



DRUG SYSTEMS INC.

Smarter medicine through innovation.™

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March 10, 2004

Dockets Management Branch  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane  
Rockville, MD 20857

To Whom It May Concern:

We are filing this Suitability Petition to request permission to file an ANADA for a generic new animal drug which differs slightly from that of the pioneer product. We wish to file an ANADA to Pharmacia and Upjohn Animal Health's ANTIROBE® (clindamycin hydrochloride) capsules for dogs and cats (NADA 120-161). Whereas the pioneer's product is an oral capsule given twice a day, our proposed generic product is an oral tablet for once a day administration

1. **PETITIONER:** Smart Drug Systems, Inc.  
181 S. Broad St., #102  
Pawcatuck, CT 06379

**CITATION:** Section 512 (n) (3) of the Federal Food, Drug and Cosmetic Act (the Act).

2. **ACTION REQUESTED:** We request permission to file an ANADA for a generic new animal drug which differs from that of the pioneer product by the following characteristics: Our generic product will be an oral tablet for once a day administration that contains twice the concentration of clindamycin, whereas the pioneer product is an oral tablet for twice a day administration.
3. **STATEMENT OF GROUNDS:** There are 5 specific variances under the Act for which a Suitability Petition may be submitted. Our petition is for two these allowed variances:

Variance #2—change in dosage form. We propose changing from the pioneer's oral capsule to an oral tablet

Variance #3--change in strength of an ingredient. We are changing the strength of the clindamycin hydrochloride in the tablet. The generic will have double the amount of clindamycin hydrochloride in each tablet presentation. However, since the generic will be given only once a day, as opposed to the pioneer's twice a day, the total daily dose of clindamycin to the animal will remain the same.

4. **ENVIRONMENTAL IMPACT:** We request a categorical exclusion under 21 CFR 25.30 (h) from the requirement to prepare an Environmental Assessment (EA), and have determined that no extraordinary circumstances exist [Federal Register 62 FR 40596; July 29, 1997]
5. **ECONOMIC IMPACT:** An Economic Impact statement will be provided upon request.
6. **CERTIFICATION:** A separate statement certifying that we have included all information unfavorable to this petition is included in this submission.

Additional essential elements of the petition:

1. **IDENTIFICATION OF DRUG:** The active ingredient in both the pioneer product and our generic is clindamycin hydrochloride.
2. **LABELING FOR THE PROPOSED PRODUCT:** Copies of the proposed labeling for the generic product and approved labeling for the pioneer product are included in this submission.

If this petition is approved, we will discuss the bioequivalence protocol with you at a later date.

May we have your permission to file an ANADA for a generic new animal drug which differs from the pioneer product in the dosage form and change in strength of an ingredient?

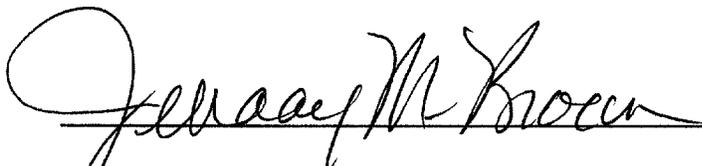
Sincerely,

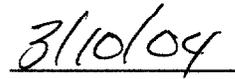


Jenaay M. Brown DVM  
Director, Regulatory Affairs

Attachment

I do hereby certify that I have included all information unfavorable to this petition;  
no unfavorable information has been intentionally withheld from this submission.

  
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Jenaay M. Brown DVM  
Director of Regulatory Affairs

  
\_\_\_\_\_  
Date