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Seven Advocacy Groups Urge Drug Company to Pull FDA Application of Animal Drug Linked to Human Antibiotic Resistance in Europe

Join Medical Groups, FDA Scientific Panel, in Opposing Drug's Approval

Washington, D.C. – Seven leading advocacy groups have urged Intervet, Inc., to drop its application to the U.S. Food and Drug Administration to approve the use of the drug cefquinome to treat respiratory disease in cattle because this use is linked to human antibiotic resistance in Europe. Intervet, along with its parent company, Organnon, was acquired by Schering-Plough last month.

Cefquinome is one of the fourth-generation cephalosporin, a class of drugs highly valued in human medicine as a treatment for serious and life-threatening infections. Use of cefquinome on European farms significantly increased levels of bacteria resistant to fourth-generation cephalosporins.

The groups' letter to Intervet follows letters to the FDA from 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), urging the agency to reject Intervet's application.

The FDA's Veterinary Medical Advisory Committee (VMAC) recommended in September against approving cefquinome, yet the agency still claims to be studying the evidence. U.S. Rep. Louise Slaughter (D-N.Y.), chair of the House Rules Committee, and the only microbiologist in Congress, also sent a letter to the FDA in January, urging it to follow VMAC's recommendation.

Organizations that signed onto the most recent letter opposing the approval of cefquinome include: the 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 and Union of Concerned Scientists.

The letter noted the industry response to the 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 in 1995. Like 4th generation cephalosporins, fluoroquinolones are critical to human medicine. In 2000, FDA documented increases in fluoroquinolone-resistant human infections caused by *Campylobacter bacteria*, and sought to cancel the approval. Abbott Laboratories, the manufacturer of one of the fluoroquinolone drugs, SaraFlox, voluntarily withdrew its product from the market. Unfortunately Bayer, the manufacturer of the other fluoroquinolone drug, Baytril, contested the cancellation, and the drug was withdrawn only after a contentious five-year battle, during which resistance rates continued to rise and the ability to treat serious human health infections was increasingly compromised.

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