Registration Renewals (Agricultural Compounds and Veterinary Medicines Act 1997)

March 2017

Contents

Annual fees and registration renewals

MPI wishes to remind registrants that annual fees are separate from renewal of product registrations. Payment of annual fees **does not** renew a product registration.

Annual fees

Annual fees are a fixed fee payable by registrants, based on the number of products registered to them. They are paid in advance, e.g. the current annual fees run from 1 October 2016 through 30 September 2017. Reminder letters are sent to registrants in June of each year, with payment due in September. The reminder letter asks you to view your list of registered products on the public register and advise us if you wish to de-register any of your products. Please note it is the responsibility of the registrant to ensure that their contact details are current, and to advise MPI of any change.

Registration renewals

Trade name products currently have a registration life cycle of three years, and must be renewed prior to the end of the three-year period. Expired products will be removed from the public register. It is illegal to import, sell, use, or manufacture a trade name product removed from the register.

Registration renewal applications are made to renew the registration period and set a new registration expiry date – no other changes can be made in a registration renewal application. To enable trade name products to remain legally registered, registrants must allow sufficient time for us to process and grant their registration renewal applications.

When should I submit a registration renewal application?

Registration renewal applications should be submitted no later than **three months** prior to the expiry date.

Variation application(s) submitted concurrently with a renewal application cannot be accepted if the registration is due to expire within three months from the date of submission. In this case, precedence must be given to processing the renewal application to ensure your product stays legally registered.

For registration renewal applications, the label plus the Registration and Product Datasheet submitted must be the same as that currently approved. The exception for labels is if mandatory label statements have changed since the last approval. In these cases we advise updating mandatory label statements (e.g. updating the management of residues mandatory statement from "It is an offence for users of this product to cause residues exceeding the relevant MRL in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards" to "It is an offence for users of this product to cause residues exceeding the relevant MRL in the Food Notice: Maximum Residue Levels for Agricultural Compounds").

If you wish to also submit a variation application, these should be submitted as soon as possible after you receive your registration renewal approval.

Should you wish to submit any type of variation application within four-to-five months of the registration expiry date, we advise that you must submit a complete Registration and Product Datasheet and label with the appropriate variation application forms. Upon granting an approval, MPI will then issue a new Certificate of Registration which will include a new expiry date, provide an approved Registration and Product Datasheet and approved label.

IMPORTANT NOTE: the registration date and expiry date can be found on the product's Certificate of Registration.

What do I need to submit for a registration renewal application?

A complete registration renewal application comprises:

- a complete signed and dated application form. The application form – 'Renewal of registration of an ACVM trade name product ACVM 1R' can be found on our website; and
- a complete label; and
- a complete signed and dated Registration and Product Datasheet. Please ensure you use the latest version of the appropriate Registration and Product Datasheet template (version August 2014), which can be found on our website: agricultural chemicals veterinary medicines vertebrate toxic agents

What do I do if I have a product registered with Condition 86 and /or Condition 101?

For risk management purposes, sometimes products are registered with conditions requiring provision of additional information. The most common of these conditions of registration are:

Condition 86
The registrant must provide a batch analysis, which confirms that the product meets the approved release specifications, from the first production batch at the new manufacturing site to the Ministry for Primary Industries for approval prior to sale of product from this new site.

Condition 101
The registrant must provide additional information specified by the Ministry for Primary Industries at or before the expiry of the current product registration period.

We advise that you must still comply with these conditions by providing the information as specified.

Renewal applications and enquiries

To streamline the receipt of registration renewal applications, please direct all renewal queries and registration renewal applications to the special email inbox: regRenewalACVM@mpi.govt.nz