

## ROZ's CORNER

The North Central Regional Aquaculture Center and the Multi-State Conservation Grant Program will fund studies on AQUI-S<sup>®</sup>, a zero withdrawal anesthetic. These studies should help keep us on track for final study reports for all data requirements to be submitted in 2008 and potential approval for 2008 or early 2009.

The company sponsors remained active in pursuing approvals for their aquaculture drug products and also received some good news: (1) Schering-Plough Animal Health submitted its Administrative New Animal Drug Application for Aquaflor<sup>®</sup> (florfenicol) for control of mortality associated with enteric septicemia in catfish to the Center for Veterinary Medicine (CVM); an approval should be coming shortly for this most important antibacterial [Editor's note: ESC claim actually approved 24 October 2005]; (2) Eka Chemicals, Inc. received acceptance letters from CVM on 6 June and 16 September regarding its hydrogen peroxide product (PEROX-AID<sup>®</sup>) microbial food safety submissions; this completes the Human Food Safety Technical Section for hydrogen peroxide; (3) Phibro Animal Health submitted a change on 21 September 2005 in its formulation to a dihydrate salt for their oxytetracycline product, Terramycin for Fish<sup>®</sup>; (4) Axcentive SARL called a meeting with CVM on 1 August 2005 to resolve the remaining issues related to their proprietary environmental assessment for their chloramine-T product, Halamid<sup>®</sup>; and (5) Bimeda, Inc. met with CVM on 23 May 2005 to clarify the remaining product chemistry data requirements for their erythromycin product, Aquamycin<sup>®</sup>.

I organized a meeting with CVM on October 5, 2005 to determine the microbial food safety requirements for oral oxytetracycline and chloramine-T. Clear paths for completing these tasks were identified. I developed a major survey to determine unmet label claim needs for aquaculture drug approvals; it went out 21 September 2005 to the 38 states that supported the Federal-State Aquaculture Drug Approval Partnership Project. Responses are due October 28, 2005. *Rosalie (Roz) Schnick, National Coordinator for Aquaculture New Animal Drug Applications, Michigan State University, La Crosse, Wisconsin.*

## CVM's NOTES

### Extralabel Use of Drugs for Aquaculture - Past and Present:

The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) allows veterinarians to prescribe extralabel uses of certain approved animal drugs and approved human drugs for animals under certain conditions. Extralabel use (ELU) refers to the use of an approved drug in a manner that is not in accordance with the approved label directions. The key constraints of AMDUCA are that any extralabel use must be by or on the order of a licensed veterinarian within the context of a veterinarian-client-patient relationship, must not result in violative residues in food-producing animals, and the use must be in conformance with the implementing regulations published at 21 CFR Part 530. A list of drugs specifically prohibited from extralabel use appears in the Code of Federal Regulations and can be found at <http://www.fda.gov/cvm/amducatoc.htm>.

Significantly, extralabel use of medicated feeds was excluded from the original ELU provisions in AMDUCA. In 2001, FDA recognized that extralabel use of medicated feed for treatment of minor species could be considered when the health of animals is threatened and suffering or death would result from failure to treat the affected animals. As a directive to its field staff, FDA wrote the Compliance Policy Guide (CPG) 615.115: Extralabel Use of Medicated Feeds for Minor Species, found at: [http://www.fda.gov/ora/compliance\\_ref/cpg/cpgvet/cpg615-115.html](http://www.fda.gov/ora/compliance_ref/cpg/cpgvet/cpg615-115.html), which described conditions under which veterinarians

could prescribe medicated feeds in an extralabel manner to treat minor species. In addition to the original conditions of ELU, the CPG imposed further constraints when the minor species are food producing animals. For aquaculture, extralabel use of medicated feed is limited to medicated feed products approved for use in aquatic species as formulated into the diet intended for the approved species.

This means that a veterinarian could order one of the approved over-the-counter (OTC) products to treat a different fish species than that described on the label, or could use the product to treat a different disease condition.

As a result of the Animal Drug Availability Act of 1996 (ADAA), a new option for regulating the distribution of new animal drugs was added to the traditional over-the-counter and prescription options. Regulations implementing the Veterinary Feed Directive (VFD) became effective in 2001; for information see <http://www.fda.gov/cvm/vfd.html>. This new VFD option was developed to provide a more tailored way to regulate what might have been called "prescription medicated feeds".

Specifically, extralabel use of VFD products is prohibited according to the regulations. Recently, FDA/CVM approved Aquaflor<sup>®</sup> (florfenicol) for the control of mortality due to enteric septicemia of catfish. For details on this new approval see [http://www.fda.gov/cvm/CVM\\_Updates/catfishapp.htm](http://www.fda.gov/cvm/CVM_Updates/catfishapp.htm). Aquaflor<sup>®</sup> was approved as a VFD product, which means it can only be distributed on the order of a veterinarian.

A few questions regarding Aquaflor<sup>®</sup> and other drugs:

**Q:** Can Aquaflor<sup>®</sup> be used in an extralabel manner under the CPG? **A:** No, as a VFD product its use is limited to the species and indication on the approved label.

**Q:** Can veterinarians continue to use the other approved over-the-counter products in an ELU manner under the CPG? **A:** Yes, the provisions of the CPG as they pertain to non-VFD products are not changed.

**Q:** Will all new products for aquaculture be limited to use only by veterinarians? **A:** It depends. New products are evaluated by FDA/CVM on the basis of safety and effectiveness, and a decision is made on whether adequate directions for use can be written for non-veterinarians. If appropriate label directions can be written and other safety issues do not preclude the condition of use, the product can be marketed OTC.

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