	5	25	7
C2.7. Would you use copper sulfate for saprolegniasis on eggs of any warmwater fish species other than channel catfish?	7	23	7

## D. PARASITE DISEASES

### D1. Initial Label Claims for Control of Mortalities Associated with Ichthyophthiriasis

Drug	Species	Projected Dates for Final Submissions
Copper sulfate	Channel catfish	2006-2007
Formalin	All fish	APPROVED

### D1. Survey for Label Claim Needs for Ichthyophthiriasis

Questions Related to Initial Label Claims After They are Approved	Yes	No	NA
D1.1. Will these approved and initial label claims meet your medicinal drug needs regarding ichthyophthiriasis?	25	12	0
D1.2. Will you use copper sulfate for ichthyophthiriasis on channel catfish?	16	11	10
D1.3. Will you use formalin for ichthyophthiriasis on any fish species?	36	1	0
Questions Related to UNMET Label Claims That Would be Pursued for Approval If Requested	Yes	No	NA
D1.4. Would you use copper sulfate for ichthyophthiriasis on any freshwater-reared salmonid species?	13	19	5
D1.5. Would you use copper sulfate for ichthyophthiriasis on any coolwater fish species?	13	16	8
D1.6. Would you use copper sulfate for ichthyophthiriasis on any warmwater fish species other than channel catfish?	18	12	7
D1.7. Would you use hydrogen peroxide for ichthyophthiriasis on any freshwater-reared salmonid species?	26	7	4
D1.8. Would you use hydrogen peroxide for ichthyophthiriasis on any coolwater fish species?	21	8	8
D1.9. Would you use hydrogen peroxide for ichthyophthiriasis on any warmwater fish species?	23	7	7
D1.10. Would you use potassium permanganate for ichthyophthiriasis on any freshwater-reared salmonid species?	15	17	5
D1.11. Would you use potassium permanganate for ichthyophthiriasis on any coolwater fish species?	15	14	8
D1.12. Would you use potassium permanganate for ichthyophthiriasis on any warmwater fish species?	19	12	6

### D2. Initial Label Claims for Control of Mortalities Associated with All External Protozoa

Drug	Species	Projected Dates for Final Submissions
Formalin	All fish	APPROVED

### D2. Survey for Label Claim Needs for All External Protozoa

Questions Related to Initial Label Claims After They are Approved	Yes	No	NA
D2.1. Will this approved and initial label claim meet your medicinal drug needs regarding all external protozoa?	28	9	0
D2.2. Will you use formalin for any external protozoa on any fish species?	37	0	0
Questions Related to UNMET Label Claims That Would be Pursued for Approval If Requested	Yes	No	NA
D2.3. Would you use copper sulfate for any external protozoa on any freshwater-reared salmonid species?	13	19	5
D2.4. Would you use copper sulfate for any external protozoa on any coolwater fish species?	14	15	8
D2.5. Would you use copper sulfate for any external protozoa on any warmwater fish species?	20	10	7
D2.6. Would you use hydrogen peroxide for any external protozoa on any freshwater-reared salmonid species?	26	7	4
D2.7. Would you use hydrogen peroxide for any external protozoa on any coolwater fish species?	20	8	9
D2.8. Would you use hydrogen peroxide for any external protozoa on any warmwater fish species?	22	7	8
D2.9. Would you use potassium permanganate for any external protozoa on any freshwater-reared salmonid species?	19	13	5
D2.10. Would you use potassium permanganate for any external protozoa on any coolwater fish species?	17	11	9
D2.11. Would you use potassium permanganate for any external protozoa on any warmwater fish species?	22	8	7

### D3. Initial Label Claims for Control of All Monogenetic Trematodes

Drug	Species	Projected Dates for Final Submissions
Formalin	All fish	APPROVED

### D3. Survey for Label Claim Needs for All Monogenetic Trematodes

Questions Related to Initial Label Claims After They are Approved	Yes	No	NA
D3.1. Will this approved and initial label claim meet your medicinal drug needs regarding all monogenetic trematodes?	29	7	1
D3.2. Will you use formalin for any monogenetic trematodes on any fish species?	35	2	0
Questions Related to UNMET Label Claims That Would be Pursued for Approval If Requested	Yes	No	NA
D3.3. Would you use hydrogen peroxide for monogenetic trematodes on any freshwater-reared salmonid species?	22	10	5
D3.4. Would you use hydrogen peroxide for monogenetic trematodes on any coolwater fish species?	18	11	8
D3.5. Would you use hydrogen peroxide for monogenetic trematodes on any warmwater fish species?	19	10	8

## E. ZERO WITHDRAWAL SEDATIVE AND ANESTHETIC

### E1. Initial Label Claims for Short-Exposure Handling Involving Sedation & Anesthesia (for tagging, grading, sorting, spawning, hormone induction, vaccination, harvesting, & collecting population assessment data)

Drug	Species	Projected Dates for Final Submissions
AQUI-S®	All freshwater fish	2008-2009
AQUI-S®	Saltwater salmonids	2008-2009

### E1. Survey for Label Claim Needs for Short-Exposure Handling Involving Sedation & Anesthesia

Questions Related to Initial Label Claims After They are Approved	Yes	No	NA
E1.1. Will these approved label claims for AQUI-S® meet your zero withdrawal anesthetic or sedative needs regarding short-exposure handling?	36	1	0
E1.2. Will you use AQUI-S® for short-exposure handling involving sedation and anesthesia on any freshwater salmonid species?	32	1	4
E1.3. Will you use AQUI-S® for short-exposure handling involving sedation and anesthesia on any saltwater salmonid species?	7	7	23
E1.4. Will you use AQUI-S® for short-exposure handling involving sedation and anesthesia on any coolwater fish species?	30	2	5
E1.5. Will you use AQUI-S® for short-exposure handling involving sedation and anesthesia on any warmwater fish species?	33	1	3

### E2. Potential Label Claim for Long-Exposure Handling Involving Sedation & Anesthesia (for transport, research, surgery, and veterinary practice)

Drug	Species	Projected Dates for Final Submissions
AQUI-S®	All freshwater fish	Beyond 2010
AQUI-S®	All saltwater salmonids	Beyond 2010

### E2. Survey for Label Claim Needs for Long-Exposure Handling Involving Sedation & Anesthesia

Questions Related to UNMET Label Claims That Would be Pursued for Approval If Requested	Yes	No	NA
E2.1. Would you use AQUI-S® for long-exposure handling involving sedation and anesthesia on any freshwater salmonid species?	27	5	5
E2.2. Would you use AQUI-S® for long-exposure handling involving sedation and anesthesia on any saltwater salmonid species?	6	10	21
E2.3. Would you use AQUI-S® for long-exposure handling involving sedation and anesthesia on any coolwater fish species?	24	5	8
E2.4. Would you use AQUI-S® for long-exposure handling involving sedation and anesthesia on any warmwater fish species?	29	1	7