

The U.S. Food and Drug Administration (FDA) and Cephalosporin Use: How Will This New Rule Affect KY Dairy Producers?



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Cephalosporins are antimicrobial agents used in human and veterinary medicine. They were introduced into human clinical use in 1964. Cephalosporins are commonly used in humans to treat pneumonia, skin and soft tissue infections, pelvic inflammatory disease, diabetic foot infections, and urinary tract infections. Newer cephalosporins are used in hospital settings to treat seriously ill patients with life-threatening diseases such as salmonellosis or shigellosis. FDA is concerned that certain extralabel uses of cephalosporins in food animals will lead to resistant strains of bacteria. Therefore this important class of drugs must be used judiciously in both human and animal medicine to slow the development of resistant organisms.

Two cephalosporin drugs are currently approved for use in dairy cows: ceftiofur and cephalixin. Cephalixin is only approved as an intramammary infusion for the treatment of mastitis caused by susceptible strains of *Streptococcus agalactiae* and *Staphylococcus aureus*. Cephalixin is the active ingredient in Today®, Tomorrow®, Cefa-Lak® and Cefa-Dry®. Ceftiofur is approved in two forms, injectable and intramammary infusion tube. Injectable ceftiofur products including EXCEDE® (ceftiofur crystalline free acid), NAXCEL® (ceftiofur sodium) and CEFTIFLEX® (ceftiofur sodium) have different treatment regimens but all are labeled for treatment of bovine respiratory disease and foot rot. EXCENEL® RTU (ceftiofur hydrochloride) is labeled for respiratory disease, foot rot, and metritis. Intramammary ceftiofur products include SPECTRAMAST® LC and DC (ceftiofur hydrochloride). SPECTRAMAST® LC is approved for treatment of clinical mastitis in lactating dairy cattle associated with coagulase-negative staphylococci, *Streptococcus dysgalactiae*, and *Escherichia coli*. SPECTRAMAST® DC is indicated for the treatment of subclinical mastitis in dairy cattle at the time of dry off associated with *Staphylococcus aureus*, *Streptococcus dysgalactiae*, and *Escherichia coli*.

Effective April 5, 2012, the FDA has issued an order that prohibits certain uses of the cephalosporin class of antimicrobial drugs in cattle, swine, chickens and turkeys. In its order, FDA is prohibiting what are called “extralabel” or unapproved uses of cephalosporins in cattle, swine, chickens and turkeys, the so-called major species of food-producing animals. Specifically, the prohibited uses include:

- Using cephalosporin drugs at unapproved dose levels, frequencies, durations, or routes of administration;
- Using cephalosporin drugs in cattle, swine, chickens or turkeys that are not approved for use in that species (e.g., cephalosporin drugs intended for humans or companion animals);
- Using cephalosporin drugs for disease prevention.

In 2008, FDA issued and then revoked an order that prohibited extralabel uses of cephalosporins in food-producing animals with no exceptions. This week’s announcement, FDA says, responds to public comment and includes the following exceptions, which protect public health while considering animal health needs:

- The order does not limit the use of cephalixin, an older cephalosporin drug that is not believed by FDA to contribute significantly to antimicrobial resistance.

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- Veterinarians will still be able to use or prescribe cephalosporins for limited extra-label use in cattle, swine, chickens or turkeys as long as they follow the dose, frequency, duration and route of administration that is on the label.
- Veterinarians may also use or prescribe cephalosporins for extralabel uses in minor species of food-producing animals such as ducks or rabbits.

What does this actually mean for the dairy producer? This rule only applies to “extralabel” use which means giving a drug to an animal in ANY WAY that is not specifically stated in the indications and directions for use on the label pasted on the bottle. Extralabel use of drugs in animals is permitted only by, or on the order of, a licensed veterinarian within the context of a valid veterinarian-client-patient relationship. This new FDA ruling still allows veterinarians to use and prescribe cephalosporin antimicrobials for other diseases not printed on the label (for example-pinkeye) as long as the treatment regimen approved on the label is strictly followed. The treatment regimen includes dose (number of cc’s or mls), route of administration (intramuscular, subcutaneous, intramammary), frequency (how many times per day to give the drug) and duration of administration (how many days of treatment). In addition, the rule stipulates that the use of human cephalosporins or small animal preparations in any type of cattle production is strictly forbidden. Cephapirin (ToDay®) is excluded from this order because it is very unlikely to cause cross-resistance to human medications but can only be used differently from the label under the direction of a veterinarian.

It is exceptionally important to keep complete treatment records up-to-date for every cow treated in the herd. A complete treatment record along with official animal identification is the best defense if an antibiotic violation is ever wrongfully traced to your dairy operation. Work with your veterinarian to establish treatment protocols including when to use products in an extralabel manner and how to officially identify individual animals.