



Wildlife Pharmaceuticals

366 35 2010 2 00

9 December 1999

Dr. Lonnie Luther  
Office of New Animal Drug Evaluation  
U.S. Food & Drug Administration  
7500 Standish Place  
Room 387, HFV-102  
Rockville, MD 20855

RE: Suitability Petition SP 99P-2733/CP 1 - Appeal of Denial

Dear Dr. Luther:

Wildlife Pharmaceuticals requests reconsideration of Suitability Petition – SP 99P-2733/CP 1, for permission to submit an ANADA for generic ketamine hydrochloride. The petition was dated 8 August 1999 and the response which was dated 5 November 1999 was received at Wildlife Pharmaceuticals on 10 November 1999.

We believe that there is substantial evidence in the published literature regarding the safety of ketamine HCl in small animals in which it is approved and that the increased concentration resulting in a smaller amount (volume) of drug to be administered does not present an unpredictable, adverse effect on the duration of the anesthesia.

We propose a telephone conference with the review team in order to defend our position.

Also, we are aware of the scheduling of ketamine (Schedule III) on 12 August 1999 subsequent to our filing of 8 August 1999. We view this action as a welcome asset and control measure in the handling of this drug product. We would be happy to provide copies of our SOPs which demonstrate very tightly controlled screening and distribution of all scheduled products in compliance with DEA regulations.

The wildlife pharmaceutical market is small and well-defined. Our veterinarians are well known to us and we deal directly with them. As stated in our original petition, we are trying to make these drugs available in concentrations required for wildlife species and eliminate the necessity for zoo/wildlife veterinarians to take finished product and have it altered by a compounding pharmacy.

99P-2733

PRC 1

We believe that a telephone conference would afford us the opportunity to address your questions or concerns and clarify any misunderstandings. We look forward to hearing from you.

Sincerely,

A handwritten signature in black ink, appearing to be 'B. Zimmerman', with a long horizontal flourish extending to the right.

B. Zimmerman  
Regulatory Affairs

PR Pharmaceuticals, Inc.  
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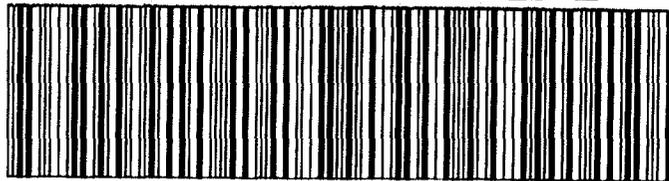
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