



Use of Drugs in Aquaculture

What every fish culturist
should know

Presented at:
Coldwater Fish Culture Course
Bozeman, Montana
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Course Overview

- **Introduction to the AADAP Program and important acronyms and definitions**
- **Legal and Judicious use of drugs in aquaculture**
 - **Individual Skill Sheet & Quiz**
- **Investigational New Animal Drug Program**
 - **Quiz**
 - **Interactive lesson activity**
- **Calculations, forms for INADs and Veterinary Feed Directives, T&E forms**
 - **Quiz**
- **BIG interactive lesson activity**



AADAP Program

- **A distinct branch of the U.S. Fish & Wildlife Service's (FWS) Division of the National Fish Hatchery System**
 - Located in Bozeman, MT
 - An outgrowth of the FWS's National INAD Office and its associated National INAD Program (NIP)
- **Mission: *to work with our partners to conserve, protect, and enhance the Nation's fishery resources by coordinating activities to obtain U.S. Food and Drug Administration approval for drugs, chemicals and therapeutants needed in aquaculture and fisheries management programs***



AADAP's Bread and Butter

What we do best and where our priorities lie



- **Partnerships**
- **Administration of Investigational New Animal Drug (INAD) exemptions and National INAD Program**
- **Research Program and generation of aquaculture drug approval data**
- **New Animal Drug Application (NADA) management**
- **Information dissemination**



Why is AADAP's Mission Important to Fish Culturists?

- Prior to the 1990s FDA chose not to regulate drug and chemical use in aquaculture (via “regulatory discretion”)
 - Hence, fisheries managers were able to use virtually anything (and everything!!) they could get their hands on to meet management objectives
- Unfortunately, in the early 1990s FDA decided (using the flip-side of regulatory discretion!) that the time had come when aquaculture needed to be regulated. Everything changed....and feast became famine.



Why is AADAP's Mission Important to Fish Culturists?

- FDA's decision to regulate left aquaculture with only 3 therapeutants and a single anesthetic approved for use in all fisheries programs
- Use of these approved drugs was limited by species, life stage, specific pathogen, and use pattern
- Effect of decision was exacerbated by FDA's broad definition of a "drug"..... that included even apparently innocuous compounds such as **ice, salt, onion, and garlic ???!**





AADAP's day-to-day activities

- **Involved in a whole spectrum of aquaculture drug activities**
 - **Research - effectiveness and safety – in support of approvals**
 - **Establish and maintain mechanism to legally use drugs not yet approved by FDA - INAD's**
 - **Petition CVM – affect CVM's position and guidelines**
 - **Coordination – Workshops, special sessions, research forums, etc.**
 - **General interaction with “everybody”**
 - **Information dissemination – website, newsletter, presentations at conferences, conduct training courses, etc.**



Information dissemination

- **AADAP Website (www.fws.gov/fisheries/aadap)**
 - **“One-stop shopping” for everything you need or want to know regarding drug and chemical use in aquaculture**
 - ❖ **FDA-approved drugs and how to use them**
 - ❖ **INAD information: available drugs, fact sheets, protocols, forms, etc.**
 - ❖ **Other drugs not yet approved by CVM and mechanisms to legally use them**
 - ❖ **Drug approval status**
- **AADAP Newsletter**
 - **Published quarterly**
 - **Electronic dissemination**



Important acronyms and definitions

- **NADA = new animal drug application (approval)**
 - A formal application submitted to FDA's Center for Veterinary Medicine by a drug company to demonstrate that its new drug is safe and effective
 - 10 – 15 yrs and >\$10M to gain FDA approval
 - Public data necessary due to low profit incentive for drug companies

- **INAD = investigational new animal drug exemption**
 - Exemption issued by CVM to allow use of an unapproved drug under strict conditions
 - Permits the legal use of the drug and release or slaughter of food animals treated with the drug
 - Permits the legal interstate transport of the drug



Important acronyms and definitions

➤ Withdrawal period

- Period of time between last administration of a drug and the time when a food animal may be released or slaughtered

➤ Extra-label use

- Veterinary prescription for the use of an approved drug for a disease condition and/or species not on the approved label
- Veterinarian must assume all responsibility for residues

➤ Veterinary Feed Directive (VFD)

- Written statement (prescription) issued by a vet that allows the use of a VFD feed drug
- VFD can only be written if a valid vet-client-patient relationship exists



Now...on to the good stuff