



JAN 13 2003

Food and Drug Administration  
Rockville MD 20857

NADA 140-890, 140-338

Pharmacia & Upjohn Company  
• Regulatory Affairs  
Attn: Thomas R. Schriemer, Director  
7000 Portage Road  
Kalamazoo, MI 49001-0199

Dear Mr. Schriemer:

This is in reference to your Drug Experience Report (DER) submission dated February 26, 2002, concerning Ceftiofur use in beef cattle, NADA 140-890.

We object to the claim that appears on Pharmacia & Upjohn Company's current web page for Excenel RTU which asserts that "**There Is No Known Resistance To EXCENEL RTU for Targeted Pathogens.**" Upon investigation a similar claim was found on the current web page for Naxcel (NADA 140-338) in beef cattle: "**There Is No Known Resistance to NAXCEL for Targeted Bovine Pathogens.**" In addition, the Excenel RTU web page contains the report of one study where there is 100% susceptibility for isolates of *Pasteurella*, *E. coli* and *Salmonella* spp. These claims are present on the websites [www.excenelrtu.com](http://www.excenelrtu.com) and [www.naxcel.com](http://www.naxcel.com), respectively, which CVM accessed January 9, 2003.

We are aware of published scientific data, e.g. Klarmann (1997)<sup>[1]</sup> and Cattle (Slaughter): NARMS Data *Salmonella*, 1997-2000<sup>[2]</sup>, demonstrating resistance to ceftiofur in *Pasteurella multocida*, *Pasteurella haemolytica* and *Salmonella* spp. These published results contradict the claim of "No Known Resistance to [ceftiofur] for Targeted Pathogens."

As this scientific knowledge renders these claims false and misleading as to the effectiveness of the product, we must request that this and all similar advertisements or promotions be stopped immediately.

Please inform us of your intentions as soon as possible or within 30 days of the receipt date of this letter. If you have any questions, you may contact us at (301) 827-6642. Thank you.

Sincerely yours,

Lynn O. Post, DVM, PhD, DABVT  
Acting Division Director, HFV-210  
Division of Surveillance  
Center for Veterinary Medicine

<sup>[1]</sup> KLARMANN, D. (1997): Antibiotic resistance of important bacteria of infectious disease in 1996 in the district of Weser-Ems in Lower Saxony. (German) Dtsch. tierarztl. Wschr. **104**, 325-335.

<sup>[2]</sup> Cattle (Slaughter): NARMS Data *Salmonella*, 1997-2000. [USDA/ARS NARMS Animal Data](http://USDA/ARS NARMS Animal Data) available on CVM/FDA web site.