SUPPLEMENTAL POLICIES

EXTRALABEL USE OF APPROVED DRUGS IN AQUACULTURE

I. Purpose:

The purpose of this guide is to summarize acceptable conditions for extralabel use of approved drugs in aquaculture.

II. Policy:

A. Extralabel use in animals of approved animal and human drugs is provided for in the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA). FDA implementing regulations are at 21 CFR 530, and were published in the FEDERAL REGISTER November 7, 1996 (61 FR 57732).

B. Extralabel drug use is required to be under the supervision of a veterinarian.

C. Provided that all requirements of the implementing regulations are met, drugs approved for terrestrial animals can be used in aquaculture.

D. AMDUCA does not permit extralabel use of an approved drug for nontherapeutic uses, including reproductive uses that are not therapeutic. Enforcement discretion will be considered on a case-by-case basis.

E. AMDUCA does not permit extralabel use of a drug that is administered through feed. However, FDA will use enforcement discretion on a case-by-case basis in certain circumstances. That is, discretion will be considered where feeds are formulated and labeled properly in accordance with medicated feed approval regulations and used extralabelly under a veterinarian's supervision.