

June 9, 2011

The Honorable Margaret Hamburg, MD
Commissioner, Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg:

We, the undersigned groups, are writing to ask you to quickly move forward with issuing a revised order of prohibition on extra-label use of cephalosporin drugs in food-producing animals as stated in the U.S. Food and Drug Administration's (FDA) Strategic Priorities for 2011-2015. There is clear evidence that the widespread extra-label use of these drugs in food-producing animals contributes to the spread of cephalosporin-resistant organisms that limit the effectiveness of these critically important drugs for both human and animal health. Cephalosporins are the treatment of choice for serious *Salmonella* infections in children, the group with the highest incidence rate, and are vital tools for treating many other serious infections.

In July 2008, the FDA first published a withdrawal order for the extra-label uses in food producing animals of these critically important drugs. An extra-label prohibition would allow the drug to continue to be used for approved indications that have been shown to be safe and effective, but would prohibit all other uses. In November 2008, the FDA withdrew the order before it could go into effect, stating that the agency needed time to review the approximately 200 comments received. Since then, the FDA has consistently stated its intent to reissue the order; however, almost three years later, the order still has not been reissued.

Since 2008, there have been outbreaks of cephalosporin-resistant *Salmonella* linked to animal products, with the most recent being *Salmonella Hadar* associated with the consumption of frozen turkey patties. In addition, data from the Centers for Disease Control and Prevention show that approximately three percent of the estimated one million human *Salmonella* cases occurring in the United States annually are resistant to cephalosporin antibiotics.

There also is new evidence that the nature of cephalosporin resistance in the U.S. may be changing for the worse. Researchers at the Ohio State University recently reported detecting in cattle *Escherichia coli* that produced cefotaximases, a class of enzymes capable of breaking down most cephalosporins. Cefotaximases have not been previously found in food-producing animals in the U.S., unlike other regions of the world. Also, a recent study from the Netherlands found that 35 percent of cephalosporin-resistant *Escherichia coli* infections in humans, mostly cefotaximase producing, likely came from poultry.

Public health authorities in Canada recently showed that a voluntary extra-label ban on cephalosporins in poultry hatcheries resulted in a reduction in cephalosporin resistance in

Salmonella isolates from sick humans as well as a reduction in resistant *Salmonella* and *Escherichia coli* isolates on poultry meat. Once the voluntary ban was lifted, resistance rose again. An extra-label ban in the U.S. could be expected to have a similar effect, as one of the primary extra-label uses of cephalosporins is in poultry hatcheries. A reduction in antibiotic-resistant *Salmonella* and *Escherichia coli* infections would have a significant positive impact on the health of U.S. children and adults.

Clearly, an extra-label prohibition on these precious drugs is warranted and past due. We call on you to reject any further delays and to reissue the prohibition on extra-label use of cephalosporins in food-producing animals.

Sincerely,

Alliance for the Prudent Use of Antibiotics
American Academy of Pediatrics
American Medical Association
American Public Health Association
Catholic Healthcare West
Consumers Union
FamilyFarmed.org
Food & Water Watch
Food Animal Concerns Trust
The Humane Society of the United States
Humane Society Veterinary Medical Association
Infectious Diseases Society of America
Institute for Agriculture and Trade Policy
Keep Antibiotics Working
Michigan Antibiotic Resistance Reduction Coalition
The National Consumers League
National Foundation for Infectious Diseases
National Resources Defense Council
The Pew Charitable Trusts
Society of Infectious Diseases Pharmacists
STOP Foodborne Illness (formerly S.T.O.P. - Safe Tables Our Priority)
Union of Concerned Scientists