Health Canada Santé Canada

Protected B When Completed

Emergency drug release (EDR) pre-positioning form
Veterinary drugs directorate (VDD)

This form is for manufacturers to request the ability to import and pre-position an unapproved drug for veterinary use in Canada for anticipated future EDR authorizations.

Complete this form and submit your request by either: Email: hc.edr-dmu.sc@canada.ca Fax: 613-946-1125

We will contact you if we require any additional information or clarity regarding your form.

We make every effort to respond to applications within 2 working days. If your request is urgent or if you have not received a response within 2 working days after submitting an inquiry or application, contact the EDR program.

Section A: Manufacturer information	
Manufacturer's name and address:	
Telephone #:	Fax #:
Email:	
Proposed date of importation:	
Total quantity to be imported:	
Format (indicate package type, size, and unit count per package):	
Lot / Batch number:	Expiration date:
Country product shipped from:	Labelling attached: O Yes O No
Country of origin labelling:	
Name and address of exporter (if product is not being shipped from the manufacturer):	
Previous authorized pre-positioning date and quantity, if any:	

Canada

Section B: Importer information	
Importer's name and address:	
Telephone #:	Fax #:
Email:	
Drug establishment licence number:	
If the drug is a controlled substance* Dealer's licence number:	
Storage facility address (if different from importer address):	
Security level of storage facility address (if relevant):	
*Controlled substance is defined as a substance that is included in Schedule I, II, III, IV or V of the *Controlled Drug and Substances Act*	

Section C: Drug information	
Drug brand name:	
Active ingredient(s):	
Route of administration:	Dosage form:
Strength:	
Indication(s):	

Section D: Shipping information
Specify current shipping arrangements, estimated shipping dates and mode of transportation.

Section E: Rationale

Specify the reasons why this product is to be pre-positioned in Canada, including justification for the quantity of product.

Section F: Attestation and signature

By signing and checking the boxes below, I attest that:

- ☐ All information above is true and correct to the best of my knowledge
- ☐ I have read and understood my roles and responsibilities outlined in the Food and Drug Regulations
- ☐ Product will only be released when individual EDR authorizations are received
- ☐ Records will be kept (including quantities and dates) with respect to the amount of product imported, released or destroyed. These records are to be made available to the EDR program upon request
- ☐ I understand that for EDR drugs that are medically important antimicrobials for veterinary use on List A **and** that were present in Canada at the time of sale, that I must report annually to the Veterinary Antimicrobial Sales Reporting (VASR) system of Health Canada on:
  - the total quantity sold or distributed
  - the approximate quantity sold or distributed for each intended animal species

  Email hc.vasr-vavr.sc@canada.ca to be added to the VASR system.

Name (First Last):	
Signature:	Date:

Veterinary Drugs Directorate (VDD)
Holland Cross Complex, Ground Floor,
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Email: hc.edr-dmu.sc@canada.ca **Website:** Emergency Drug Release