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April 11, 2007

The Honorable Andrew von Eschenbach, MD
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

The American Academy of Pediatrics (AAP), a non-profit professional organization of 60,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, would like to express serious concerns regarding the application for the use of cefquinome as a therapeutic treatment in certain livestock.

The American Academy of Pediatrics is concerned that the approval of cefquinome for use in livestock could have profound consequences for the efficacy of 4th generation cephalosporins in human health. These drugs are critical to health care providers' efforts to treat infectious disease, particularly among children. Increased resistance to cephalosporins will lead to higher health care costs, more suffering, and needless deaths.

Antimicrobial resistance has particularly serious implications for children.¹ Children are at increased risk of developing bacterial infections compared with adults and are at great risk of severe complications if they become infected. Because the immune system of a child is less mature than that of an adult, antibiotics are critically important to fighting infection in this population.

Cephalosporins are one of the most widely used classes of antibiotics in children, second only to the penicillins, and are used for a variety of illnesses. They are important drugs in the treatment of acute infectious emergencies such as septic shock and meningitis. The cephalosporin that is most similar to cefquinome, known as cefepime, is a so-called 4th generation cephalosporin. Fourth generation cephalosporins have the widest spectrum of activity against bacteria of all of the cephalosporins. Cefepime specifically is a drug of last resort in that resistance has already begun to appear in all the other cephalosporins. Because there is limited resistance to cefepime here in the United States, it is frequently given to children with cancer who are highly immuno-compromised, as well as to children with severe bacterial infections caused by bacteria resistant to other commonly used antibiotics. If widespread use of cefquinome leads to resistance to it and cefepime, the consequences could be severe for our most vulnerable patients.

The American Academy of Pediatrics recognizes that a wide range of efforts is needed to combat antimicrobial resistance. The AAP has taken a leadership role in pressing the medical profession, and particularly pediatricians, to reduce the prescription of antibiotics.

Due to these efforts, the prescription of antibiotics to children decreased dramatically through the 1990s.ⁱⁱ While reducing prescription rates is an important step, however, it cannot alone stem the rising tide of antimicrobial resistance. The Academy urges the FDA to bear in mind its role in fighting antimicrobial resistance when reviewing the use of cefquinome for use in food-producing animals.

In conclusion, the American Academy of Pediatrics has grave concerns regarding the potential approval of a 4th generation cephalosporin for use in food-producing animals. The special vulnerabilities of infants, children, and adolescents to microbial infections compel our nation to set standards that will safeguard their health against this threat. The American Academy of Pediatrics calls on the FDA to preserve the efficacy of 4th generation cephalosporins in human health. We thank you for your commitment to promoting the health of our nation's children.

Sincerely,



Jay E. Berkelhamer, MD, FAAP
President

Cc: Stephen Sundlof, DVM, PhD, Director, Center for Veterinary Medicine
Louise M. Slaughter, MPH, Member of Congress

JB:cp

ⁱ Shea KM, Committee on Environmental Health, Committee on Infectious Diseases. Nontherapeutic Use of Antimicrobial Agents in Animal Agriculture: Implications for Pediatrics. *Pediatrics*. Vol. 114 No. 3 September 2004, pp. 862-868.

ⁱⁱ Finkelstein JA, Stille C, Nordin J, et.al. Reduction in antibiotic use among US children, 1996-2000. *Pediatrics*. Vol. 112 No. 3 Pt. 1 September 2003, pp. 620-627.