



FDA Approves Pfizer Animal Health's EXCEDE® (Ceftiofur Crystalline Free Acid) Sterile Suspension for Horses

First Long Acting Antibiotic Formulation Licensed for Horses

FOR IMMEDIATE RELEASE

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LAS VEGAS – February 15, 2010 – Pfizer Animal Health today announced that the U.S. Food and Drug Administration (FDA) has approved EXCEDE® Sterile Suspension as the first safe and effective, long-acting antibiotic formulation licensed for horses. EXCEDE Sterile Suspension is the newest addition to Pfizer Animal Health's extensive portfolio of equine products backed by scientific research and innovation in the field of equine medicine.

EXCEDE Sterile Suspension is indicated for the treatment of lower respiratory tract infections in horses caused by susceptible bacterial strains of *Streptococcus equi* ssp. *zooepidemicus*. EXCEDE acts as a sustained release product that offers an extended duration of action with fewer injections compared to other antibiotic treatments on the market. The low risk of side effects and proven efficacy and safety in an extended release formulation make EXCEDE for horses a true innovation. Veterinarians administer two intramuscular injections to affected horses 4 days apart. Therapeutic drug concentrations against *Streptococcus equi* ssp. *zooepidemicus* are maintained for a total of 10 days from the initiation of treatment.

“EXCEDE Sterile Suspension has been used by veterinarians for many years with great success in cattle and swine,” said Dr. Thomas Lenz, Senior Director, Equine Veterinary Services. “Pfizer Animal Health is excited to be able to offer this safe and effective antibiotic for treatment in horses in just two doses for a full course of therapy.”

EXCEDE Sterile Suspensions is a cephalosporin antibiotic in the form of Ceftiofur Crystalline Free Acid. Ceftiofur, like other β -lactam antimicrobials, exerts a bactericidal effect by inhibiting bacterial cell wall synthesis. This interference is due primarily to covalent binding to the penicillin-binding proteins (PBPs), which are essential for synthesis of the bacterial wall. After intramuscular injection, ceftiofur is released from the crystalline form in oil over time, and then rapidly metabolized to desfuroylceftiofur, the primary active metabolite. Ceftiofur is the only cephalosporin approved for use in horses and is known for its low toxicity and high margin of safety.

New market research from Pfizer Animal Health shows that 1 in 4 horse owners and caretakers are not fully compliant.¹ A number of horse owners feel that trying to administer oral or injectable medications negatively impacts their relationship with the horse. With only two required doses, EXCEDE Sterile Suspension makes it easy for horse owners and veterinarians to fully complete treatment, while causing minimal stress to the horse.

“Using EXCEDE as recommended ensures optimal safety and efficacy for treatment.” said Dr. Lenz. “A long-acting antimicrobial will allow equine veterinarians to achieve optimal compliance with minimal dosing, a true innovation compared to current therapeutic regimens.”

Important Safety Information: As with all drugs, the use of EXCEDE Sterile Suspension is contraindicated in animals with known allergy to ceftiofur or to the β -lactam group (penicillins and cephalosporins) of antimicrobials. Do not use EXCEDE in horses intended for human consumption. The

administration of antimicrobials in horses under conditions of stress may be associated with diarrhea, which may require appropriate veterinary therapy. Though safe in cattle when properly administered, inadvertent intra-arterial injection is possible and fatal. EXCEDE has a pre-slaughter withdrawal time of 13 days in cattle. Do not use in calves to be processed for veal. For complete details, refer to the full prescribing information at <http://www.EXCEDE.com/PI>.

For more information on EXCEDE Sterile Suspension visit www.Excede.com. Pfizer Animal Health, a business of Pfizer Inc., is a world leader in discovering and developing innovative animal prescription medicines and vaccines, investing an estimated \$300 million annually in animal health product research and development. Pfizer Animal Health's industry-leading U.S. equine product portfolio now includes a wide range of biologics, parasiticides and sedatives / analgesics trusted by veterinarians, including many from Fort Dodge. For more information on how Pfizer Animal Health helps horses to live longer, healthier lives, visit www.PfizerAH.com.

1. Proprietary Market Research, Equine Antibiotics: Compliance and Barriers to Administration, Data on file, Pfizer Animal Health, May 2008.

Editors: Images to accompany this release are available for download from the Equine Writers' Resource section at www.equineresources.com