

PolicyPennings by Daryll E. Ray & Harwood D. Schaffer

FDA restricts use of cephalosporin in food-producing animals years after original order

On January 6, 2012, three-and-one-half years after it “published an order prohibiting the extralabel use of cephalosporin antimicrobial drugs in food-producing animals” and over three years after it revoked that order, the Department of Health and Human Services, Food and Drug Administration (FDA) reissued that order with some modifications <http://www.gpo.gov/fdsys/pkg/FR-2012-01-06/pdf/2012-35.pdf>. In issuing the order the FDA said, “we are issuing this order based on evidence that certain extralabel uses of these drugs in these animals will likely cause an adverse event in humans and, therefore, present a risk to the public health.”

The FDA is allowing a 60 day comment period ending on March 6, 2012. Information on how to submit comments can be found at the above internet address. The rule will become effective 30 days later, April 5, 2012.

The order was originally issued July 8, 2008 with a “60-day comment period and a 90-day effective date for the final order.” In response to requests, the comment period was extended until November 1, 2008, with the effective date extended to November 30, 2008.

“The Agency received many substantive comments on the July 3, 2008 order of prohibition. Therefore, to allow more time to fully consider the comments, FDA decided to revoke the order so that it would not take effect November 30, 2008. Accordingly...the FDA withdrew the final rule and indicated that if, after considering the comments and other relevant information the Agency decided to issue another order of prohibition addressing this matter, FDA would follow the procedures...that provide for a public comment period prior to implementing the new order.”

The new order prohibits “the extralabel use of cephalosporin antimicrobial drugs (not including cephalixin [an early form of cephalosporin]) in cattle, swine, chickens, and turkeys: (1) for disease prevention purposes; (2) at unapproved doses, frequencies, durations, or routes of administration; and (3) if the drug is not approved for that species and production class.”

The term “extralabel use” is defined in FDA regulations as meaning “actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to: (1) use in species not listed in the labeling; (2) use for indications (disease or other conditions) not listed in the labeling; (3) use at dose levels, frequencies, or routes of administration other than those stated in the labeling; and (4) deviation from the labeled withdrawal

time based on these different uses.”

In prohibiting extralabel use, the new rule allows for the continued use of cephalosporin in accordance with labeled conditions including the treatment of disease in approved species and production classes. The new rule also allows extralabel exceptions including the: “(1) use of approved cephalixin products in food-producing animals; (2) use to treat or control an extralabel disease indication as long as such use adheres to a labeled dosage regimen (i.e., dose, route, frequency, and duration of administration) approved for that species and production class; and (3) use in food-producing minor species.”

In issuing the rule, “FDA is concerned that certain extralabel uses of cephalosporins in food-producing major species are likely to lead to the emergence and dissemination of cephalosporin-resistant strains of foodborne bacterial pathogens. If these drug-resistant bacterial strains infect humans, it is likely that cephalosporins will no longer be effective for treating disease in those people. The Agency is particularly concerned about the extralabel use of cephalosporin drugs that are not approved for use in food-producing major species because very little is known about their microbiological or toxicological effects when used in food producing animals. Therefore, FDA is issuing an order prohibiting, with limited exceptions, the extralabel use of cephalosporins in food-producing major species because...it has determined that such extralabel use likely will cause an adverse event and, therefore, presents a risk to the public health.”

The response to the rule has been muted because a number of experts believe that the cephalosporin order will have limited impact on the meat animal production because extralabel uses are minimal. The greatest concern about the rule is the belief by many in the industry that this rule may signal a greater willingness on the part of the FDA to issue future rules that include drugs of greater importance to animal agriculture.

In the next column we will review the use of cephalosporin in humans and animals, the issue of antibiotic resistance, and the extralabel uses that are of greatest concern to the FDA.

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