



DRUG SYSTEMS INC.

Smarter medicine through innovation.™

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 Pfizer Animal Health's AMOXI-TABS® (amoxicillin) for dogs and cats (NADA 055-078 and 055-081). Whereas the pioneer's product is an oral tablet 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 amoxicillin, 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 one these allowed variances:

Variance #3--change in strength of an ingredient. We are changing the strength of the amoxicillin in the tablet. The generic will have double the amount of amoxicillin in each tablet presentation.

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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 amoxicillin 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 amoxicillin.
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 only in the 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.

A handwritten signature in black ink, appearing to read "Jerray M. Brown". The signature is written in a cursive style with a large initial "J".

Jerray M. Brown DVM
Director, Regulatory Affairs

A handwritten date in black ink, appearing to read "3/10/04".

Date