Notice of Application to Vary the Conditions of a Registered Trade Name Product (Notice No. MPI 683)

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: **Lepto 3-Way**

Reference: A008314

Active Ingredient and Concentration:

Inactivated cultures of *Leptospira interrogans*: serovars *hardjo*, *copenhageni* and *pomona.*

Formulation Type: Aqueous solution or suspension

General Use Claim:

For the vaccination of cattle against leptospirosis.

For the vaccination of cattle, sheep, deer and goats against leptospirosis caused by *L. borgpetersenii* serovar *hardjo* (*hardjo-bovis*) and *L. interrogans* serovars *copenhageni* (*icterohaemorrhagiae*) and *pomona*. To prevent the shedding in urine of leptospirae of these serovars, and thus reduce the risk of human leptospirosis infection.

Proposed Variation to Conditions:

For the vaccination of cattle, sheep, deer and goats and dogs against leptospirosis.

For the vaccination of cattle, sheep, deer and goats against leptospirosis caused by *L. borgpetersenii* serovar *hardjo* (*hardjo-bovis*) and *L. interrogans* serovars *copenhageni* (*icterohaemorrhagiae*) and *pomona*. To prevent the shedding in urine of leptospirae of these serovars, and thus reduce the risk of human leptospirosis infection.

Also as an aid in the prevention of leptospirosis in dogs caused by *L. borgpetersenii* serovar *hardjo* (*hardjo-bovis*) and *L. interrogans* serovars *copenhageni* (*icterohaemorrhagiae*) and *pomona*. Provides protection against reproductive losses in cattle due to *L. borpetersenii* serovar *hardjo*.

High Risk Calves: Calves deemed to be at high risk may be vaccinated from as young as four weeks of age. However, they must still receive a second dose four to six weeks after the first AND, where the primary vaccination is completed before six months of age, a booster dose at six months of age is essential.

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:

Virbac New Zealand Limited, 26–30 Maui Street, Pukete Park, Hamilton 3200. Postal Address: PO Box 10305, Te Rapa, Hamilton 3241.

Dated at Wellington this 13th day of September 2016.

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

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