Approvals Operations Group
Regulation and Assurance
Ministry for Primary Industries
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Ministry for Primary Industries
Manatū Ahu Matua

Approval to Import and Sell Incorrectly Labelled Veterinary Medicines, Agricultural Chemicals or Vertebrate Toxic Agents ACVM 16 (July 2015)

- **This form is only for the use of product registrants when requesting importation for sale of their own products.**
- This form can be used to request approval for the importation of product that is registered in New Zealand but will not be imported or sold with the approved New Zealand label. See the criteria for importation under this approval (attached as an appendix) to confirm applicability before proceeding.
- Send this signed, completed application form, labels and fee (if not an approved creditor) electronically to the Ministry for Primary Industries at the above address.
- If there are any changes to the details provided in this application after the application has been submitted, you must promptly inform the Ministry for Primary Industries of the changes in writing.
- Refer to the Privacy Act 1993 and Official Information Act 1982 notices at the end of this form regarding collection of information by the Ministry for Primary Industries.

1. Registrant Details	
Full legal name	
Address	
Phone	
Email	
Are you the registrant of the imported product?	**Delete one: Yes No** Approvals will be issued only to the product registrant.
Name of premises and address for redirection	

2. New Zealand Registered Product Details	
Full trade name of product	
New Zealand registration number	
Active ingredients	
Quantity to be imported	

3. 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?	**Delete one: Yes No** 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?	**Delete one: Yes No** Approvals will be issued only if the labels are attached.

4. Applicant Statement

NOTE: This declaration does not abrogate the provisions of any other legislation such as the Hazardous Substances and New Organisms Act 1996 and/or the Toxic Substances Regulations 1983 and/or Biosecurity Act 1993. Refer to EPA NZ (www.epa.govt.nz) and/or Biosecurity NZ for further information.

I confirm that:

- I am authorised to make this application as the registrant OR a person with legal authority to act on behalf of the registrant noted in section 1; and
- the information supplied in and with this application is truthful and accurate to the best of my knowledge.

Name		**Tel**	
Signature		**Email**	
		Date	

5. MPI Service Charge

ON PAYMENT THIS BECOMES A TAX INVOICE GST No: 64-558-838

APPLICATION FEE: $178.25 (inc. GST) for each application. If multiple applications are made simultaneously, the first is charged as above, and subsequent applications are charged at $89.13 (inc. GST) per half hour or part thereof spent assessing them. An initial payment of $178.25 must accompany any application. The remainder will be invoiced if applicable.

PAYMENT OPTIONS:

Payments comprising multiple fees must be supported by a remittance advice. Please attach your advice to this application or send it separately to: **MPI Approvals, PO Box 2526, Wellington 6140**.

MPI does not accept cash. Payment must be made using one of the following methods. (Please fill in the appropriate section.)

APPROVED CREDITOR

DIRECT CREDIT:

1. Pay into Bank Account no. **03 0049 0001709 002**
2. In the 'Reference' details, put the code: **IMPILP**
3. Enter the date of deposit and the payee name on this form below:

Date of Deposit		**Payee Name**	

CHEQUE:

1. Make the cheque payable to **Ministry for Primary Industries**.
2. Attach the cheque to this application.

CREDIT CARD:

1. Type of card you wish to use: (delete one) VISA MasterCard
2. Fill in the card details below:

Card No: | | | | | | | | | | | | | | | |

Name on Card		**Expiry Date**	
Signature			

Collection of Information

Collection of Personal Information

Pursuant to Principle 3 of the Privacy Act 1993, we advise that:

- This information being collected is required to support your application for import approval under the Agricultural Compounds and Veterinary Medicines Act 1997, and for the purpose of administering the Act; and
- The recipient of this information, which is the agency that will collect and hold the information, is the Ministry for Primary Industries, PO Box 2526, PO Box 2526, Wellington 6140; and
- The provision of this information is necessary in order to process this application; and
- The supply of this information is voluntary; and
- Failure to provide the requested information is likely to result in a return of the application form to the applicant, and in accordance with the ACVM Act, may ultimately result in a refusal to approve the importation; and
- Under Principles 6 and 7 of the Privacy Act 1993, you have the right of access to, and correction of, any personal information which you have provided; and
- 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 MPI.

Collection of Official Information

All information provided to the Ministry for Primary Industries is official information and may be subject to a request made under the Official Information Act 1982.

If a request is made under that Act for information you have provided in this application, the Ministry for Primary Industries will consider any such request, taking into account its obligations under the Official Information Act 1982 and any other applicable legislation.

Details of importation

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

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).**

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).

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

4. Identify any differences between the New Zealand 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 New Zealand current approval.

Appendix

Criteria for approval

Approval will be issued via this mechanism only 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 (that is, 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 New Zealand market must apply:

    a. The result of unforeseen circumstances, for example, demand outstripping ability to supply and there will be significant issues if the product is not supplied, or

    b. The result of limited product sales where it is not viable to maintain New Zealand 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 be granted only for supply to specified individuals where imminent need for product can be satisfactorily established.