



SP 04P-0127 / PRC1

OCT 27 2004

Smart Drug Systems, Inc.  
Attention: Jenaay M. Brown, DVM  
Director, Regulatory Affairs  
181 S. Broad Street, #102  
Pawcatuck, CT 06379

Dear Dr. Brown:

In your petition for reconsideration dated June 9, 2004, you requested re-examination of your suitability petition that was filed March 16, 2004, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic copy of Pharmacia & Upjohn Co.'s clindamycin hydrochloride. The product is indicated for the treatment of skin infections (wounds and abscesses) due to susceptible strains of coagulase-positive staphylococci (*Staphylococcus aureus* or *S. intermedius*); deep wounds and abscesses due to susceptible strains of *Bacteroides fragilis*, *Prevotella melaninogenica*, *Fusobacterium necrophorum*, and *Clostridium perfringens*; dental infections due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenica*, *F. necrophorum*, and *C. perfringens*; and osteomyelitis due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenica*, *F. necrophorum*, and *C. perfringens*. The proposed product would contain twice the amount of clindamycin hydrochloride given once daily in an oral tablet dosage form, whereas the pioneer product is an oral capsule administered twice daily, Pharmacia & Upjohn Company's, ANTIROBE (NADA 120-161).

The original suitability petition was denied because safety and effectiveness studies other than bioequivalence studies would be required for approval of the proposed product. After careful examination of your petition for reconsideration, we are denying your petition.

A change in strength may be sought through a suitability petition under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA). FDA is required to approve a petition seeking a strength that differs from the strength of the pioneer drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strength. FDA has determined that the proposed increase in strength would require effectiveness studies because the effectiveness of the proposed dosing has not been established. This change in strength is not supported by the approved labeling for the pioneer product and it is not reasonable to assume that, due to the higher dose, the proposed product would be efficacious for the proposed indications.

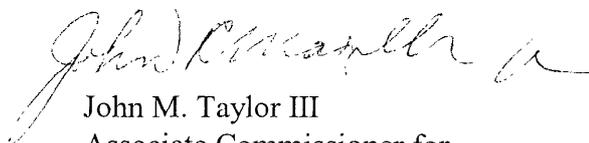
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In your petition, you state that it is reasonable to expect that a higher daily dose of 5.0 mg/lb will reach a steady state above the minimum inhibitory concentration (MIC) at approximately the same time as two lower doses and be equally effective. You also state that whether the depletion to the MIC level of the proposed 5.0 mg/lb dose maintains the blood level at or above the MIC in the same manner as the pioneer's twice daily dosing of 2.5 mg/lb is an issue to be determined by a bioequivalence study. FDA disagrees that the products' differences could be addressed through a bioequivalence study. Since the two products would have different dosings, they would have different blood level profiles and, therefore, the proposed product would need additional data on effectiveness.

If you wish to consider an NADA submission, you may contact Dr. Melanie Berson, Director, CVM's Division of Therapeutic Drugs for Non-Food Animals, (301) 827-7540, for any questions on the specific requirements.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "John M. Taylor III".

John M. Taylor III  
Associate Commissioner for  
Regulatory Affairs