



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

FEB - 6 2001

NADA 140-863

Bruce W. Martin, D.V.M., Ph.D.  
Manager of Regulatory Affairs  
Elanco Animal Health  
A Division of Eli Lilly  
2001 W. Main Street  
Greenfield, IN 46140

Dear Dr. Martin:

We refer to your promotional "belly band" piece for Paylean (ractopamine HCl, NADA (140-863) in the November 15, 2000 issue of National Hog Farmer. The approved indications for use of Paylean are: "For the increased rate of weight gain, improved feed efficiency, and increased leanness in finishing swine fed a complete ration containing at least 16% crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight." The statements made in the "belly band" promotional piece are: "10.6 lbs heavier carcass weights; 1.3% (absolute %) increased carcass yield; 1.3% (absolute %) improvement in fat-free lean estimate; and Up to 20.6% increased ADG and up to 15.2% improved feed efficiency." We question the statements made in the promotional piece. Promotional statements must be supported by data submitted to the approved NADA. Otherwise, promotional material should not be used or post-approval data that support these statements should be submitted for our review.

Please inform us of your intentions within 30 days after receiving this letter. If you have any questions, you may contact us at (301) 827-0158.

Sincerely yours,

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