



**FILE COPY**

September 4, 2001

Anne Nallen  
Regulatory Affairs  
Cross Vetpharm Group Ltd.  
Broomhill Road  
Tallaght  
Dublin 24  
IRELAND

Dear Ms. Nallen:

Your petition requesting the Food and Drug Administration to file a ANADA Suitability application for Oxytetracycline 300 mg/mL Injection for intravenous use in cattle was received by this office on 09/04/01. It was assigned docket number 01P-0385/CP 1 and it was filed on 09/04/01. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe  
Dockets Management Branch

01P-0385

ACK 1