

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

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Cephalosporins are very effective antimicrobial agents used in human and veterinary medicine. The FDA issued an order that prohibits certain uses of the cephalosporin class of antimicrobial drugs in cattle, swine, chickens and turkeys effective April 5, 2012. Two cephalosporin drugs are currently approved for use in dairy cows: ceftiofur and cephapirin. Trade names of ceftiofur used in dairy cattle include EXCEDE®, NAXCEL®, CEFTIFLEX®, EXCENEL® RTU, SPECTRAMAST® LC and DC. The preparations containing cephapirin are Today®, Tomorrow®, Cefa-Lak® and Cefa-Dry®. In its order, FDA is prohibiting what are called “extra-label” or unapproved uses of cephalosporins due to the possibility of creating resistant strains of harmful bacteria. The term “*extralabel use*” refers to use of an approved drug in an animal in any manner that does not follow the approved labeling. By restricting these uses, it is hoped that this drug class will be used less frequently and only at the appropriate dose and duration in order to preserve its usefulness.

How this ruling impacts dairy producers

With the new rule, extra-label use of cephalosporins in animals is permitted only by, or on the order of, a licensed veterinarian 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). Veterinarians will still be allowed to prescribe cephalosporins for other diseases not printed on the label (for example-Excede® for pinkeye), but the treatment regimen must not be altered in any other way. Examples of commonly occurring extra-label drug uses of cephalosporins on dairy farms which are now forbidden (even under the direction of a veterinarian) under the new rule include:

- Changing the dose-Infusing two tubes of Spectramast®LC into an affected quarter when the directions call for one tube to be administered per quarter.
- Changing the route of administration-Giving Excede® subcutaneously in the neck instead of the base of the ear.
- Changing the frequency of use-Administering Spectramast®LC twice a day instead of once a day as directed.
- Administering a drug to a different production class- Administering Spectramast®DC to a lactating dairy cow that is not being dried off.
- Changing the withholding times-Not observing the 72-hour milk discard after administration of the last treatment of Spectramast® LC.
- Changing the amount of drug per injection site-Giving more than 15 mL of Excenel®RTU per injection site for post-partum metritis.

What is Extra-label Drug Use?

“Extra-label drug use” regulations do not exclusively apply to prescription drugs. Any drug, whether purchased at a farm supply store, through the internet, from the veterinarian, or

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borrowed from the neighbor and then used in an animal in some way which is different than printed on the label is deemed “extra-label use” and is regulated by the FDA. Under the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA), extra-label 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.

On a dairy, a valid veterinarian-client-patient relationship has several specific components.

1. A veterinarian takes responsibility for making medical judgments regarding the cow's health and the need for medical treatment, and the dairy producer agrees to follow the veterinarian's instructions.
2. The veterinarian is familiar with the cow and can provide a general or preliminary diagnosis for her medical condition.
3. The veterinarian is available for follow-up in the event of adverse reactions or treatment failure.

Therefore, a valid veterinarian-client-patient relationship exists only when the veterinarian has recently seen, and is personally familiar with, how the cow is cared for by either physically examining the animal during a “sick cow” visit or on a routine herd visit.

Extra-label drug use in food producing animals carries additional requirements because of the potential for drug residues in milk and meat. The complete extra-label use requirements are found in Title 21 of the U.S. Code of Federal Regulations, Part 530 (21 CFR part 530).

Requirements for extra-label drug use in food producing animals include:

- A valid veterinarian-client-patient relationship must exist as described above.
- There is no approved animal drug available. Either:
 - There is an approved drug but it is not in the correct form or concentration or is not labeled for the disease in progress.
 - The approved animal drug is clinically ineffective for its approved use and an effective substitute is needed.
- The veterinarian must carefully evaluate and diagnose the condition requiring treatment. Extra-label drug use should only occur in circumstances when an animal's health is threatened, or suffering or death may occur if treatment is not administered. It is never used for enhanced performance or for reproductive management.
- The veterinarian must establish a scientifically appropriate withdrawal period, based on appropriate scientific information, if available. If it cannot be established, the drug must not be used or the treated animal must never enter the food supply.
- The veterinarian must ensure that the treated animal's identity is carefully documented and maintained.
- The veterinarian must ensure that the assigned withdrawal times are observed and no illegal drug residues occur in any food producing animal receiving extra-label drug treatment.

Careful adherence to existing laws will extend the useful lives of the antibiotics available now and protect the public from drug residues in meat and milk. Recognizing these responsibilities is an integral part of being a responsible veterinarian and dairy producer in today's market.