

**STEERING COMMITTEE**

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Responsibility

Safe Tables Our Priority  
(S.T.O.P.)

Sierra Club

Union of Concerned  
Scientists

Waterkeeper Alliance

March 4, 2008

Fred Hassan  
Chairman and Chief Executive Officer  
Schering-Plough  
2000 Galloping Hill Road  
Kenilworth, N.J. 07033-0530

Dear Fred Hassan:

On behalf of Keep Antibiotics Working, a coalition of groups with more than nine million members, the undersigned organizations urge Schering-Plough to withdraw its new animal drug application to the Food and Drug Administration (FDA) for the approval of cefquinome. This action is justified given the critical importance of cefquinome and other fourth generation cephalosporins for treating human disease and the unnecessary risk to their effectiveness posed by the approval of cefquinome for treatment of respiratory disease in cattle.

We made a similar request to the company on May 9, 2007, just after your acquisition of Intervet, and received a response from Susan Wolf, Vice-President Corporate Governance, stating that you would not comment on the new drug application until the combination with Organon BioSciences was complete. That event has now occurred.

The evidence that animal use of cephalosporins creates a human health risk is clear and mounting. Extended spectrum beta-lactamase producing gram negative bacteria, which are resistant to cephalosporins, are on the increase around the world and are found frequently in livestock. In the United States, levels of cephalosporin-resistant *Salmonella enterica* in both humans and livestock are well above federal public health goals. A World Health Organization expert meeting, convened in Copenhagen in May 2007, confirmed the need for greater efforts to address the resistance to third and fourth generation cephalosporins stemming from veterinary drug use. Making a higher generation cephalosporin available for livestock use in the U.S. will only contribute to this growing public health problem

It would be irresponsible to go forward with the application for approval of cefquinome. In September 2006, FDA's Veterinary Medicine Advisory Committee (VMAC) discussed resistance to cephalosporins potentially resulting from use of cefquinome in cattle, and then voted that Intervet had failed to show that use of the drug in cattle would be safe. There is also a strong consensus against approval among the public health

community in the United States. Moreover, cefquinome is not necessary to treat cattle: 14 other drugs are already approved for respiratory disease treatment in these livestock.

By accepting the findings of VMAC and withdrawing the cefquinome application, Schering-Plough would send a strong signal that the company is committed to protecting public health and to fulfilling its stated vision of earning trust.

Thank you for considering and acting on this request.

Please direct responses to Richard Wood, Chair of KAW's Steering Committee, at P.O. Box 14590, Chicago, IL 60614; (773) 525- 4952; or [RWood@foodanimalconcerns.org](mailto:RWood@foodanimalconcerns.org).

Sincerely,



Richard Wood  
Steering Committee Chairman  
Keep Antibiotics Working

Steven Roach  
Food Animals Concerns Trust

Margaret Mellon, Ph.D.  
Union of Concerned Scientists

David Wallinga, M.D.  
Institute for Agriculture and Trade Policy

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Donna Rosenbaum  
Safe Tables Our Priority