

Notice of Application to Vary the Conditions of a Registered Trade Name Product (Notice No. MPI 787)

Maree Zinzley, Manager Approvals Operations of the Ministry for Primary Industries (MPI), acting under delegated authority from the Director-General of MPI, gives notice, under section 14(1) of the Agricultural Compounds and Veterinary Medicines Act 1997 ("Act"), that the following variation application has been made to a registered trade name product under section 9(2) of the Act:

Trade Name: **Zolvix Plus Broad Spectrum Oral Anthelmintic for Sheep and Cattle**

Reference: A011107-04

Active Ingredients and Concentrations:

Monepantel 25mg/mL

Abamectin 2mg/mL

Formulation Type: Liquid

Current Claims:

Monepantel is a member of the class of anthelmintics called the Amino-Acetonitrile Derivatives (AADs) while Abamectin is a member of the Macrocylic Lactone (ML) class of anthelmintics.

ZOLVIX PLUS is effective for the treatment and control of sensitive strains of nematodes (roundworms), including nematodes that have single, dual or triple resistance to macrocylic lactones (including moxidectin resistant strains), benzimidazoles (white drenches), imidazothiazoles (levamisole and morantel (clear drenches) and salicylanilide (eg closantel)-resistant strains, in sheep. ZOLVIX PLUS is also effective against AAD-sensitive immature (L4) stages of *Haemonchus contortus* and *Teladorsagia circumcincta* where a combination of a macrocylic lactone and derquantel is less effective.

Proposed New Claims (changes in bold):

Monepantel is a member of the class of anthelmintics called the Amino-Acetonitrile Derivatives (AADs) while Abamectin is a member of the Macrocylic Lactone (ML) class of anthelmintics.

ZOLVIX PLUS is effective for the treatment and control of sensitive strains of nematodes (roundworms), including nematodes that have single, dual or triple resistance to macrocylic lactones (including moxidectin resistant strains), benzimidazoles (white drenches), imidazothiazoles (levamisole and morantel (clear drenches) and salicylanilide (eg closantel)-resistant strains, in sheep, **beef cattle and non-lactating dairy cattle**. ZOLVIX PLUS is also effective against AAD-sensitive immature (L4) stages of *Haemonchus contortus* and *Teladorsagia circumcincta* **in sheep** where a combination of a macrocylic lactone and derquantel is less effective.

Any person may make a written submission to the director-general concerning this application.

Under sections 16 and 17 of the Act, a written submission:

- a. must state in full the reasons for making the submission; and
- b. may state any decision sought on that application; and
- c. must be received by the director-general no later than 30 working days after the date of notification in the *New Zealand Gazette*.

Under section 18 of the Act, a copy of every submission will be forwarded to the applicant for the applicant's information.

The following address is:

- a. where submissions on this application are to be sent; and
- b. where requests for copies of the public information relating to the application can be sent; and
- c. where public information relating to the application can be viewed; and
- d. the director-general's address for service:

ACVM Group, Ministry for Primary Industries, Pastoral House, 25 The Terrace, Wellington 6011. Postal Address: PO Box 2526, Wellington 6140.

The applicant's address for service is:

Elanco Animal Health (division of Eli Lilly and Company NZ Limited), Level 1, 123 Ormiston Road, Botany Junction, Auckland. Postal Address: 112 Wharf Road, West Ryde, New South Wales 2114, Australia.

Dated at Wellington this 7th day of July 2017.

MAREE ZINZLEY, Manager Approvals Operations, Ministry for Primary Industries (acting under delegated authority).

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