



ADVICE SUMMARY

APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

Product name: FARNAM WORMA PASTE FOR HORSES
Applicant: INTERNATIONAL ANIMAL HEALTH PRODUCTS PTY LTD
Product number: 46724
Application number: 43346

Purpose of Application and Description of Use: Registration and label approval of a 107.2 mg/g oxfendazole and 214.4 mg/g piperazine paste formulation for the worming of horses.

Active Constituent(s): OXFENDAZOLE
PIPERAZINE (as dihydrochloride)

Regulatory Decision:

To grant the application subject to the following conditions:

Standard Conditions of Registration/Approval

1. Containers must meet AgVet Code Regulation 18
2. Product must not be supplied without meeting GMP Requirements
3. Label must contain an Expiry Date and Batch Number

For full conditions, refer to http://www.apvma.gov.au/advice_summaries/adv_summaries.shtml.

Non-Standard Conditions of Registration/Approval

External Efficacy Reviewer

An external reviewer evaluated dissolution data comparing the current and revised formulations who determined that both formulations behaved in a similar fashion and that the efficacy claims for the new formulation could be transferred (with minor amendments) to the previously approved formulation.

Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
17816	S	Antoni Lominski	Comparative Dissolution Studies of an oil-based and water-based formulations	4th October, 2007	Efficacy and Safety	Efficacy	Applicant	

* S = Data submitted with the application