

J-11-323/9-5 ORIG
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Pfizer Animal Health

24 June 2005

John W. Hallberg, D.V.M., Ph.D.
Associate Director
Regulatory Affairs

Dr. John K. Harshman, Acting Staff Chief (HFV-104)
FDA/Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855

Dear Dr. Harshman:

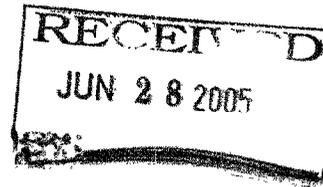
**RE: Suitability Petition for Review and Action for a Generic Version of a
Ceftiofur Hydrochloride Sterile Suspension**

Pharmacia & Upjohn Company (P&U), a Division of Pfizer Inc. is submitting this suitability petition for FDA review and concurrence. P&U is requesting FDA's permission to submit an abbreviated new animal drug application (ANADA) for a generic version of EXCENEL[®] RTU, ceftiofur hydrochloride sterile suspension as approved under NADA 140-890. P&U is proposing one modification to the existing product label for EXCENEL RTU. P&U proposes to limit the route of injection to only the subcutaneous route of administration for cattle instead of both subcutaneous and intramuscular routes as approved for the pioneer product. The suitability petition is attached to this letter. P&U requests FDA's prompt approval of this petition.

Please contact me at (269) 833-2482 if you have any questions on this submission.

Sincerely,

John W. Hallberg, D.V.M., Ph.D



JWH/cs
Attachments

2005P-0277

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