March 7, 2003

Dr. William T. Flynn, HFV-2
Center for Veterinary Medicine
Food and Drug Administration
7519 Standish Place
Rockville, MD 20855

RE: Guidance Document #152 (Docket 98D-1146)

Dear Dr. Flynn:

This letter is to provide some additional comment on CVM draft guidance # 152 titled "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern." We apologize for the delay in submitting comments but we have only recently become aware of particular aspects of the guidance specific to domestic aquaculture. Our concern is that the limited information presented in the guidance regarding domestic aquaculture provides an incomplete picture that could bias or mislead FDA reviewers or the public. The National Aquaculture Association (NAA) is a national aquaculture trade association representing a diversity of aquaculture animal species and interests. Our comments focus on Appendix B and C of guidance document # 152.

Appendix B: Human exposure to bacteria of human health concern via animal-derived foods.

The draft guidance proposes a qualitative risk assessment that relies on several components including food consumption patterns in the US population and prevailing contamination levels on food. While the FDA recommends drug sponsors reference most current data in their submissions, Table B1 in Appendix B grossly over-estimates the consumption of **farm-raised** seafood. Table B1 combines all seafood (wild capture and farm raised) together to estimate per capita consumption (per capita seafood consumption is now down to 14.6 lbs). Only about 25- 35 % of the seafood consumed in the US is farm raised, the greater portion (65-75 %) being wild captured. Of the 25-35 % that is farm raised, a significant portion is imported. Indeed, the USDC estimates 70 % of all seafood consumed in the US is imported. This suggests that at best only about 5.3 lbs per capita is farm raised seafood and only about 1.6 lbs per capita is domestically produced farm raised seafood. It is the 1.6 lbs per capita that FDA should use in judging relative risks.

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The estimated per capita consumption in Table B1 also combines fish and shellfish together and lumps all species together. In the US, farm raised shellfish rarely if ever are purposefully exposed to antibiotics so should be excluded from per capita consumption estimates. Since any antimicrobial drug approved for use in the US aquaculture industry is species specific, e.g. only catfish, salmonids or lobster for oxytetracycline, it is inappropriate and misleading to lump all aquatic animals together. Lumping unjustifiably raises the risk level. The only domestically produced aquatic animal species consumed in the US in sufficient volume to be regulatory reported by the US Census Bureau is farm-raised catfish and that consumption is a low 1-1.2 lbs/capita/year. Thus, for qualitative risk analysis purposes, all domestic aquacultured species should be treated individually and each would fall in the **low** qualitative risk ranking.

The domestic consumption of individual aquaculture species is so low and the incidence of food borne pathogens associated with farm raised fin fish so rare, that there is very little information on the prevalence of *Salmonella* or *Campylobacter*. Recent CDC data do not identify any seafood with *Salmonella* or *Shigella* isolates. Again, this suggests the qualitative risk factor associated with farm-raised seafood is exceedingly low.

Appendix C. Re-evaluating the safety of currently approved antimicrobial new animal drugs.

FDA proposes to re-evaluate the safety of currently approved antimicrobials. This would include the two antimicrobials approved for limited use in the domestic aquaculture industry (oxytetracycline for catfish, salmonids and lobster; and a potentiated sulfonamide for catfish and salmonids only). Given the low per capita consumption and low prevalence of human food borne pathogens on domestically produced farm raised aquaculture species, we suggest domestic aquaculture should be ranked very low in prioritization for re-evaluation of currently approved antimicrobials.

We hope this information is helpful in putting the relative contribution of domestic aquaculture into perspective with regard to antimicrobial resistance issues.

Sincerely,

John R. MacMillan, Ph.D.
President