



APPLICATION FOR RENEWAL OF VETERINARY BIOLOGICS ESTABLISHMENT LICENCE AND PRODUCT LICENCE

To be completed by Canadian manufacturers. See Renewal Guide.

Section 1 Manufacturer Information (To be completed by all applicants)

Name of Manufacturer		Street Address		
City	Province	Postal Code	Establishment No.	

List addresses of all facilities where manufacturing, testing, packaging, labelling, storage or distribution activities are performed. These facilities will be listed on the Establishment Licence. A new facility must be pre-approved by VBS.

Name	Street Address	City	Province	Postal Code

Section 2 Renewal Information

Number of Products to be Renewed	Renewal Period (check one)	
	<input type="checkbox"/> 1 year	<input type="checkbox"/> 2 years

ESTABLISHMENT LICENCE Renewal Fee (\$60)	x	Renewal Period (1 yr. or 2 yrs.)	=	Total ESTABLISHMENT LICENCE Renewal Fee
\$ _____		_____		\$ _____
Enter this amount on CFIA / ACIA 4720				

PRODUCT LICENCE Renewal Fee (\$120)	x	Renewal Period (1 yr. or 2 yrs.)	=	Total PRODUCT LICENCE Renewal Fee
\$ _____		_____		\$ _____
Enter this amount on CFIA / ACIA 4720				

PRODUCT Renewal Fee (\$120)	x	Total Number of Products	x	Renewal Period (1 yr. or 2 yrs.)	=	Total PRODUCT Renewal Fee
\$ _____		_____		_____		\$ _____
Enter this amount on CFIA / ACIA 4720						

Section 3 Additional Information (if applicable)

Section 4 Signature

Name of Applicant	Title
_____ Signature	_____ Date (YYYY-MM-DD)



GUIDE FOR RENEWAL OF ESTABLISHMENT LICENCE AND PRODUCT LICENCE FOR VETERINARY BIOLOGICS MANUFACTURED IN CANADA

This guide explains the renewal procedure for *Veterinary Biologics Establishment Licence* and *Veterinary Biologics Product Licence*.

The establishment and product licences may be renewed for **one** year or **two** years. In order to be eligible for the two-year renewal option, **all** 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.

How to apply for renewal of establishment licence and product licence?

Step 1. Identify the products to be renewed on the current product licence

This package includes a copy of the current *Veterinary Biologics Establishment Licence* and *Veterinary Biologics Product Licence*. The manufacturer should decide on the products they would like to renew for the upcoming year(s). For each product listed on the current licence, 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 licence (The products indicated by an ✗ will be designated 'inactive', and will be deleted from the product licence. The inactive product will be eligible for inclusion on the product licence within three years from the date of inactivation upon updating the product file and payment of the appropriate product renewal fee).

Count the number of products identified by a ✓ and enter the total number in SECTION 2 of the RENEWAL APPLICATION. Attach the *Veterinary Biologics Establishment Licence* and *Veterinary Biologics Product Licence* with your application.

We also recommend that you verify the accuracy of the information contained on the current licences and note any corrections, (i.e., any errors in name, address, etc.) as these minor amendments may be incorporated into the renewed licence at this time without extra charges.

Step 2. Complete the Renewal Application (CFIA / ACIA 5214) (YELLOW)

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

SECTION 1. Please fill in the name and address of the manufacturer, and list all facilities where manufacturing, testing, packaging, labelling, storage or distribution activities are performed. These facilities will be listed on the *Veterinary Biologics Establishment Licence*. **Please note that a new facility must be pre-approved by VBS.**

SECTION 2. Please select the renewal period (i.e., one year or two years) and fill in the number of products you wish to renew for the upcoming year(s). Calculate the total fee for ESTABLISHMENT LICENCE, PRODUCT LICENCE, and PRODUCT renewal, and enter these amounts in the *Application for Services* (CFIA / ACIA 4720).

Renewal fee:

The **ESTABLISHMENT LICENCE renewal fee** is \$60.00 per year (see Items 6.3 in *Summary of Fees and Services Related to Veterinary Biologics* CFIA / ACIA 5189).

The **PRODUCT LICENCE renewal fee** is \$120.00 per year (see Items 7.4 in *Summary of Fees and Services Related to Veterinary Biologics* CFIA / ACIA 5189).

The **PRODUCT renewal fee** is \$120.00 per product per year (see Items 7.5 in *Summary of Fees and Services Related to Veterinary Biologics* CFIA / ACIA 5189).

There is a 7% GST on the above fees.

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



GUIDE FOR RENEWAL OF ESTABLISHMENT LICENCE AND PRODUCT LICENCE FOR VETERINARY BIOLOGICS MANUFACTURED IN CANADA CONT'D.

SECTION 3. Add any supplementary information if necessary.

SECTION 4. Sign and date the form, and print your name and title.

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 a licence.

- Completed and signed RENEWAL APPLICATION
- Completed and signed *Application for Services* (CFIA / ACIA 4720)
- A copy of the current *Veterinary Biologics Establishment Licence* and *Veterinary Biologics Product Licence* 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, Nepean, 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>