



U.S. Fish & Wildlife Service

The Aquatic Animal Drug Approval Partnership Program

Fact Sheet: 17- α Methyltestosterone INAD 11-236

INAD objective/purpose:	Collect supportive and pivotal data needed to establish the effectiveness of 17- α methyltestosterone when fed as a feed additive to larval tilapia to produce populations comprising over 90% male fish.
Drug name:	17- α methyltestosterone (MET)
Source of drug/feed:	Rangen Inc.
Address:	P.O. Box 706 Buhl, ID 83316
Contact:	Attention: David Brock Phone: 1-800-657-6446 x ext. 1332 Fax: 208-543-8037 email: dbrock@rangen.com
Target pathogen(s):	Not Applicable
Method of administration:	Medicated-feed treatment
Treatment dosage:	9 milligrams (mg) MET per kilogram (kg) fish per day <u>Note:</u> MET will typically be incorporated into standard tilapia feed at a rate of 60 mg MET per kg feed; fish should be fed at 15% body weight per day.
Treatment regimen:	28 consecutive days
Withdrawal period:	Batch Culture: 120 days (from last day of treatment). <u>Note:</u> Batch culture is defined as when all fish in a group/lot enter and leave the lot at the same time. Partial Harvest/Restock Culture: individual minimum weight of 350 grams per fish. <u>Note:</u> Partial harvest/restock culture is defined as the mixing of different lots of fish during the grow-out period and selective harvest from the production unit at various times.
Required test parameters:	Investigator needs to report general fish behavior and any adverse effects relating to treatment.
Limitations or restrictions on use of drug:	No re-treatment of fish is allowed. Investigator must follow all instructions in the Study Protocol for INAD 11-236 regarding drug acquisition and handling, fish treatment and disposition, and data reporting requirements. Investigator must submit written assurance that procedures and/or mitigations are in place to insure 17MET will not be released in effluents or leached to groundwater at concentrations > 1ppb <u>before</u> use under the INAD. Contact AADAP for more information
Required INAD fee:	Drug discharge must be in compliance with local NPDES permitting requirements. \$700.00/facility/year
AADAP Contact Information:	Ms. Bonnie Johnson, FWS-AADAP Phone: 406-994-9905 email: bonnie_johnson@fws.gov