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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 Pfizer Animal Health's CLAVAMOX® (amoxicillin trihydrate/clavulanate potassium) tablets for dogs and cats (NADA 055-099). 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

- 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).

- 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 amount of drug, whereas the pioneer product is an oral tablet for twice a day administration.
- 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 trihydrate/clavulanate potassium in the tablet. The generic will have double the amount of amoxicillin trihydrate/clavulanate potassium in each tablet presentation.

2004P-0128

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