



September 1, 1998

ANADA 200-033

Giovanni Parrinello, Ph.D.
Director, Research & Development
Macleod Pharmaceuticals, Inc.
2600 Canton Court, Suite C
Fort Collins, CO 80525

Dear Dr. Parrinello:

We refer to your Drug Experience Report (DER) dated July 31, 1998, for UNIPRIM™, ANADA 200-033.

We call your attention to the promotional piece (UPO93759 REV. 7/95) entitled "Attention SMZ Tablet Users!" The leading paragraph states, "Now your clients and their horses can enjoy the benefits of UNIPRIM compared to human generic tablets. Horses definitely recover quicker because UNIPRIM gives higher tissue levels sooner, and levels that last for 24 hours."

The statements "...enjoy the benefits of UNIPRIM compared to human generic tablets," and "Horses definitely recover quicker because UNIPRIM gives higher tissue levels sooner..." are considered false and misleading and in violation of the regulations promulgated under 21 C.F.R. §202.1(e)(6)(ii). In the article entitled "A comparison between two blood level studies following oral dosing in horses with either Trimethoprim/Sulfadiazine Powder (UNIPRIM) or human generic SMZ tablets" which appeared in *The Highlander*, Summer 1997, there is comparison of UNIPRIM to human generic Trimethoprim/ Sulfamethoxazole. The conclusion is that the higher blood levels achieved with UNIPRIM could explain the apparent quicker clinical response. This information is then used in your promotional piece stating horses definitely recover quicker because UNIPRIM gives higher tissue levels sooner. This does not constitute substantial evidence. It is not appropriate to compare UNIPRIM with products which have not been approved for the same indication, and then use the information for promotional purposes.

Page 2 - Giovanni Parrinello

We request that you immediately discontinue using this promotional piece and that in the future, you do not again use this claim. Please inform us of your intentions within 30 days of receipt of this letter. If you have any questions, feel free to call us at (301) 827-6642.

Sincerely yours.



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