



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 28 2004

NADA 110-315
NADA 118-123
NADA 135-906
ANADA 200-221
ANADA 200-224
ANADA 200-346

Stan R. Spurlin
Vice President
Division of Ivy Laboratories
Ivy Animal Health, Inc.
8857 Bond Street
Overland Park, KS 66214

Dear Mr. Spurlin:

This letter refers to your New Animal Drug Applications for Component E-C with Tylan, Component E-S with Tylan, Implus C, Steer-OID and Calf-OID (NADA 110-315); Compudose 200 and Compudose 400 (NADA 118-123); Heifer-OID (NADA 135-906); Component TE-G and Component TE-S (ANADA 200-221); Component TH-S (ANADA 200-224); Component TE-200, Component TE-200 with Tylan, Component TE-H, Component TE-H with Tylan, and Component TE-IH (ANADA 200-346).

The Center for Veterinary Medicine (CVM) has recently issued guidance to the veal industry regarding hormone implants in veal calves. The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) veterinarians have found evidence of unapproved hormone implants in veal calves being presented for slaughter at several establishments. CVM defines veal calves to include any pre-ruminating calf, regardless of breed, intended to be, or having been, processed for veal. There are no FDA-approved growth-promoting hormone implants for veal calves, and the extra-label use of non-therapeutic new animal drugs such as these growth-promoting hormonal implants is illegal.


We note that the current labeling for your products does not display what we consider to be the standard warning against use of the hormone implant in pre-ruminating calves. To preclude illicit use of hormone implants in veal calves, we request that you submit supplemental New Animal Drug Applications providing for the revised labeling to include a veal calf warning on all labeling components as soon as possible or in any event within 3 months of receipt of this letter. The warning statement should be included as a second paragraph under the existing **Warning** section. It should read:

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

We wish to inform you that we are sending similar letters to all sponsors whose NADAs or ANADAs have been identified to be in a similar situation as yours. To facilitate handling, we request that you submit all correspondence related to this initiative to the undersigned.

Please inform us of your intentions as soon as possible. If you have any questions you may reach us at (301) 827-6642.

Sincerely,



Mohammad I. Sharar, DVM., M.Sc.
Team Leader
Post-Approval Review Team, HFV-216
Division of Surveillance
Center for Veterinary Medicine