CENTER FOR SCIENCE IN THE PUBLIC INTEREST • ENVIRONMENTAL DEFENSE • FOOD ANIMAL CONCERNS TRUST • INSTITUTE FOR AGRICULTURE AND TRADE POLICY • NATIONAL CATHOLIC RURAL LIFE CONFERENCE • THE HUMANE SOCIETY OF THE UNITED STATES • UNION OF CONCERNED SCIENTISTS

May 9, 2007

Christopher Ragland, President
Intervet, Inc.
P.O. Box 318
405 State St.
Millsboro, DE 19966

Dear Mr. Ragland:

We, the undersigned members of the Keep Antibiotics Working coalition (KAW), request that Intervet withdraw its new animal drug application to the Food and Drug Administration (FDA) for approval of cefquinome. Keep Antibiotics Working is a coalition of health, consumer, agricultural, environmental, humane, and other advocacy groups with more than nine million members working to protect public health through the promotion of the responsible use of antibiotics in animal agriculture.

As you know, on September 25, 2006, a majority of the Veterinary Medicine Advisory Committee (VMAC) found that the risk assessment prepared by your company did *not* demonstrate that cefquinome is safe with respect to the potential for transfer of antimicrobial resistant organisms to humans. Serious concerns regarding the approval of the drug were raised in testimony presented by the Centers for Disease Control and Prevention, the American Medical Association, the Infectious Disease Society of America, and KAW members Food Animal Concerns Trust and the Union of Concerned Scientists. All of these organizations are concerned that the widespread use of fourth-generation cephalosporins in cattle would spur emergence of human pathogens impervious to the drugs, undercutting their effectiveness in human medicine.

In the months since the VMAC meeting, prominent medical and public health groups have written directly to FDA Commissioner von Eshenbach asking him not to approve cefquinome. We have enclosed the letters to FDA from the American Academy of Pediatrics, the American Public Health Association, the American Medical Association, the Infectious Diseases Society of America, and the Alliance for the Prudent Use of Antibiotics. Each of these letters concludes that FDA's "reasonable certainty of no harm to human health" standard has not been met and that the effectiveness of valuable human drugs would be undercut if cefquinome were approved. In addition, numerous respected newspapers across the country and political spectrum have editorialized against FDA approving cefquinome, including the *Baltimore Sun*, *Boston Globe*, *Buffalo News*, *Chicago Sun-Times*, *Columbus Dispatch*, *Hartford Courant*, *Honolulu Star Bulletin*, *Los Angeles Times*, *Minneapolis Star-Tribune*, *New York Times*, *Sacramento Bee*, *San Jose Mercury News* and *Washington Post* (editorials are attached).

As you consider our request, we ask that you reflect on company responses following FDA's efforts in 2000 to cancel the approval of two fluoroquinolone drugs that FDA had approved for use in poultry over objection from the Centers for Disease Control and others in 1995. Like 4th generation cephalosporins, fluoroquinolones are critical to human medicine. Five years after their poultry approval, FDA observed increases in human infections with the foodborne pathogen, *Campylobacter*, resistant to fluoroquinolones. On the basis of this information, the agency sought to withdraw the approval. Abbott Laboratories, the manufacturer of one of the drugs, SaraFlox, voluntarily withdrew its product from the market. Unfortunately Bayer, the manufacturer of Baytril, contested the cancellation. Baytril was finally withdrawn after a contentious five year administrative process, during which resistance rates continued to rise and the ability to treat serious human health infections was increasingly compromised.

We can ill afford to risk a similar scenario with fourth generation cephalosporins, antibiotics critically important for treating illnesses in children and adults.

We ask you to follow the example of Abbott Laboratories when it was faced with evidence that continued use of its antibiotic was putting a valuable class of human antibiotics at risk: voluntarily withdraw your application for the approval of cefquinome as an animal drug.

Taking this action to protect the public health would redound to the credit of Intervet.

Thank you for considering and acting on this request. Please contact Richard Wood, Chair of KAW's Steering Committee, at P.O. Box 14590, Chicago, IL 60614; (773) 525-4952; or RRWood@fact.cc.

Sincerely,

Benjamin Cohen
Senior Staff Attorney, Center for Science in the Public Interest

Rebecca Goldburg
Senior Scientist, Environmental Defense

Richard Wood
Executive Director, Food Animal Concerns Trust

David Wallinga
Director of Food and Health Program, Institute for Agriculture and Trade Policy

Br. David Andrews
Executive Director, National Catholic Rural Life Conference

Mimi Brody
Director of Federal Affairs, The Humane Society of the United States

Margaret Mellon
Director of Food and Environment, Union of Concerned Scientists

encl: Letters from medical groups and editorials

cc:
Mr. Fred Hassan
Chairman of the Board and Chief Executive Officer, Schering-Plough Corp.

Dr. Andrew C. von Eschenbach
Commissioner of the U.S. Food and Drug Administration

Dr. Stephen Sundlof
Director of the Center for Veterinary Medicine, U.S. Food and Drug Administration

Dr. Ruurd Stolp
President, Intervet International