Health Canada Santé Canada

Protected B When Completed

Drug Establishment Licence (DEL) application form (FRM-0033)

Application information

Table 1. Drug establishment licence information (existing DEL holders only)
Drug Establishment Licence (DEL) # (if applicable)**:**

Table 2. Application type
□ **New application**
□ **Amendment** (Complete Table 3)
□ **Canadian warehouse**
□ **Alternate sample retention site application**
□ **Request cancellation** "I confirm that I have ceased licensable activities for DEL# (*10XXXX-X/3-00XXXX-X*) _____ on (*yyyy-mm-dd*) _____, and currently do not have any active Drug Identification Numbers (DINs). I would like to request that my establishment licence be cancelled".
□ **Request re-instatement**
□ **Request re-activation**

Canada

Table 3. Summary of amendment type(s)				
Section		Action		
		Add	Remove	Modify
Part A: Company information		☐	☐	☐
Part B: Canadian building information		☐	☐	☐
Section 1	Building name Address information Contact information	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐
Section 3.0/3.1	Activity Category Drug Class Class	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐
Section 4.0/4.1	Product information	☐	☐	☐
Foreign building information				
Section 5.0/5.1	Company name Building name Address information Activity Category Class Product information	☐ ☐ ☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐ ☐ ☐
Part C: Canadian warehouse		☐	☐	☐
Part D: Alternate sample retention site		☐	☐	☐

Table 4. Fee information and attachments

Small business mitigation

Option 1 (both boxes **must** be selected):

□ We certify that we meet the definition of a small business at the time of this filing and have applied for small business status for our company with Health Canada and have received confirmation prior to submitting this submission/application.

□ We understand that failure to hold a valid small business status with Health Canada at the time of submitting this submission/application will result in the full fee being charged.

Option 2:

□ I am **not** applying for the small business mitigation.

Important: If left blank, or if option 2 is selected, the full fee will be charged and you will **not** be considered for the small business mitigation.

Fee exemption

□ I certify that I meet the definition of a Publicly Funded Health Care Institution.

□ I certify that I am a branch or agency of the Government of Canada or of a province or territory.

See section 3 of the *Fees in Respect of Drugs and Medical Devices Order* for more details.

DEL calculation chart

□ I have attached the completed DEL calculation chart.

Table 5. Other attachments

□ Cover letter for this application

□ GMP evidence to support the addition/renewal of foreign buildings

Complete PART B > Section 5 for each foreign building

□ Table A form

Part A: Company information

Company name:		DEL # (if applicable):
Is this establishment a DIN owner? □ Yes □ No	Drug class: □ Human □ Human and veterinary □ Veterinary only	

Company address

Building name or number (if applicable):		
Street:		Suite and/or P.O. box:
City:	Province:	Postal code:
Contact person and title:		Language: □ English □ French
Telephone:	Fax:	Email:

Mailing address □ Same as establishment address

Company name (if different from establishment name):		
Street:		Suite and/or P.O. box:
City:	Province:	Postal code:
Mailing contact and title:		Language: □ English □ French
Telephone:	Fax:	Email:

Billing address □ Same as establishment address □ Same as mailing address

Company name (if different from establishment name):		
Street:		Suite and/or P.O. box:
City:	Province:	Postal code:
Billing contact and title:		Language: □ English □ French
Telephone:	Fax:	Email:

Emergency contact information (24/7 or outside business hours)

Contact person and title:		Language: □ English □ French
Telephone:	Fax:	Email:

Signature of signing authority

Name of authorized signing official:	Title:
Signature:	Date (yyyy-mm-dd):

Part B: Canadian building information

Section 1.0: Address information

□ same as establishment address □ same as mailing address □ same as billing address

Building name or number (if applicable):	Dwelling-house: □ Yes □ No	DEL # (if applicable):
Street:		Suite or P.O. box:
City:	Province:	Postal code:
Contact Person:		Language: □ English □ French
Title:		Email:
Phone		Fax:

Section 2: Drug Good Manufacturing Practices (GMP) inspection information

Has this building undergone a drug GMP inspection by a Health Canada inspector: □ Yes □ No

Date of last drug GMP inspection (yyyy-mm-dd): _____

Section 3.0: Domestic finished dosage form class information		
Activity	Category	Class of finished dosage forms
1 = Fabricate 2 = Package/ Label 3 = Test 4 = Import 5 = Distribute 6 = Wholesale	1 = Pharmaceutical 2 = Vaccine 3 = Biological 4 = Radiopharmaceutical 5 =(for Wholesalers only) = [1]Prescription Drug List (PDL), Schedule G, Narcotics, and/or [2]Drug containing Cannabis	Please use the dosage form associated with the drug's market authorisation issued by Health Canada available in the Drug Product Database online query at https://health-products.canada.ca/dpd-bdpp/index-eng.jsp
Enter only **one** category per line.		Enter all that apply. (S) is used to indicate sterile dosage
e.g. 1, 2, 3	1	Solution-S, powder-S, tablet, capsule

