



SEP 5 2000

NADA 055-070  
NADA 055-069

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

Dear Ms. Rockney:


This is in reference to your submissions dated August 03, 2000, concerning Orbenin-DC, Cloxacillin Benzathine, NADA 055-069 and Dariclox, Cloxacillin Sodium, NADA 055-070. The submissions included a reprint of a 1999 article from the Journal of Dairy Science "Comparison of Seven Antibiotic Treatments with No Treatment for Bacteriological Efficacy Against Bovine Mastitis Pathogens" and three product profile sheets.

The product profile sheets for benzathine cloxacillin and sodium cloxacillin, list one of the advantages as "...antibiotic resistance is extremely rare" which is deemed an unsubstantiated claim. In addition, the parts of the labeling providing other information concerning dosage, warnings, hazards, side effects, precautions, etc. are not the same in language and emphasis as contained in the approved labeling [21 CFR 201.105(d)(1)]. Accordingly, we find these labeling pieces to be false and misleading, and therefore violative of section 502(a) of the Act.

We request that you stop using these labeling pieces immediately and in the future devise your promotional material listing only the approved claims.

Please inform us of your intentions within 30 days of the receipt of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely yours,



Mohammad I. Sharar, DVM, MSc.  
Team Leader, Marketed Product Scientific  
And Regulatory Review Team II, HFV-216  
Division of Surveillance  
Center for Veterinary Medicine