



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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• SP 04P-0128/CP 1

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

Dear Dr. Brown:

We refer to your suitability petition filed March 16, 2004, in which you requested permission to submit an abbreviated new animal drug application (ANADA) for a generic product that differs from an approved new animal drug. The proposed pioneer product is Pfizer's Clavamox[®] (amoxicillin trihydrate/clavulanate potassium) tablets, which is intended for use in dogs and cats (NADA 055-099). Your proposed product would contain twice the amount of amoxicillin trihydrate/clavulanate potassium given once daily in an oral tablet dosage form whereas the pioneer's product is an oral tablet administered twice daily.

Your proposed product differs from the pioneer product in strength and dosage regimen. A change in strength is one of the five variances in the pioneer product which can be sought through a suitability petition under section 512(n)(3) of the FDCA, as amended. Pursuant to that provision, we are required to approve the petition unless we determine that investigations must be conducted to establish the safety and effectiveness of the proposed product. We conclude that your petition must be denied because investigations must be conducted to show the safety and effectiveness of your proposed product.

The increase in strength and the change in dosage regimen of amoxicillin trihydrate/clavulanate potassium will necessitate evaluation of the target animal safety and effectiveness of the proposed product. Based on your request, we will require an original new animal drug application (NADA) for the proposed product.

If you disagree with our denial of your suitability petition, you may petition for reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Such petition should be submitted in accordance with § 10.20 in the format outlined in § 10.33. The petition must be based solely on the information and views contained in your original petition. The petition for reconsideration should be submitted no later than 30 days after the date of this denial of the suitability petition and must be filed with the Division of Dockets Management, Food and Drug Administration, HFA-305, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please refer to docket number 04P-0127 in any submission regarding this original suitability petition.

2004 P-0128

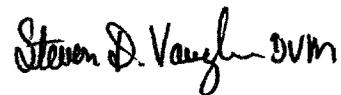
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If there is additional information not included as part of your original submission that you would like the agency to consider, you should submit a new petition under § 10.30 and include all necessary information to the Division of Dockets Management at the address noted above.

This action in response to your suitability petition does not alter the requirements for approval of a new animal drug, nor assure approval of the new animal drug.

If you wish to discuss or have any questions, you may call Dr. Lonnie W. Luther, Chief, Generic Animal Drug Team, (301) 827-8549. For the requirements of a new animal drug application you may call Dr. Melanie R. Berson, Director, Division of Therapeutic Drugs for Non-Food Animals, (301) 827-7543.

Sincerely yours,

A handwritten signature in black ink that reads "Steven D. Vaughn DVM". The signature is written in a cursive style with a large, stylized 'S' and 'V'.

Steven D. Vaughn, DVM
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine