DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 21 2001

NADA 55-099

Tracey D. Rockney
Director, Regulatory Affairs
Pfizer Inc.
Animal Health Group
235 East 42nd Street
New York, NY 10017

Dear Ms. Rockney:

We refer to your Drug Experience Report dated September 24, 2001 for Clavamox (amoxicillin trihydrate, clavulanate potassium) tablets, (NADA 55-099). The promotional material included in this submission consists of small (CLA0801022) and large (CLA0801022) Clavamox branding cards. On both cards, it reads that "No change in resistance patterns have been found." We note that this statement is based on a reference to canine and feline susceptibility data dated 1991-1993.

It is false and misleading to draw conclusions regarding antimicrobial resistance in companion animals based on data collected approximately 10 years ago. We request that you remove such statements from your promotional materials.

We wish to remind Pfizer of the commitment made when it signed the new animal drug application Form FDA 356V that the labeling and advertising will be neither false nor misleading, and that promotional claims will be in accord with those approved. We request that further distribution of this material be discontinued. We would further request that you carefully review all promotional material prior to release to ensure violative material is not distributed. As we have previously stated, we consider antimicrobial resistance to be a serious public health issue and a very important Center priority. Please inform us of your intentions as soon as possible but not later than 30 days following receipt of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely,

Vitolis Vengris, D.V.M., Ph.D.
Team Leader, Marketed Product Scientific
and Regulatory Review Team I, HFV-214
Division of Surveillance
Center for Veterinary Medicine.