[1]Came into force December 19, 2013 (Repeal of Schedule F)

[2] Came into force October 17th, 2018

Section 3.1: Domestic active pharmaceutical ingredient information

Activity	Category	Drug Class		Class of final API forms
1 = Fabricate a. Chemical synthesis b. Extraction c. Cell culture/fermentation d. Isolation/recovery from natural sources e. Other (specify) 2 = Package 3 = Label 4 = Test a. Chemical b. Microbial c. Sterility d. Other (specify) 5 = Import	1 = API 2 = List A API for Veterinary use[1]	Human	Veterinary	1 = Solid 2 = Liquid 3 = Gas
Enter only **one** activity per line.				Enter all that apply.[2]
e.g. 4	e.g. 1, 2	e.g. Yes	e.g. No	e.g. 1, 2

[1]Active pharmaceutical ingredients set out in List A that are for veterinary use

[2]The sterilization of API should be entered in section 3 under the activity fabricate and the drug category Pharmaceutical, dosage form API (solid, liquid or gas).

Section 4.0: Domestic Finished Dosage Form (FDF) class product information

Product name	Drug class		Schedule / PDL[3]	DIN[4]	Activity[5]				
	H[1]	V[2]			F	P/L	T[6]	D[6]	W[6]

[1]Drug for human use
[2]Drug for veterinary use
[3]Drug category listed in Table 2 of section C.01A.008 of the Food and Drug Regulations
[4]Drug Identification Number
[5]F=Fabricate, P/L=Package/Label, T=Test, D=Distribute, W=Wholesale
[6]For the activity of **test, distribute and wholesale,** it is only required to provide drug information for drugs that are narcotics as defined in the Narcotic Control Regulations or controlled drugs as defined in subsection G.01.001(1) in the Food and Drug Regulations

Section 4.1: Domestic Active Pharmaceutical Ingredients (API) information (complete only if applying to fabricate and package/label)			
API name	Associated Drug Identification Number (DIN)	Activity	
		F	P/L

Section 5.0: Finished Dosage Form (FDF) foreign building information

Foreign company name and building address information

Foreign company name:		
Foreign building name:		
Street:		City:
Province/State:	Country:	
Postal code/ZIP code:	Building in an MRA country? □ Yes □ No	Are activities covered by an MRA? □ Yes □ No
Reason for submission: □ Renew(NERBY) □ Add □ Remove □ Amend		

Canadian building information (complete only if submitting Section 5 separately)

Canadian company name:		
Drug establishment licence number (10XXXX-X/3-00XXXX-X):		
Contact person and title:		
Telephone:	Fax:	Email:

Name of authorized signing official:	**Title:**
Signature:	**Date (yyyy-mm-dd):**

Activity, Category and Dosage Form Class Information		
Activity	**Category**	**Class of finished dosage form**
1 = Fabricate 2 = Package 3 = Label 4 = Test a. Biological b. Chemical c. In process d. Microbiological -Sterility e. Microbiological f. Physicochemical g. Stability h. Other (specify)	1 = Pharmaceutical 2 = Vaccine 3 = Biological 4 = Radiopharmaceutical 5 = (for Wholesalers only) = [1]Prescription Drug List (PDL), Schedule G, Narcotics, and/or [2]Drug containing Cannabis	Please use the finished dosage form associated with the drug's market authorisation issued by Health Canada available in the Drug Product Database online query at https://health-products.canada.ca/dpd-bdpp/index-eng.jsp.
Enter only **one** category per line.		Enter all that apply. (S) is used to indicate sterile dosage form.
e.g. 1, 3a,3b,3h	1	Solution-S, powder-S, tablet, capsule

[1]Came into force December 19, 2013 (Repeal of Schedule F)

[2] Came into force October 17th, 2018

Finished Dosage Form (FDF) Product Information (Complete only if applying for: fabricate, package/label and/or test)							
Product name	Drug class		Schedule / PDL[1]	DIN[2]	Activity		
	Human	Vet.			F[3]	P/L[3]	T[3]

[1] Drug category listed in Table 2 of section C.01A.008 of the Food and Drug Regulations
[2]Drug Identification Number
[3]F=Fabricate, P/L=Package/Label, T=Test

