



Date: June 3, 1998

NADA 12-491

Robin R. Marks, DVM, JD
Manager, Animal Science Regulatory Affairs
Elanco Animal Health
2001 West Main Street
Greenfield, IN 46140

Dear Dr. Marks:

We refer you to your promotional piece found in the January 1998, issue of the Swine Practitioner. The approved Tylan enteric disease claim at the 40 g/t level 21 CFR 558.625 (f)(vi)(b)(i), is indicated for treatment and control of swine dysentery (vibrionic) or as a non-therapeutic growth promotor. The promotional piece in question makes a broader claim, "maintain enteric health."

We object to this promotional statement since it insinuates that tylan has a broader application than indicated in the approved labeling -which is for swine dysentery (vibrionic).

We request that you stop using this promotional statement and in the future use only approved claims in promotional pieces. The revised labeling should be submitted as a DER as soon as possible

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

Sincerely yours,

Vitolis E. Vengris, D.V.M. PhD
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Regulatory Review, Team 1
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