



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 12 1999

NADA 131-918

Ms. Celia C. Castaneda
Regulatory Compliance Specialist
Shering-Plough Animal Health Corporation
1095 Morris Avenue
Union, N J 07083

Dear Ms. Castaneda:

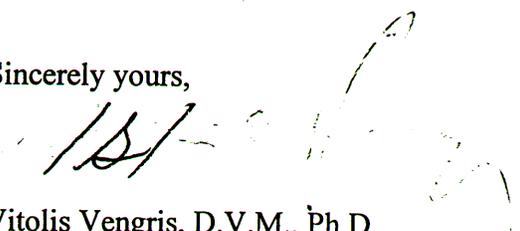
We refer to your promotional piece entitled "TRUST TRIBRISSEN FIRST", detailer number SPAH-TRI-4 for Tribriszen 48% Injection Sterile and Tribriszen 400 oral paste, NADA 131-918. We have reviewed this promotional item and find it to be violative.

This promotional item is violative because it fails to provide a fair balance and lacks risk information as required by 21 CFR 202.1(e)(5)(ii) For example, the use of efficacy information such as "...one product treats a broad range of infections, may influence a generalized use as a broad spectrum antibiotic" triggers the need to present important risk information.

We ask that this promotional piece and similar promotional material being used or intended to be used in the future be immediately stopped. In addition, we request that you review your company policies to give due consideration and attention to promotional practices and ensure that your promotional materials comply with the requirements of FDA regulations.

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

Sincerely yours,



Vitolis Vengris, D.V.M., Ph.D.
Marketed Product Scientific and
Regulatory Review, Team 1,
HFV-214
Division of Surveillance
Center for Veterinary Medicine