



WYOMING GAME AND FISH DEPARTMENT

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January 5, 2007

Dear Fisheries Administrator,

You recently received survey results forwarded by the Fisheries and Water Resources Policy Committee of the Association of Fish and Wildlife Agencies (AFWA) outlining pending aquaculture drug approvals and identified needs still unmet under the Federal-State Aquaculture Drug Approval Partnership Project. The committee's Drug Approval Working Group (DAWG) has reviewed the survey results and we are now asking agencies raising coolwater and warmwater fish for assistance in completing further studies so these needs can be added to the pending label approvals for chloramine-T and hydrogen peroxide.

Through your assistance with the project, the following drug approvals are very close.

Control of mortality by chloramine-T and hydrogen peroxide in all freshwater-reared salmonids due to bacterial gill disease,

Control of mortality by chloramine-T in walleye due to external columnaris disease,

Control of mortality by hydrogen peroxide in all coolwater fish species and channel catfish due to external columnaris disease,

Control of mortality by hydrogen peroxide in all freshwater-reared fish eggs due to saprolegniasis.

Although a considerable amount of research has been conducted and accepted by the Food and Drug Administration (FDA) for all freshwater-reared finfish, complete data packages exist primarily for coldwater (salmonid) drug claims. To fully utilize the accepted data for cool- and warmwater species, additional effectiveness studies are needed to complete the following packages.

Control of mortality by chloramine-T and hydrogen peroxide in all coolwater and warmwater fish species due to bacterial gill disease,

Control of mortality by chloramine-T in coolwater fish species other than walleye and all warmwater fish species due to external columnaris disease,

Control of mortality by hydrogen peroxide in warmwater fish species other than channel catfish due to external columnaris disease,

Control of mortality by hydrogen peroxide in all coolwater and warmwater fish species other than channel catfish due to saprolegniasis.

If you need these drug uses, we need your help to complete pivotal and/or supportive clinical field trials.

The Aquatic Animal Drug Approval Partnership (AADAP) Program of the US Fish and Wildlife Service is available and prepared to work with your agency to conduct these important investigations. The following tables identify the remaining effectiveness studies tentatively needed to complete the data packages for the claims listed above. These are studies you could potentially conduct in your 2007 production cycle.

Coolwater Species

Bacterial Gill Disease			
Drug	# Pivotal studies	# Supportive studies	Fish species
Chloramine-T (1)*	2	1	Any coolwater species
Hydrogen peroxide (8)	2	1	Any coolwater species
External columnaris disease			
Chloramine-T (4)	1	1	Any coolwater species except walleye
Saprolegniasis			
Hydrogen peroxide (3)	2	1	Any coolwater species

*Ranking in the unmet needs survey

Warmwater Species

Bacterial Gill Disease			
Drug	# Pivotal studies	# Supportive studies	Fish species
Chloramine-T (10)*	2	1	Any warmwater species
External columnaris disease			
Chloramine-T (4)	2	1	Any warmwater species
Hydrogen peroxide (2)	1	1	Any warmwater species except channel catfish
Saprolegniasis			
Hydrogen peroxide (11)	0	1	Any warmwater species except channel catfish

*Ranking in the unmet needs survey

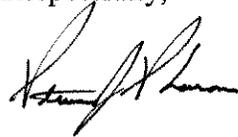
Pivotal effectiveness studies are clinical field trials performed at your facility, conducted under AADAP protocols, and completed with on-site assistance from AADAP staff. Supportive effectiveness studies are performed under production conditions by facility staff following AADAP protocols and with guidance and logistic support provided by AADAP. These studies require limited cost, if any, from your staff excluding time and use of their facility. Dr. Dave Erdahl (406-994-9904) or AADAP staff (<http://fisheries.fws.gov/aadap>) can best discuss study potentials and specifics with your personnel.

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Being recognized as part of an FDA clinical field trial and contributing to a national aquaculture initiative can be a different and rewarding experience for hatchery personnel. Participating facilities and investigators for publicly supported aquaculture approvals, such as formalin and oxytetracycline for skeletal marking, have been cited in the Freedom of Information summary accompanying these approvals (<http://www.fda.gov/cvm/aqualibtoc.htm>).

In summary, we are extremely close on achieving several approvals on hydrogen peroxide and chloramine-T for all freshwater species. With a few additional studies, the current label claims can be expanded to include a substantially greater number of species. These studies can be completed over a very short time frame if study locations and species are available and coordinated. Please consider taking the initiative to assist in the needed studies so all freshwater fish production can fully benefit from these drugs.

Respectfully,



Steve Sharon
Chair, Drug Approval Working Group

SS/DE/DP/RS

cc: Drug Approval Working Group members
Eric Schwaab, AFWA
Doug Hansen, Fisheries and Water Resources Policy Committee Chair
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