SUPPLEMENTAL POLICIES

EXTRALABEL USE OF APPROVED DRUGS IN AQUACULTURE

I. Purpose:

The purpose of this document 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. Enforcement discretion may be considered on a case-by-case basis.

E. FDA will not object to the extra-label use of approved aquaculture medicated feeds for other indications of use and/or other aquaculture species if all the conditions in Compliance Policy Guide, 615.115, Extra-label Use of Medicated Feeds for Minor Species, are followed. For fish, this applies only to the two Type A medicated articles currently approved for use in fish, Romet and Terramycin.