

I-008069-P-0069

August 15, 2006

University of Arizona  
Environmental Research Laboratory  
Dept. of Soil, Water and Environ. Sciences  
College of Agriculture and Life Sciences  
Attention: Rodney R. Williams  
2601 E. Airport Drive  
Tucson, AZ 85706-6985

Subject: Assessment on effect of OTC residues on human intestinal flora

Dear Mr. Williams:

Your assessment on effects of OTC residues present in shrimp on the human intestinal flora is acceptable as provided in an Investigational New Animal Drug (INAD) file submission dated June 15, 2006.

Based on the pivotal residue depletion study used to determine the withdrawal time in shrimp, the amount of OTC residues present in shrimp fed for 14 days with a medicated feed containing up to 4 g OTC/kg of feed, following a 2-day withdrawal, would probably not cause any adverse effect on the intestinal flora of the consumer.

In future correspondence, please discuss only one submission per letter. We suggest including the following information in a subject line before the salutation of your letter: the date of this letter, our identifier, I-008069-P0069, and a brief summary of your request. Please submit your correspondence directly to the Document Control Unit (HFV-199), marked to my attention. If you have questions, please contact Dr. Kevin Greenlees, Acting Team Leader, Toxicology Team, at 301-827-6977.

Sincerely,

Lynn G. Friedlander, Ph.D.  
Acting Director, Division of Human Food Safety  
Office of New Animal Drug Evaluation  
Center for Veterinary Medicine