

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	d by all applicants)				
Name of Mar	nutacturer			Street Address			
City		<u> </u>	Province		Postal Code		Establishment No.
City			Province		Postal Code		Establishment No.
List addresse on the Estab	es of all facilities where man lishment Licence. A new fa	nufacturing, test cility must be p	ing, packaging, labelling, store re-approved by the Canadia	orage or distribution activi n Centre for Veterinary B	tes are perfor iologics.	med. These facil	ities will be listed
	Name		Street Address	City		Province	Postal Code
Continu 0	Den eurol laferra etien						
Section 2	Renewal Information						
The annual ESTABLISHMENT LICENCE Renewal Fee is <u>\$ 60.00</u> Enter this amount on CFIA / ACIA 4720							
	The annual PRODUCT LICENCE Renewal Fee is \$ 120.00 Enter this amount on CFIA / ACIA 4720						
	PRODUCT Renewal Fee (\$120) Total Number of Products to be renewed Total PRODUCT Renewal Fee \$ × = \$						
				Enter	this amount on	CFIA / ACIA 4720	
Section 3	Additional Information (if	applicable)					
Section 4	Signature						
Name of Applicant			Tit	le			
Applicant							
		S	Signature		Date	e (YYYY-MM-DD)	
CFIA / ACIA 52	under the provi	y be accessible or p isions of the Access	to Information Act.	renseignements peuvent être ac on ce que prescrit la <i>Loi sur l'accè</i>	cessibles ou protes à l'information.	égés	Canadä

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.

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. For each product listed on the current licence, please place a check mark (\checkmark) beside those products which you wish to renew, and a cross (\times) beside those products which you would like to delete from the licence (The products indicated by an \times 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 \checkmark 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 the Canadian Centre for Veterinary Biologics**.

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

Annual Renewal fee:

The **ESTABLISHMENT LICENCE renewal fee** is \$60.00 (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 (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** (see Items 7.5 in *Summary of Fees and Services Related to Veterinary Biologics* CFIA / ACIA 5189).

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			
	Canadian Centre for Veterinary Biologics			
	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 613-773-7408. Our forms and guidelines are available on the internet at:

http://www.inspection.gc.ca/english/anima/vetbio/fore.shtml