Required GMP evidence documents	
The final and most recent (within the last 3 years) inspection report signed issued by:	
□ Regulatory authority for a site outside its jurisdiction.	Specify authority:
□ Qualified authority for a site within its jurisdiction.	Specify authority:
□ Qualified authority for a site outside its jurisdiction.	Specify authority:
□ the corrective actions taken, signed by a responsible official of the foreign building (if applicable)	
□ a copy of the Site Master File, or a similar document such as a quality manual	
□ a Letter of Authorization (LoA) to reference a GMP evidence package from a previously submitted application	

Section 5.1: Active pharmaceutical ingredients foreign building information

Canadian building information (complete only if submitting Section 5.1 separately)

Canadian company name:		
Drug establishment licence number (10XXXX-X/3-00XXXX-X):		
Contact person and title:		
Phone:	Fax:	Email:

Attestation and undertaking

I _____ *<name>* attest to the following statements:

1. I have signing authority for _____ *<DEL applicant/company name>* and am the contact person with respect to this application and any subsequent related matters that may arise.
2. All the information about the foreign buildings presented in this application is up to date, accurate and complete.
3. The records regarding the quality of the active pharmaceutical ingredient in support of Table A are maintained on my premises at _____ _____*<address>.*

I understand that Health Canada may at any time request and/or inspect the records relevant to determining the foreign building's compliance with the applicable Good Manufacturing Practices (GMP) requirements, notwithstanding the fact that I am not required to provide them to Health Canada at this time as part of this application. I undertake to provide any requested records in one of the two official languages of Canada (English or French) within 48 hours of receiving the request from Health Canada in writing. In the event that a situation arises where the health and safety of Canadians is potentially at risk, I undertake to make every reasonable effort to provide them to Health Canada on an expedited basis.

I further undertake to notify Health Canada if an event occurs at any foreign building that could affect the quality, safety or efficacy of an active pharmaceutical ingredient.

Name of senior official:	Title of senior official:
Signature of senior official:	Date (yyyy-mm-dd):
Name of quality assurance official:	Title of quality assurance official:
Signature of quality assurance official:	Date (yyyy-mm-dd):

Foreign buildings conducting API-related licensable activities

A Table A must be submitted with your FRM-0033.

Note: (1) If Table A is not completed, the application will be treated as incomplete. Submit Table A along with FRM-0033 electronically.

(2) Applications that do not include the most recent version of Table A (available from DELU at hc.del.questions-leppp.sc@canada.ca) will be treated as incomplete.

SECTION 5.2 Active pharmaceutical ingredients – non-compliant foreign building information

Foreign building name and address information

Foreign company name:	
Street:	City:
Province/State:	Country:
Postal code/ZIP code:	

Activity, category and dosage form class information

Activity	Category	Class of Final API Form
1 = Fabricate 2 = Package/Label 3= Test	1 = Active pharmaceutical ingredient 2 = List A API for veterinary use*	1 = Solid 2 = Liquid 3 = Gas
Enter only **one** category per line.		Enter all that apply.
e.g. 1, 2	1	1, 2

* Active pharmaceutical ingredients set out in List A that are for veterinary use

Part C: Canadian Warehouse Information		
Warehouse company name:		
Building name (if applicable):		
Date of last drug GMP inspection (yyyy-mm-dd):		
This warehouse is used for storage of products from DEL # (10XXXX-X/3-00XXXX-X):		
Street Address:		Suite and/or P.O. box:
City:	Province:	Postal code:
Contact person and title:		Language: □ English □ French
Phone:	Fax:	Email:
Warehouse company name:		
Building name (if applicable):		
Date of last drug GMP inspection (yyyy-mm-dd):		
This warehouse is used for storage of products from DEL # (10XXXX-X/3-00XXXX-X):		
Street Address:		Suite and/or P.O. box:
City:	Province:	Postal code:
Contact person and title:		Language: □ English □ French
Phone:	Fax:	Email:
Warehouse company name:		
Building name (if applicable):		
Date of last drug GMP inspection (yyyy-mm-dd):		
This warehouse is used for storage of products from DEL # (10XXXX-X/3-00XXXX-X):		
Street Address:		Suite and/or P.O. box:
City:	Province:	Postal code:
Contact person and title:		Language: □ English □ French
Phone:	Fax:	Email:

Part D: Alternate sample retention site application		
Building where samples are to be retained (Company name & address)	Product name	Drug Identification Number (DIN)

Privacy notice

Privacy notice

The personal information you provide to Health Canada is governed in accordance with the *Privacy Act*. We only collect the information we need to administer the Food and Drugs Regulations authorized under the *Food and Drugs Act*.

In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the *Privacy Act*.

For more information: The personal information banks for these collections are described in HC PPU 407 and HC PPU 408 available online at infosource.gc.ca. In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact the Health Canada's Privacy Management Division at 613-948-1219 or hc.privacy-vie.privee.sc@canada.ca.

You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

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