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FDA Urged to Heed Advisory Committee's Advice to Reject Animal Drug Linked to Antibiotic Resistance in Humans *Drug Manufacturer Vows to "Continue to Pursue Approval Activities"*

Washington, DC – The U.S. Food and Drug Administration (FDA) is being urged to follow the recommendation of the FDA's scientific advisory committee to reject the use of cefquinome for treating respiratory disease in cattle linked to antibiotic resistance in human medicine. Despite this negative recommendation, the drug's manufacturer, Intervet, has not withdrawn its application - as is usually done after advisory committee rejections. In fact, "the company says it is convinced that cefquinome use in livestock will not create public health concerns...Intervet will continue to pursue approval activities." (See full text of Intervet news release at <http://www.anguselist.com/volume12/v12anguselist14.html>).

Cefquinome is a 4th generation cephalosporin, a class of drugs that is highly valued in human medicine as treatment for serious and life-threatening infections. Growing scientific evidence shows that use of antibiotics in poultry, swine and beef cattle that are identical or similar to important antibiotics used in human medicine promotes development and spread of antibiotic-resistant bacteria that can be transferred to people via air, food, soil and water, making it harder to treat infections in humans.

"The FDA's handling of scientific advice is under increasing public scrutiny, with critics alleging the agency sometimes gives industry or ideological interests priority over science and public health," wrote Richard Wood, Steering Committee Chair of the Keep Antibiotics Working coalition (KAW), in a letter to the FDA's acting commissioner Dr. Andrew C. von Eschenbach (see letter text at http://www.keepantibioticsworking.com/new/resources_library.cfm?RefID=89428). "An FDA decision to disregard its own scientific advisory committee's recommendation on 4th generation cephalosporins would fuel those concerns. Such an approval would be a big step backward for the public health."

On September 25, the FDA's Veterinary Medicine Advisory Committee (VMAC) voted to reject the claim of cefquinome's manufacturer, Intervet, that the new cattle drug could be considered safe for human health. At that meeting, the American Medical Association and Infectious Disease Society of America joined KAW members in testifying that use of cefquinome in cattle could increase cephalosporin-resistant *E. coli* and *Salmonella* bacteria, two major causes of food poisoning in humans (see AMA, IDSA, KAW and UCS testimony at www.keepantibioticsworking.com).

KAW has reason to be concerned that the FDA may reject VMAC's advice. Two years ago, in a vote on another cattle drug, Tulathromycin, the meeting summary of VMAC's recommendation on the drug's extra-label use (use not indicated on the label) did not clearly reflect the opposition of the committee.

"The public expects, and the law requires, that advisory committee records accurately reflect the events of the day and the substance of the committee's deliberations," the KAW letter concluded. "The arguments [against approving Cefquinome for use in cattle] are even stronger in light of the likelihood that the drug would be approved without strong prohibitions on extra-label use and thus would be used in other food animals, including swine and poultry."

In Europe, where Cefquinome has already been approved and used in livestock under the brand name Cobactin, *E. coli* and *Salmonella* bacteria isolated from animals have already been found to carry resistance to this and other cephalosporins. In the U.S, where 4th generation cephalosporins have not yet been approved for use in animal agriculture, resistance to these drugs is uncommon.

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