



OCT 12 2001

NADA 097-505

Thomas R. Schriemer, Director
Regulatory Affairs
Pharmacia & Upjohn Company
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Mr. Schriemer,

We refer to your submission for Annual Drug Experience Report dated July 20, 2001, concerning Lincomix[®] 20/50 Feed Medication (lincomycin hydrochloride, NADA 097-505). The submission includes two promotional items identified as G00236E and G00236M. The latter item, G00236E, entitled "*Research Insight, Mycoplasmal pneumonia and PRRS interaction*" is in violation of the Federal Food, Drug, and Cosmetic Act (FFDCA) and applicable regulations because it contains misleading claims. Specifically we object to the following:

"LINCOMIX, unlike any other approved feed medication, gets to the infection site because it concentrates in the ELF, instead of elsewhere in the respiratory tract."

These claims are misleading. We are not aware of adequate and well-controlled studies demonstrating concentration of lincomycin in epithelial lining fluid. Furthermore we are not aware of evidence that lincomycin concentrates to any greater or lesser degree than any other antimicrobial product.

The approved claims for use of your product in swine are "**for treatment and control of swine dysentery**", "**for reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae***", and "**for increase in rate of weight gain in growing-finishing swine**". Only these benefits are acceptable for use in promotional and advertising materials regarding swine.

Unapproved claims, recommendations, or suggestions in labeling causes your product to be misbranded under the FFDCA. We request you to immediately stop using this unsubstantiated claim in your future promotional materials. We remind you of the commitment you made when you signed the new animal drug application (NADA) form FDA-356 that labeling and advertising would prescribe, recommend, or suggest product usage only in accord with labeling provided for in the approved application.

If you wish to submit a supplemental NADA in support of these new claims, please contact the Office of New Animal Drug Evaluation. We expect to receive your response within 30 days of receipt of this letter. If you have any questions you may contact us at (301)827-6642.

Sincerely yours,



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

