ASSOCIATION OF FISH AND WILDLIFE AGENCIES – DRUG APPROVAL WORKING GROUP

QUESTIONNAIRE: TO DETERMINE UNMET FISH DRUG NEEDS AS THEY RELATE TO FISH DISEASE CONCERNS AND FISHERIES MANAGEMENT ISSUES

Introduction – The Drug Approval Working Group (DAWG), a working group of the Association of Fish and Wildlife Agencies Fisheries and Water Resources Policy Committee, would like to assess the current and future unmet drug needs of fish culturists, fish health professionals, and fisheries management biologists. Although several new drugs have been added to the collective fisheries "medicine chest" over the past 10 years, the number of U. S. Food and Drug Administration (FDA)-approved fish drugs is still relatively limited. As certain priority drugs have been approved for specific claims, collaborative research efforts of the DAWG and its partners' have shifted to reflect new priorities - including generating data to support new approvals, identifying emerging disease issues for which treatment options are currently limited or non-existent, and seeking approval for non-therapeutic drugs such as those used for skeletal marking, spawning, sex reversal, and fish sedation/anesthesia.

The purpose of this survey is to canvass the aquaculture and fisheries arena and to determine:

1. Fish drug needs related to freshwater diseases/pathogens of concern to fisheries professionals, specifically those for which there is no:
    a. Effective FDA-approved drug, or
    b. Effective unapproved drug that is available for FDA-authorized use under an Investigational New Animal Drug (INAD) exemption

2. Fish drug needs for non-therapeutic freshwater purposes (spawning, marking, sedation, sex reversal, etc.) for which there is no:
    a. Effective FDA-approved drug
    b. Effective unapproved drug that is available for FDA-authorized use under a INAD exemption

3. Fish drug needs for the culture and/or management of marine fish species in seawater environments.

Results from this survey will be used by the DAWG to 1) establish DAWG priorities and direction of effort; 2) engage with current sponsors or find new drug sponsors as needed; and 3) generate data to support new approvals or new (expanded) claims for drugs that are currently approved. Questionnaire answers will be strictly confidential, and no personal, agency, or organization information will be divulged in any report summarizing questionnaire results.

Please complete the attached survey by answering each question to the best of your ability, or simply responding with a "NA" if the question is not applicable to you or your situation. Please return the survey by September 5th, 2017 to DAWG Committee Chairman, Steve Sharon, at steve.sharon@wyo.gov.

To ensure that you are fully up-to-date with respect to 1) what drugs are currently approved by FDA and for what specific treatment use(s) each drug is approved; 2) what drugs are available under INAD exemption; and 3) what drugs are considered to have deferred regulatory status – please review the information provided below before proceeding to the questionnaire. However, please remember that if a drug is not approved by FDA for a specific use that you believe is important, we are interested in hearing about it – regardless of whether or not it may be currently available under an INAD or deferred regulatory status.

Available FDA Approved Drugs:

1. **Chorulon®** (chorionic gonadotropin) – spawning aid for all male and female broodfish

2. **Formalin** (PARASITE-S, FORMALIN-F, AND FORMACIDE-B) – control of:
    a. External protozoa and monogentic trematodes in all finfish
    b. Fungus (Saprolegniasis) on all finfish eggs
    c. Protozoan parasites in Penaeid shrimp

3. **35% Perox Aid®** (hydrogen peroxide) – control of mortality due to:
    a. Bacterial gill disease in all freshwater-reared salmonids
    b. External columnaris in freshwater-reared coolwater finfish and channel catfish
    c. Fungus (Saprolegniasis) on freshwater-rearedfinfish eggs

4. **Halamid® Aqua** (chloramine-T) – control of mortality due to:
    a. Bacterial gill disease in all freshwater-reared salmonids
    b. External columnaris in walleye and freshwater-reared warmwater fish

5. **Oxytetracycline hydrochloride** (PENNOX®343 and TERRAMYCIN-343) - mark skeletal tissue of finfish fry and fingerlings

6. **Tricaine-S** (MS-222) - temporary immobilization of fish
    a. Of the families Ictaluridae, Salmonidae, Esocidae, and Percidae
    b. At water temperatures > 10°C

7. **Aquaflor®** (florfenicol) – control of mortality due to:
    a. Furunculosis in freshwater-reared salmonids
    b. Coldwater disease in all freshwater-reared salmonids
    c. Columnaris in all freshwater-reared finfish
    d. ESC in catfish
    e. Streptococcal septicemia associated with *Streptococcus iniae* in freshwater-reared warmwater finfish

8. **Terramycin® 200 for Fish** (oxytetracycline dihydrate) - control of mortality due to:

a. Bacterial hemorrhagic septicemia (BHS) and pseudomonas disease in catfish
b. Coldwater disease, furunculosis, ulcer disease, bacterial hemorrhagic septicemia, and pseudomonas disease in all freshwater-reared salmonids
c. Columnaris disease in all freshwater-reared *Oncorhynchus mykiss*
d. Gaffkemia in lobster
e. Mark skeletal tissue of Pacific salmon

9. **Romet 30/Romet TC** (sulfadimethoxine and ormetroprim) - control mortality due to:
    a. Furunculosis in salmonids
    b. Enteric septicemia in catfish

Drugs Currently Available Under an INAD exemption:

1. **Aquaflor®** (florfenicol medicated feed)**:** for use-patterns (e.g., bacterial pathogens and fish species) not currently approved

2. **Terramycin® 200 for Fish** (oxytetracycline dihydrate medicated feed): for use-patterns (e.g., bacterial pathogens and fish species) not currently approved; feed marking

3. **Slice®** (emamectin benzoate medicated feed): for the control of external parasites in freshwater and marine finfish

