

## **FDA NEWS RELEASE**

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### **FDA to protect important class of antimicrobial drugs for treating human illness**

*Agency issues order prohibiting certain uses in food-producing animals*

The U.S. Food and Drug Administration today issued an order that prohibits certain uses of the cephalosporin class of antimicrobial drugs in cattle, swine, chickens and turkeys effective April 5, 2012.

Antimicrobial drugs are important for treating disease in both humans and animals. This new order takes into consideration the substantial public comment FDA received on a similar order that it issued in 2008, but revoked prior to implementation.

FDA is taking this action to preserve the effectiveness of cephalosporin drugs for treating disease in humans. Prohibiting these uses is intended to reduce the risk of cephalosporin resistance in certain bacterial pathogens.

Cephalosporins are commonly used in humans to treat pneumonia as well as to treat skin and soft tissue infections. In addition, they are used in the treatment of pelvic inflammatory disease, diabetic foot infections, and urinary tract infections. If cephalosporins are not effective in treating these diseases, doctors may have to use drugs that are not as effective or that have greater side effects.

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. Today's announcement 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 cephapirin, an older cephalosporin drug that is not believed by FDA to contribute significantly to antimicrobial resistance.
- 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.

"We believe this is an imperative step in preserving the effectiveness of this class of important antimicrobials that takes into account the need to protect the health of both humans and animals," said Michael R. Taylor, Deputy Commissioner for Foods.

The new order of prohibition has a comment period that will begin on Jan. 6, 2012 and close on March 6, 2012. To comment on the order of prohibition, visit [www.regulations.gov](http://www.regulations.gov) and enter FDA-2008-N-0326 in the keyword box. Following the comment period, the FDA will consider the comments prior to the order of prohibition going into effect on April 5, 2012.

For more information:

Questions and Answers on FDA's Cephalosporin Order of Prohibition:

<http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm054434.htm>

Federal Register Display (this link is temporary and will change when the notice publishes on Jan. 6, 2012:

[http://www.ofr.gov/OFRUpload/OFRData/2012-00035\\_PI.pdf](http://www.ofr.gov/OFRUpload/OFRData/2012-00035_PI.pdf)

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