



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 28 2004

NADA 009-576
NADA 011-427
NADA 141-043

Ann Hokinson
Assistant Manager
Pharmaceutical Regulatory Affairs
Fort Dodge Animal Health
800 5th Street, N.W.
Fort Dodge, Iowa 50501

Dear Ms. Hokinson:

This letter refers to your New Animal Drug Applications for Synovex S and Synovex C, (NADA 009-576); Synovex H, (NADA 011-427); Synovex Plus, (NADA 141-043).

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