



REQUEST FORM TO ADD A DRUG TO LIST B

List B is a list of veterinary drugs that are allowed to be imported into Canada for personal use for food producing animals. Products on List B cannot be imported for sale or given to someone else, even if the distribution is for free.

“Importation for personal use”, also known as importation for own use, means importation by an individual for use on animal(s) under their care.

Before you start filling out the form

Please check that the product you want to apply for is not already on List B. List B can be found by clicking [here](#).

If the product you are looking for **is on List B**, you do **not** need to fill out this form. You can import the product. Please see below “Information for importing a List B product”.

How to submit a request to add a drug to List B

If you cannot find the product you want to import on List B, you can submit a request that a product be added to List B using this form.

It is recommended that you contact your producer association to make a request on your behalf. Alternatively, you can submit a request that the drug be added to List B by filling out this form.

To submit this information, you can email to List B-VDD liste B-DMV@hc-sc.gc.ca, or mail to:

Veterinary Drugs Directorate
Attn: SKMD (List B Products)
14 - 11 Holland Avenue
Ottawa, Ontario
K1A 0K9 (Address Locator - 3000A)

It is important to note that each request can include only one dosage form and one animal species.

In this form:

Part A – Product Information
Part B – Product Assessment against the eligibility criteria
Part C – Required Documents
Part D - Requestor Information and Attestation
Information for Importing a List B product



PART A: PRODUCT INFORMATION

This section is asking for information about the foreign product requested for List B and the Canadian comparable product.

Instructions for filling out Part A

Fill out the table below by entering the foreign product and Canadian product information.

You can find the foreign product information on the foreign product label.

- If you do not have a copy of the foreign product label, you can access it on the manufacturer's website.
- For products approved by the US FDA, the Approved Animal Drug Products database, also known as Green Book ([link](#) here) contains the required information.

To find the Comparable Canadian product information, go to the Drug Product Database ([link](#) here) and follow these **tips**:

Tip 1: In the **Search by other criteria** section, under **Status**, click on **Select All**. The Veterinary Drugs Directorate will look at the status for you during the review of your request.

Drug Product Database online query
From [Health Canada](#)

Due to the fact that the information originated with an organization that is not subject to the Official Languages Act, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

Search criteria
You may search by either a) drug identification number (DIN), b) Anatomical Therapeutic Chemical (ATC) code, or c) by company or one or more of the various other product characteristics listed. When typing inside fields, do not include punctuation marks such as hyphens, commas, colons, brackets and wildcard characters (%).

Search by drug identification number

Drug identification number (DIN):

Search by Anatomical Therapeutic Chemical

Anatomical Therapeutic Chemical (ATC):

Search by other criteria

Status:
Company:
Product name:

Select a status
Select all
Approved
Cancelled Post Market
Cancelled Pre Market
Dormant
Marketed

- ▲ If a problem with the safety of the Canadian product or the foreign product is identified during the review, your request may be rejected.

Tip 2: Enter the same active ingredient as the foreign product.

Search by other criteria

Status:

Company:

Product name:

Active ingredient(s):

Tip 3: Under **Class(es)**, click on **Veterinary**.

Search by other criteria

Status:

Company:

Product name:

Active ingredient(s):

Active ingredient group number:

Class(es):

Tip 4: Under **Route(s) of administration**, select the same route of administration as the foreign product, such as topical or oral.

Route(s) of administration:

Tip 5: Under **Dosage form(s)**, select the same dosage form as indicated for the drug you imported, such as bolus, and hit the **Search** button.

Dosage form(s):



Tip 6: Select a comparable Canadian product for which the **schedule** is “OTC” (non-prescription) or **Schedule G (CDSA IV)** for an implant and that has the **same strength**.

- ▲ If there is “**No match found**”, the foreign product does not have a comparable Canadian product and is **not eligible for List B**.

Search results summary

From [Health Canada](#)

[New search](#)

Search criteria

- Status: Select all
- Active ingredient(s): Here
- Class(es): Veterinary
- Route(s) of administration: Oral
- Dosage form(s): Bolus
- Schedule(s): Select all

Search results

No match found

Your search does not match with any of the products in the database.

[New search](#)

- **It is important to note that each request can include only:**
 - **1 dosage form**
 - **1 animal species**
- **You may have to fill out additional requests for the same product.**



Part A - Product Information	
Foreign product (as per the product label and the Green Book (link here) for a US FDA approved product):	Canadian product (as per the Drug Product Database Product Information (link here)); see tips above to help your search):
a) Brand Name:	a) Brand Name:
b) Company Name:	b) Company Name:
c) Active Ingredient(s):	c) Active Ingredient(s):
d) Dosage Form: Choose an item.	d) Dosage Form: Choose an item.
e) Route(s) of Administration (you may select more than 1):	e) Route(s) of Administration (you may select more than 1):
<input type="checkbox"/> Intramuscular <input type="checkbox"/> Oral <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Topical <input type="checkbox"/> Other (specify):	<input type="checkbox"/> Intramuscular <input type="checkbox"/> Oral <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Topical <input type="checkbox"/> Other (specify):
f) Strength(s) (as it appears on top of the label; you may include more than 1):	f) Strength(s) (you may include more than 1):
g) Animal Species: Choose an item.	g) Animal Species: Choose an item.
h) Authorization Number (for example: NADA or ANADA):	h) Drug Identification Number (DIN):

