



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

SEP 28 2000

NADA 055-099  
NADA055-101

Tracy D. Rockney  
Associate Director, Regulatory Affairs  
Pfizer Inc, Animal Health Group  
812 Springdale Drive  
Exton, Pennsylvania 19341-2803

Dear Ms. Rockney:


This is in reference to your submission dated March 28, 2000, concerning Clavamox Tablets (amoxicillin, clavulanic acid ), NADA 055-099 and Clavamox Drops, NADA 055-101.

This submission includes five (5) pieces of Promotional Labeling, namely the Dental Client Education Brochure, coded CLA9902, Dental Client Poster, coded CLA9903, Dental Client Educational Dental Chart and Marker, coded CLA010001, Dental Client Placard, coded CLA010002, and Dental Client Notepad, coded CLA 010003. We have the following comments and requests:

The Dental Client Education Brochure (coded CLA9902) is considered labeling which fails to provide full prescribing information, in other words, the reproduction of the package insert as required under 21 CFR 201.105(d)(1).

We request that you stop using the cited material in the promotion of your product and inform us of your intentions as soon as possible or in any event within 30 days of the date of this letter. If you have any questions, please contact us at (301) 827-6642.

Sincerely yours,



Mohammad I. Sharan, DVM., M.Sc  
Team Leader, Marketed Product Scientific  
and Regulatory Review Team II, HFV-216  
Division of Surveillance  
Center for Veterinary Medicine