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28 January, 1998

DOCKET COMMENT

Dockets Management Branch (HFV-305)
Food and Drug Administration
12420 Parklawn Drive
Room 1-23
Rockville, MD 20857

Re: Docket No. 97N-0217 - Discussion of CVM proposal to increase the availability of approved animal drugs for minor uses and minor species (MUMS): Changes to marketing exclusivity.

Dear Sir / Madam:

We wish to comment on CVM's proposal to increase the availability of approved animal drugs for minor uses and minor species as called for under the Animal Drug Availability Act (1996).

It is common knowledge that one reason pharmaceutical firms are reluctant to undertake the development of drugs for minor uses and minor species (MUMS) is the lack of financial reward after approval is received. One method of increasing the incentive for firms to take upon themselves the devotion of time and money is to modify the provisions of marketing exclusivity.

An example is to offer for the initial MUMS approval an additional two years marketing exclusivity on all previous approvals for that product. Subsequent MUMS approvals for that product should then be rewarded with lesser extensions (18 months then 12 months) of marketing exclusivity of all current approvals.

By way of illustration, Dewormo™ (benzimidole) suspension 10% for horses, cattle and swine has been approved for several years. The horse and cattle approvals have no remaining marketing exclusivity, whereas, the swine approval has one further year. As a reward for doing the required work to obtain the initial MUMS approval, an additional two years marketing exclusivity would be granted to all approvals for that product. The total exclusivity for the horse and cattle approvals would therefore be two years, and three years for the swine approval. Under our proposal, additional generic ANADA approvals would not be granted during this time. The next MUMS approval should be granted 18 months additional marketing exclusivity on all approvals for that product and each subsequent MUMS approval should be granted 12 months additional marketing exclusivity on all approvals for that product.

97N-0217

Hoechst

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A member of the Hoechst Group

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C107

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Such modifications would provide sufficient financial incentive for sponsors to undertake the work required. The diminishing returns would discourage misuse of the system. Importantly, minor uses and minor species would be served by having approvals which they would not otherwise have.

Thank you for this opportunity to comment.

Sincerely,

A handwritten signature in cursive script that reads "WR Dodemaide".

Dr WR Dodemaide, BVSc
Manager, Regulatory Affairs

cc: Dr GA (Bert) Mitchell, CVM (HFV-1)

Hoechst Roussel Vet

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W. R. Dodemaide - S160E

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MAIL



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