PART B – PRODUCT ASSESSMENT AGAINST THE ELIGIBILITY CRITERIA

This section is asking you to check information about the foreign product against certain eligibility criteria. By **signing Part D** of this document, you are confirming that the foreign product meets these criteria.

Part B. Eligibility criteria to add product to List B

1. The foreign product is a non-prescription drug for animals in Canada.

- **To find out:** check the **Canadian product** in the Drug Product Database. ([link here](#)).

[Tip: For faster results, you may search by entering the Drug Identification Number \(DIN\).](#)

Drug Product Database online query

From [Health Canada](#)

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Search criteria

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Search by drug identification number

Drug identification number (DIN):

Search by Anatomical Therapeutic Chemical

Anatomical Therapeutic Chemical (ATC):

Search by other criteria

Status:

The product meets this criterion if the information under **Schedule** is:

- ✓ **OTC** (over-the-counter) or
- ✓ **Schedule G (CDSA IV)** for an implant

Search results

Filter items Showing 1 to 10 of 28 entries | Show entries

List of returned drug products

Status	Class	PM	Schedule	#	A.I. name
Marketed	Veterinary	No	OTC	2	
Marketed	Veterinary	No	Schedule G (CDSA IV)	2	PROPRIONATE

2. The foreign product is in its final dosage form and within its commercial packaging.

The product meets this criterion if there is:

- ✓ **dosage and administration section** on the foreign product label.



- | |
|--|
| <p>3. The foreign product is not a medicated premix.
The product meets this criterion if there is:
<input checked="" type="checkbox"/> no “mixing in feed” direction on the foreign product label.</p> |
| <p>4. The foreign product does not contain a medically important antimicrobial (antibiotic).
• To find out: Check out List A (link here)
Tip: To search List A, hit “Ctrl F” and a white box will appear on the top left side. Type in the active ingredient (e.g., Penicillin). If the active ingredient is in List A, it will be highlighted in yellow.
The product meets this criterion if:
<input checked="" type="checkbox"/> you cannot find the active ingredient on List A.</p> |

PART C – REQUIRED DOCUMENTS

To submit a complete request, include all documents listed in the table below. Please note that if any document is missing, your request will be placed “on hold” until all documents are received. Once complete requests are received, they will be processed on a “first come first serve” basis.

Part C. Requested Documents
<p><input type="checkbox"/> This form completed, signed, and dated <input type="checkbox"/> Readable copy of the foreign product label</p> <p><u>If you do not work for a producers association, you are recommended to include:</u> <input type="checkbox"/> Letter of support signed and dated from your national association for the foreign product identified in Part A. This document should be included with the <u>request</u>. or <input type="checkbox"/> You are not a member of a producers association, explain why you are submitting this request:</p>



PART D – REQUESTER INFORMATION AND ATTESTATION

Part D. Canadian Requester Information and Attestation		
1. By signing this document you are acknowledging that the information and material included is accurate and complete.		
Requester's Name	Signature	Date (YYYY/MM/DD)
Address (Street No, Street Name, City, Province/Territory, Postal Code)		
Telephone Number	E-mail Address	
If you are a representative of a producers association, fill out these 2 additional boxes:		
Name of Producers Association		Job Title
For a request in hard copy , mail all documents to: Veterinary Drugs Directorate Attn: SKMD (List B Products) 14 - 11 Holland Avenue Ottawa, Ontario K1A 0K9 (Address Locator - 3000A)	For an electronic request , email all documents listed in Part C to: List B-VDD liste B-DMV@hc-sc.gc.ca	



INFORMATION FOR IMPORTING A LIST B PRODUCT:

Once the product is on List B, here are some tips to help you import a List B product:

Before the importation

- The drug must be on List B **with the same**
 - brand name
 - manufacturer name
 - dosage form (such as solution or bolus)
 - route of administration (such as topical or oral)
 - strength or concentration
 - active ingredient(s)
 - species
- the quantity imported must be a 90-day supply or less

During the importation

At the border we look for information such as the species and the number of animals you want to treat; to decide if you meet the rules on personal importation. A lack of sufficient information can result in **refusal** of your shipment entering Canada.

After the importation and before using the drug on your food-producing animals

- You have to follow:
 - the directions for use on the label of a comparable Canadian product
 - the withdrawal period as included on the Canadian comparable product label

To find the label of the comparable Canadian product, go to Part A of this form and follow the **Tips**.