



# APPLICATION FOR APPROVAL TO IMPORT AND SELL INCORRECTLY LABELLED VETERINARY MEDICINES, PLANT COMPOUNDS OR VETEBRATE TOXIC AGENTS

THIS FORM IS FOR THE USE OF PRODUCT REGISTRANTS WHEN REQUESTING IMPORTATION FOR SALE OF PRODUCTS REGISTERED IN THEIR NAME ONLY.

This form can be used to request approval for the importation of product that is registered in NZ but will not be imported or sold with the approved NZ label. See the criteria for importation under this approval attached as appendix 1 to confirm applicability before proceeding. See appendix 2 for further information regarding the approval process.

## 1 Fees

Each application attracts a fee of \$123.75 (incl. GST). An initial payment of \$123.75 is required to accompany any application unless the applicant is an approved creditor in which case the fee will be invoiced upon request. Make cheques payable to NZFSA.

Fee attached      Yes/No/Approved creditor

## 2 REGISTRANT DETAILS

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_ E-mail: \_\_\_\_\_

Are you the registrant of the imported product?

Yes

No

*Note that approvals will be issued to the registrant of the product only.*

Name of premises and address for redirection:

\_\_\_\_\_  
\_\_\_\_\_

### 3 NZ REGISTERED PRODUCT DETAILS

Full trade name of product: \_\_\_\_\_

New Zealand registration number: \_\_\_\_\_

Active ingredient/s and quantity:

\_\_\_\_\_

### 4 IMPORTED PRODUCT DETAILS

Full trade name of product: \_\_\_\_\_

Overseas registration number (if applicable): \_\_\_\_\_

Is the imported product identical to the NZ registered product in all respects other than label content?

Yes

No

*Note that approvals will be issued only if the answer is yes.*

Quantity to be imported: \_\_\_\_\_

Are 2 copies of all labelling that will be attached to the imported product provided?

Yes

No

*Note that approvals will be issued only if the labels are attached.*

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### APPLICANT'S SIGNATURE

**NOTE:** This declaration does not abrogate the provisions of any other legislation; Hazardous Substances and New Organisms Act 1996 and/or the Toxic Substances Regulations 1983 Refer to ERMA NZ <sup>Note 3</sup> on [www.ermanz.govt.nz](http://www.ermanz.govt.nz).

**DECLARATION:** I declare that the information provided is true and correct.

Registrant's signature: \_\_\_\_\_ Date: \_\_\_\_\_

This information being collected is required to support your application for approval under the Agricultural Compounds and Veterinary Medicines Act 1997, and for the purpose of administering the Act. The agency collecting and holding this information is:  
Agricultural Compounds and Veterinary Medicines Group  
New Zealand Food Safety Authority  
P O Box 2835, Wellington

You have the right of access to, and correction of, personal information supplied in this form as provided by the information privacy principles in section 6 of the Privacy Act 1993. This document may be reviewed and amended if there are changes in New Zealand's import policy or the animal health status of the originating country or for any other reason, at the discretion of the ACVM Group.

# Attachment 1

## DETAILS OF IMPORTATION

- 1 Provide justification for the requested approval. Refer to the criteria attached as appendix 1 and confirm that the criteria as specified is met for the proposed approval to be issued:

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- 2a *For importations that have been requested as a result of **unforeseen product shortage only** answer the following:*

Provide details of the intended recipients of product proposed for importation under this temporary approval. Include justification for the quantity requested and the maximum timeframe over which product will be released for sale (noting that the temporary approval will expire at this time).

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- 2b *For importations that have been requested as a result of **predictable product unavailability only** answer the following:*

Identify the intended recipient(s) of product proposed for importation under this temporary approval including name(s) and address(es). Include justification for the quantity requested and the maximum timeframe over which product will be released for sale to the named recipients (noting that the temporary approval will expire at this time).

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3 Provide details of the management of the product from the time of importation to the time of sale.

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4 Identify any differences between the NZ approved label and the imported product label. State the actions that are proposed to ensure that purchasers of the product will receive all necessary information to enable the product to be used as per the NZ current approval.

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## Appendix 1

### Criteria for Approval

Approval will only be issued via this mechanism if the following criteria are fulfilled:

1. The registrant of the registered TNP must make the request and be in a position to maintain control of product from the time of importation until the time of sale to the prescribing veterinarian or end user (i.e. product must not be made available to third party wholesalers or intended for retail shelves).
2. Product requested for importation must be identical to a product currently registered in New Zealand in all respects other than the label.
3. One of the following two circumstances resulting in correctly labelled product being unavailable to the NZ market must apply; those being either
  - a. The result of unforeseen circumstances e.g. demand outstripping ability to supply and there will be significant issues if the product was not supplied; or
  - b. The result of limited product sales where it is not viable to maintain NZ labelled stock on-hand and where the alternative to not being able to supply incorrectly labelled product is the withdrawal of the registered TNP from the market This is considered to be predictable product unavailability.
4. Where 3b applies, approval will only be granted for supply to specified individuals where imminent need for product can be satisfactorily established.

## Appendix 2

### Approval Process

Approval will only be considered upon receipt of the following:

1. Completed and signed application form; and
2. Fee or advice to invoice; and
3. 2 Copies of the imported product label (as it will appear, and all labeling).

Failure to provide any of the required data elements will result in processing delays. The ACVMG endeavors to provide approval within 15 working days. Note that regardless of the outcome the applicable fee will not be refunded.

Should further clarification be required regarding the application during the assessment process the applicant will be contacted. This is likely to result in processing delays.

Following assessment the application will be forwarded for consideration by the Decision Making Committee. Conditions of approval will be recommended, as well as a maximum quantity of product and time period over which importation may occur. Although some standard conditions will apply (e.g. imported product cannot be specifically advertised for sale) it is possible that specific conditions will also be required to reflect the risk management systems proposed by the applicant.

If approved, the applicant will receive notification via an approval letter that will also contain the conditions of approval and any advice considered necessary. In addition, a temporary approval certificate will be supplied that must be provided to MAF Quarantine at the time of importation. When the total product allowance has been imported or the temporary approval has expired the certificate must be surrendered to a MAF Quarantine Officer. If declined, the rationale for the decision will be notified in writing.

The temporary approval is complementary to, and does not replace the current approval. All conditions approved as per the current approval with the exception of the condition that requires product labeling to comply with the approved text remain applicable to product imported under the temporary approval.

## Notes

**Note 1: Other legislation**

Apart from the Agricultural Compounds and Veterinary Medicines Act 1997, there are other laws relating to or prohibiting the importation of goods. Approval under this system does not absolve applicants of the need to comply with these laws.

**Note 2: New approvals**

If details of the product or the import arrangements vary from those specified on this form, a new form must be completed.

**Note 3: ERMA New Zealand Contact Details**

To obtain information regarding hazardous substances, contact;

ERMA New Zealand  
P O Box 131  
Wellington  
Phone: (04) 916 0433  
Fax: (04) 914 0433