4. **17 α Methyltestosterone** (medicated feed use)**:** for sex-reversal in tilapia fry

5. **Chloramine-T:** for use-patterns (e.g., bacterial pathogens and fish species) not currently approved

6. **35% Perox Aid®** for use-patterns (e.g., ectoparasites and fish species) not currently approved

7. **Oxytetracycline hydrochloride** (immersion)**:** for use-patterns not currently approved, including therapeutic treatment of bacterial pathogens (e.g., bacterial coldwater disease and external columnaris)

8. **Diquat:** for the control of mortality caused by bacterial gill disease and external flavobacteriosis

9. **AQUI-S® 20E** (eugenol)**:** for sedation up to 15 min - immediate release for freshwater and marine field use; 3-d withdrawal period for hatchery use

10. **LHRHa:** for use as a spawning aid for a variety of fish species

11. **Common Carp Pituitary:** for use as a spawning aid for a variety of fish species

12. **Ovaplant and OvaRH** (sGnRH)**:** for use as a spawning aid for a variety of fish species

13. **Channel Catfish Pituitary:** for use as a spawning aid for a variety of catfish species

14. **Calcein:** for use to mark skeletal or calcified tissue of fish and mussels

15. **Erythromycin** (medicated feed)**:** to control mortality caused by *Renibacterium salmoninarum* (causative agent of BKD) in salmonids

16. **Erythromycin** (injection)**:** for use to control (reduce) the vertical transmission of *Renibacterium salmoninarum* (causative agent of BKD) from female salmonid broodfish to progeny; and to control mortality caused BKD in salmonids

Drugs Currently Considered by FDA to have *Deferred Regulatory Status*[1]:

1. **Copper sulfate**: for the control of mortality caused by external bacteria, external parasites, and fungus on finfish and finfish eggs

2. **Potassium permanganate**: for the control of mortality caused by external bacteria, external parasites, and fungus on finfish and finfish eggs

[1] *By definition, deferred regulatory status means that FDA has chosen not to enforce and/or regulate use of such compounds at this time*

CONFIDENTIAL INFORMATION FROM THE QUESTIONNAIRE RESPONDENT

Name: _____

Position: _____

Agency/Organization/Facility name: _____

_____

Email address_____

Telephone number_____

QUESTION 1. What are the disease(s)/pathogen(s) of concern for which you would like to see an effective FDA-approved drug?

Fill in Table 1 as completely as possible, including:

a. Name of pathogen/disease or general category (e.g., external parasites);

b. Fish species name or temperature grouping of species (i.e., salmonids, coolwater, warmwater), and indicate if it is for freshwater (FW) or marine (M) use;

c. Name of active ingredient (i.e., chloramine-T) or drug (Aquaflor®) you would like to see approved for this particular use. If no drug is available or known, enter NEW;

d. Leave row blank if the disease/pathogen "pre-listed" is not an issue for fish reared at your facility; and

e. Use "Other" rows to indicate disease/pathogens that are not pre-listed but are an issue of concern at your facility

Example:

Disease	Pathogen (if known)	Fish species/grouping	Suggested therapeutant(s)
Furunculosis	Aeromonas salmonicida	Atlantic salmon (M)	Romet 30
Bacterial kidney disease	Renibacterium salmoninarum	Chinook salmon (M)	Florfenicol/erythromycin
Copepods	Salmincola	Rainbow trout (FW)	Emamectin benzoate

Table 1: Fish diseases/pathogens of concern at your facility, fish species affected, and the drug you would like to see approved to effectively control mortality or reduce pathogen load. Please be aware that it is not likely that FDA will approve any important human drug for use on fish (e.g., penicillin).

Disease	**Pathogen (if known)**	**Fish species/grouping**	**Suggested therapeutant**
Bacterial gill disease			
Coldwater disease			
Columnaris			
Flavobacteriosis			
Edwardsiella tarda septicemia			
Enteric redmouth disease			
Enteric septicemia			
Furunculosis			
Vibriosis			
Motile Aeromonas septicemia			
Coldwater vibriosis			
Piscirickettsiosis			
Bacterial kidney disease			
Streptococcal disease			
Ichthyophthiriasis			
Ichthyobodiasis			
Sea Lice			
Copepods			
External protozoan			
Monogenetic trematodes			
Saprolegniasis			
Other			

Other			
Other			

QUESTION 2. Are there any emerging diseases that you are concerned about for which there are no FDA-approved drugs or drugs in the approval pipeline

Fill in table 2 with the disease and/or pathogen that is emerging and fish species or species grouping of concern. Please denote whether this is a concern in freshwater finfish (FW), marine finfish (M), or both

Table 2. Emerging fish disease or infectious fish pathogens and target fish species

Disease/pathogen	Fish species or grouping

QUESTION 3. What are your 3 top non-therapeutic drug needs that would enhance your ability to meet your management/production goals?

Fill in Table 3 as completely as possible, including:

a. Purpose for drug need (i.e., spawning aid, sedation/anesthesia, marking skeletal tissue, sex reversal, production of XX or YY males, etc.);

b. Fish species drug will be used on;

c. If applicable, indicate whether fish (direct) or parents (indirect) would be treated;

d. Name of active ingredient (i.e., chloramine-T) or drug (Aquaflor®) you would like to see approved for this particular use. If no drug is available, enter NEW; and

e. If you have fewer than 3 non-therapeutant drug needs, simply leave rows blank

Example

Treatment purpose	Fish species	Direct/Indirect	Suggested drug(s)
Gender Manipulation	Tilapia, rainbow trout	Direct	Methyltestosterone, estradiol

Table 3 – Non-therapeutic drug needs, including purpose for treating fish , fish species or temperature grouping of fish,

Treatment purpose	Fish species/grouping	Which life stage treated	Suggested drug(s)