

HHS:PHS:FDA:CFSAN:OFS:DPDFS:DEB:

5100 Paint Branch Parkway
College Park, MD 20740-3835

M-I-12-12

September 27, 2012

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Cephalosporin - Order of Prohibition

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) issued an order prohibiting certain uses of the cephalosporin class of antimicrobial drugs in cattle, swine, chickens, and turkeys. These are considered the major species of food-producing animals. The order went into effect on April 5, 2012.

A copy of the Federal Register document is available at <http://www.gpo.gov/fdsys/pkg/FR-2012-01-06/pdf/2012-35.pdf>

Prohibited uses include:

- Using cephalosporin drugs at dose levels, frequencies, durations, or routes of administration different from those on the approved manufacturer's label;
- 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); and
- Using cephalosporin drugs for disease prevention.

If a cephalosporin drug (not including cephalosporin) is observed on a dairy farm that is being used or labeled in an extralabel manner that does not comply with these prohibited uses it would be considered a violation (five (5) point debit) of Item 15r-Drug and Chemical Control of the Grade "A" Pasteurized Milk Ordinance (PMO).

The following exceptions to the prohibition apply:

- Extralabel use of approved cephalosporin products in food-producing animals;
- Used to treat or control an extralabel disease indication, as long as this use adheres to a labeled dosage regimen (i.e., dose, route, frequency, and duration of administration) approved for that particular species and production class; and
- 21 CFR Part 530 compliant, extralabel use in food-producing minor species, such as sheep, goats, etc.

Currently, cephapirin is not approved for use in humans. Cephapirin, a first-generation cephalosporin, has a narrow spectrum of activity compared to newer generations of cephalosporins, like ceftiofur. For these reasons, cephapirin is less likely to cause cross-resistance to drugs in other cephalosporin classes. Furthermore, cephapirin is currently only approved for use in food-producing animals as an intramammary infusion formulation for dairy cattle. Because the impact of cephapirin on antimicrobial resistance among bacteria of public health concern is substantially less than other, newer generation cephalosporins, and its unique dosage form restricts the extent of its extralabel use significantly, the Agency determined that it was appropriate to exclude cephapirin products from the prohibition order.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, State Milk Regulatory/Rating Agencies, State Laboratory Evaluation Officers and State Milk Sanitation Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will be available on the FDA Web Site at <http://www.fda.gov> at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to robert.hennes@fda.hhs.gov.

A handwritten signature in black ink, appearing to read "Robert F. Hennes", is centered on a light gray rectangular background.

Robert F. Hennes, RS, MPH
CAPT U.S. Public Health Service
Dairy and Egg Branch

Attachment: "CVM Update" entitled "Cephalosporin Order of Prohibition Goes Into Effect".

Cephalosporin Order of Prohibition Goes Into Effect

April 6, 2012

The U.S. Food and Drug Administration (FDA) announced today that the order of prohibition of cephalosporins originally published on January 6, 2012 is now effective.

The order prohibits certain uses of the cephalosporin (excluding cephapirin) class of antimicrobial drugs in cattle, swine, chickens and turkeys.

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.

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.

The order had a comment period of 60 days that began on January 6, 2012 and closed on March 6, 2012. The FDA carefully reviewed all submitted comments and determined that the order of prohibition, as published on Jan 6, 2012, should go into effect on April 5, 2012 without further revision or delay.