

USFWS INAD PROGRAM: AQUACULTURE DRUG REGISTRATION AND INAD ADMINISTRATION^{AFS}

Dave Erdahl, Jim Bowker, Dan Carty, Bonnie Johnson, and Molly Poehling
USDI Fish and Wildlife Service
Bozeman Fish Technology Center
National Investigational New Animal Drug Office
Bozeman, MT 59715

Very few drugs are approved for use in aquaculture, and the utility of these drugs is severely restricted by species, pathogen, and environmental conditions. Compassionate Investigational New Animal Drug (INAD) exemptions allow for the widespread, legal use of unapproved drugs and chemicals and provide an important mechanism to assist aquaculturists and fisheries managers to meet program objectives. The USDI Fish and Wildlife Service (FWS) National INAD Office (NIO) was formed in 1995 to administer and monitor the use of FWS INADs at federal aquaculture facilities. Since then, the role of the office has expanded to include (1) participation in an international effort to obtain U.S. Food and Drug Administration (FDA) approvals of drugs for use in aquaculture, (2) a pivotal study research program, and (3) the establishment of the National INAD Program (NIP) through which non-FWS aquaculture facilities (i.e., state, tribal, and private) can piggy-back on FWS INADs. Maintaining INAD drug use is extremely important because an initial approval for one drug can take years and usually requires generating and submitting six "data packages" to FDA for review. The six "data packages" include product chemistry, mammalian toxicity, tissue residue depletion, environmental fate, pivotal efficacy, and target animal safety. Since 1997, the NIO's pivotal study research program has been very involved in conducting pivotal efficacy and target animal safety studies. The focus of this effort has been to generate data to support new animal drug approvals for the use of chloramine-T and oxytetracycline in salmonids. Because work on chloramine-T and oxytetracycline is nearly

complete, current efforts are focusing on generating efficacy and target animal safety data for Aqui-S (a potential zero-withdrawal anesthetic) and florfenicol (a potent, broad spectrum antibiotic). In addition, the NIO continues to administer and monitor the federal and non-federal use of 12 INADs. Non-federal participation on FWS INADs is administered through the National INAD Program, which is more commonly referred to as the Piggy-backin' Program. In addition to allowing widespread access to needed drugs, objectives of the Piggy-backin' Program are to consolidate the INAD process, eliminate duplication of effort, reduce workloads and costs, ensure compliance with FDA guidelines, and generate supportive efficacy and target animal safety data. Supportive data can be extremely useful in obtaining an initial aquaculture drug approval or in expanding an existing aquaculture drug label. Ultimately, the work carried out by the NIO helps provide safe and efficacious drugs, chemicals, and therapeutants to aquaculturists and fisheries managers throughout the United States.