

The Campaign to End Antibiotic Overuse

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SCHERING PLOUGH URGED TO WITHDRAW CATTLE ANTIBIOTIC APPLICATION BECAUSE OF THREAT TO HUMAN HEALTH

FDA Advisory Board Recommended Against the Application in 2006

Washington, DC – Keep Antibiotics Working, a coalition of consumer, environmental, science and humane organizations, today urged Schering-Plough to withdraw its application to the Food and Drug Administration (FDA) for the approval of cefquinome to treat respiratory disease in cattle. Approval of this antibiotic could put human patients at risk when treated with similar, critically important drugs.

In September, 2006, the FDA's Veterinary Medicine Advisory Committee recommended against approving the antibiotic, yet the application still has not been formally rejected by the FDA or withdrawn by Schering Plough.

Cefquinome is a fourth-generation cephalosporin, a class of antibiotics highly valued in human medicine as a treatment for life-threatening infections, many of which are resistant to other antibiotics. Schering Plough inherited the drug application last year when it purchased the European company Intervet and its parent company, Organon BioSciences.

Four of the nation's top medical organizations, the American Medical Association (AMA), Infectious Diseases Society of America (IDSA), American Academy of Pediatrics (AAP) and American Public Health Association (APHA), have urged the FDA to reject this application.

The coalition's letter cites mounting evidence that use of cephalosporins in animals creates a human health risk. 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 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 fourth-generation cephalosporin available for widespread use in cattle will make an already bad situation worse," said Dr. Margaret Mellon, senior scientist at the Union of Concerned Scientists. "In the future, Schering Plough should look for animal antibiotics among drugs not used in human medicine."

The coalition's letter points out that cefquinome is not needed to treat cattle: 14 other drugs are already approved for respiratory disease treatment in these livestock.

AMA, IDSA, AAP and APHA are among the more than 350 health, agriculture, and other groups nationwide that also have endorsed proposed federal legislation to phase out the use of antibiotics that are important in human medicine as animal feed additives within two years. The Preservation of Antibiotics for Medical Treatment Act is sponsored by Senate Health Committee Chairman Edward Kennedy (D-MA) and Senators Olympia Snowe (R-ME), Susan Collins (R-ME), Sherrod Brown (D-OH) and Jack Reed (D-RI) in the Senate (S. 549) and Rep. Louise Slaughter (D-NY), the only microbiologist in Congress, and 38 other House members in the U.S. House of Representatives (H.R. 962).

The coalition's letter is available at http://www.keepantibioticsworking.com/new/resources_library.cfm?RefID=101814