

APPLICATION FOR RENEWAL OF VETERINARY BIOLOGICS PRODUCT REGISTRATION AND IMPORT PERMIT

Please complete a separate form for each US or foreign manufacturer. See Renewal Guide.

Section 1 Manufacturer Information (To be completed by all applicants)				
Name of Manufacturer			Street Address	
City	Province/State - Country		Postal/Zip Code	Establishment No.
Section 2 Product Renewal Information (To be completed by manufacturer or the authorized representative)				
Number of Products to be Renewed		Renewal Period (check one) <input type="checkbox"/> 1 year <input type="checkbox"/> 2 years		
Product Renewal Fee* \$ _____	Total Number of Products x _____	Renewal Period (1 yr. or 2 yrs.) x _____	Total Product Renewal Fee = \$ _____	
* \$195 for US products and \$120 for other foreign products			Enter this amount on CFIA / ACIA 4720	
Section 3 Importer Information (To be completed by importer)				
Name of Importer			Street Address	
City	Province	Postal Code	Telephone	Fax Number
Type of Importer (Check all applicable)	End User: Veterinarian <input type="checkbox"/> Laboratory <input type="checkbox"/> Producer/Farmer <input type="checkbox"/> Distributor/Retailer <input type="checkbox"/>			
Ports of Entry				
<u>List of Canadian Warehouses and Distribution Centres (attach a list if necessary)</u> A new warehouse or distribution centre must be pre-approved by VBS				
Name	Street Address	City	Province	Postal Code
Section 4 Import Permit Renewal Information (To be completed by importer)				
Renewal Period (check one)		<input type="checkbox"/> 1 year <input type="checkbox"/> 2 years		
Permit Renewal Fee (\$120.00) \$ _____	Renewal Period (1 yr. or 2 yrs.) x _____	Total Permit Renewal Fee = \$ _____		
			Enter this amount on CFIA / ACIA 4720	
Section 5 Additional Information (if applicable)				
Section 6 (to be completed by all applicants)				
Name of Applicant			Title	
_____			_____	
Signature			Date (YYYY-MM-DD)	

GUIDE FOR RENEWAL OF PRODUCT REGISTRATION AND IMPORT PERMITS FOR VETERINARY BIOLOGICS MANUFACTURED IN USA AND OTHER COUNTRIES

Introduction:

This guide explains the renewal procedure for veterinary biological products and import permits. Normally, manufacturers are responsible for the renewal of the product registration and Canadian importers are responsible for the renewal of the import permits. However, depending on the business relationship with the manufacturer, a Canadian importer may, or may not, have authority to renew the product registration on the manufacturer's behalf.

If your firm is a Canadian subsidiary or division of the manufacturer or your firm has been granted access to product files by the manufacturer, then you may apply both for the product renewal and permit renewal.

If your firm is an independent importer, then have the manufacturer renew the product registration. Since an import permit cannot be renewed before the renewal of the product registration, it is the importer's responsibility to coordinate the submission of renewal applications with the manufacturer. Likewise, manufacturers should consult with their Canadian importers before submitting their product renewal application to the Veterinary Biologics Section.

Two-year renewal option:

The product registration and import permit may be renewed for one year or two years. In order to be eligible for the two-year renewal option, all identified products must be renewed for two years. For example, Manufacturer A has identified ten licensed products for renewal. In order to be eligible for two-year renewal option, Manufacturer A must renew all ten products for two years. We cannot renew some products for two years and others for one year.

Once the products are renewed for two years, then Canadian importers may also request the renewal of their import permit for a period of two years.

Renewal fee:

Product renewal fee: The product renewal fee is \$195.00 per product per year for the US products and \$120.00 per product per year for other foreign products (see Items 1.3 and 2.3 in *Summary of Fees and Services Related to Veterinary Biologics* CFIA / ACIA 5189). There is no tax on product renewal fees.

Permit renewal fee: The import permit renewal fee is \$120.00 per permit per year (see Items 1.4 and 2.4 in *Summary of Fees and Services Related to Veterinary Biologics* CFIA / ACIA 5189). There is no tax on permit renewal fees.

The renewal fee for two years will be twice the annual fee.

How to apply for renewal of product registration and import permits?

Step 1. Identify the products to be renewed on the current import permit

This package includes a copy of the current annual import permit. The manufacturer and Canadian importer should consult and decide on the products they would like to renew for the upcoming year(s). For each product listed on the current permit, please place a check mark (✓) beside those products which you wish to renew, and a cross (×) beside those products which you would like to delete from the import permit (The products indicated by an × will be designated 'inactive', and will be deleted from the import permit. The inactive product will be eligible for inclusion on the import permits within three years from the date of inactivation upon updating the product file and payment of the appropriate product renewal fee).

We also recommend that you verify the accuracy of the information contained on the current permits and note any corrections, (e.g., any errors in name, address, etc.) as these minor amendments may be incorporated into the renewed permit at this time without extra charges. Any request for change in product code, assign name, and trade name must be submitted with the supporting information.

Count the number of products identified by a ✓ and enter the total number in SECTION 2 of the RENEWAL APPLICATION and attach the import permit with your application.

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Step 2. Complete the Renewal Application (CFIA / ACIA 5213) (BLUE)

You are no longer required to submit a cover letter with your application. Please complete the applicable SECTIONS of the RENEWAL APPLICATION as explained below.

If you are applying for **both the product renewal and permit renewal**, then complete all SECTIONS of the RENEWAL APPLICATION. Calculate the total product renewal fee in SECTION 2 and permit renewal fee in SECTION 4 and enter these amounts in Application for Services (CFIA / ACIA 4720).

If you are applying for **product renewal only**, then complete SECTIONS 1, 2, and 6 of the RENEWAL APPLICATION. Calculate the total product renewal fee in SECTION 2 and enter this amount in Application for Services (CFIA / ACIA 4720).

If you are applying for **permit renewal only**, then complete SECTIONS 1, 3, 4, and 6 of the RENEWAL APPLICATION. Please make sure the products you have identified are renewed by the manufacturer. Calculate the total permit renewal fee in SECTION 4 and enter this amount in Application for Services (CFIA Form 4720).

A new warehouse or distribution centre must be pre-approved by VBS.

Step 3. Complete the Application for Services (CFIA / ACIA 4720):

Complete the Application for Services (CFIA / ACIA 4720) and attach with your application.

Step 4. Payment:

Attach a cheque or money order payable to the Receiver General for Canada or authorize a credit card (VISA or MasterCard) payment on the Application for Services (CFIA / ACIA 4720).

Step 5. Mail the application:

Please make sure that your application includes the following required documents. Incomplete applications will delay the issuance of an import permit.

- Completed and signed RENEWAL APPLICATION
- Completed and signed *Application for Services* (CFIA / ACIA 4720)
- A copy of the most current import permit identifying the products to be renewed
- Payment (cheque, money order or credit card authorization)

Please send the completed application to:

Dr. G.A. Gifford, National Manager
Veterinary Biologics Section
Canadian Food Inspection Agency
59 Camelot Drive
Ottawa, Ontario, Canada K1A 0Y9

Questions?

If you have any questions or require any help in completing your renewal application, please contact us at (613) 225-2342 ext. 4656. Our forms and guidelines are available on the internet at:

<http://www.inspection.gc.ca/english/anima/vetbio/vbpbve.shtml>