DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Donald M. Lucas, Ph.D.
Director, Clinical Development &
Regulatory Affairs
Hoffmann-La Roche Inc.
45 Waterview Boulevard
Parsippany, NJ 07054-1298

APR 16 1998

Dear Dr. Lucas:

This is a follow-up to our telephone conversation of April 7, 1998. We refer to your "Transmittal Of Periodic Reports And Promotional Material For New Animal Drugs" (Form FDA 2301) dated February 17, 1998, regarding promotional material for Aureomycin®, NADA# 048-761.

We bring your attention to the Tech Bulletin entitled, "DESI for AUREOMYCIN® (chlortetracycline) in Poultry." In the table on the last page of this bulletin under "Drug (use level)", the percentage of amprolium when used in combination with ethopabate and 100-400 g/ton of AUREOMYCIN is not consistent with approved levels. According to Title 21, Code of Federal Regulations §558.58, amprolium and ethopabate are approved to be used in combination with chlortetracycline as follows:

Amprolium 113.5 to 227 g/ton (0.0125% to 0.025%) and ethopabate 3.6 g/ton (0.0004%)

We request that you stop using this bulletin and inform us of your action in writing within 30 days of receipt of this letter.

If you have any questions, you may contact Dr. Vengris at (301) 827-6642.

Sincerely yours,

Frederick D. Doddy, V.M.D., M.S.
VMO, Marketed Product Scientific and
Regulatory Review, Team 1
Center for Veterinary Medicine