



...America's Voice for Safe Food

3759 N Ravenswood Ave. #224

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March 6, 2012

The Honorable Margaret A. Hamburg, M.D.
Commissioner
C/o Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 2085

Re: Docket No. FDA-2008-N-0326:
"New Animal Drugs; Cephalosporin Drugs; Extralabel Animal Drug Use; Order of Prohibition"

Dear Commissioner Hamburg,

STOP Foodborne Illness (STOP) appreciates the opportunity to submit comments on the Food and Drug Administration's final rule prohibiting certain extralabel uses of cephalosporin antimicrobial drugs in certain food producing animals, as published in the *Federal Register* on January 6, 2012. STOP is a national nonprofit public health organization dedicated to the prevention of illness and death from foodborne pathogens – including antibiotic resistant ones. Antibiotic resistance impacts public health when people consume food contaminated with antimicrobial resistant bacteria resulting from the exposure of food animals to antimicrobials, including cephalosporins.

STOP supports the new restrictions on the use of cephalosporins in food producing major species of animals as proposed by the Food and Drug Administration (FDA). Cephalosporins are among the most critically important antibiotics in human medicine. Two populations that are most at risk of foodborne illness are children and immune compromised individuals, and they are also the patients most in need of an effective antibiotic treatment for salmonellosis with minimal side effects. Indeed, ceftriaxone or cefotaxime, third-generation cephalosporins, are often the treatment of choice for severely complicated pediatric salmonellosis because unlike other antibiotics, such as fluoroquinolones and tetracyclines, there are no warnings or precautions for use in pediatric medicine.

STOP is a national nonprofit public health organization dedicated to the prevention of illness and death from foodborne pathogens by:

- Advocating for sound public policy**
- Building public awareness**
- Assisting those impacted by foodborne illness**



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At this time it is understood that the FDA is not planning to prohibit extralabel use of cephalosporins in food-producing minor species because the Agency does not believe that this use represents a significant risk to public health, as these species are consumed less frequently. Since cephalosporins are approved for use in sheep and goats, there is less potential for extralabel use in these species. Although people may consume these animal species less often, any practice that selects for resistant genes is concerning.

This rule is overdue in light of recent outbreaks. In December of 2011 there was an outbreak from *Salmonella* Typhimurium contaminated ground beef in the Northeast which tested resistant to cephalosporins. This resistance causes an increased risk of hospitalization and possible treatment failure in infected individuals. Another signal that this ruling is overdue is evidence from the National Antimicrobial Resistance Monitoring System (NARMS) which shows that cephalosporin-resistant *Salmonella* isolates from cattle and turkeys was higher in 2010, than in any other year.

STOP does believe that the final rule is a positive measure, however wishes to raise concerns to be further considered by the agency.

- STOP recommends that the FDA specifically track cephalosporin sales and prescriptions to show evidence that use is noticeably declining. This data should be compared to annual reports of cephalosporin resistant pathogens in both human and animal populations.
- Additionally STOP would like to encourage the FDA to restrict the extralabel use of gentamicin in poultry. Rates of resistance to gentamicin in bacterial isolates at the retail level in poultry are already high. As cephalosporins will no longer be approved for extralabel use in hatcheries it is reasonable to expect that gentamicin will be utilized as an alternative. FDA should monitor closely through NARMS any increases in resistance to gentamicin. FDA must work alongside USDA to identify alternatives to antibiotic use to control for chick and poul mortality.

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There is clear scientific evidence that the overuse and injudicious use of antibiotics in food animals threatens human health. STOP believes that the extralabel ban of certain cephalosporins is an important step, but that more needs to be done to limit non-therapeutic antibiotic use in food animals – particularly of antibiotics critically and highly important in human medicine. Many further steps need to be taken by FDA to address the injudicious use of antibiotics in food animal production. If pending voluntary measures do not help to address antibiotic resistant the Agency is well within its authority to issue formal regulations excluding non-therapeutic uses in food animal production.

Sincerely,

Deirdre Schlunegger

Deirdre Schlunegger
CEO

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