Health Canada Santé Canada

**Protected B** When Completed

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

**Application information**

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

| **Table 2. Application type (select the one type that applies)** |
|---|
| ○ New application |
| ○ Amendment (Complete Table 3) |
| ○ Canadian warehouse |
| ○ Alternate sample retention site application |
| ○ Request cancellation<br>"I confirm that I have ceased licensable activities for DEL# (10XXXX-X/3-00XXXX-X)_____on (yyyy-mm-dd) _____. 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) (select all that apply) | | | | |
|---|---|---|---|---|
| **Section** | **Action** | | | |
| **Part A: Company information:** | | ○ Add | ○ Remove | ○ Modify |
| **Part B: Canadian building information:** | | ○ Add | ○ Remove | ○ Modify |
| **Section 1** | Building name: | ○ Add | ○ Remove | ○ Modify |
| | Address information: | ○ Add | ○ Remove | ○ Modify |
| | Contact information: | ○ Add | ○ Remove | ○ Modify |
| **Section 3.0/3.1** | Activity: | ○ Add | ○ Remove | ○ Modify |
| | Category: | ○ Add | ○ Remove | ○ Modify |
| | Drug Class: | ○ Add | ○ Remove | ○ Modify |
| | Class: | ○ Add | ○ Remove | ○ Modify |
| **Section 4.0/4.1** | Product information: | ○ Add | ○ Remove | ○ Modify |
| **Foreign building information** | | | | |
| **Section 5.0/5.1** | Company name: | ○ Add | ○ Remove | ○ Modify |
| | Building name: | ○ Add | ○ Remove | ○ Modify |
| | Address information: | ○ Add | ○ Remove | ○ Modify |
| | Activity: | ○ Add | ○ Remove | ○ Modify |
| | Category: | ○ Add | ○ Remove | ○ Modify |
| | Class: | ○ Add | ○ Remove | ○ Modify |
| | Product information: | ○ Add | ○ Remove | ○ Modify |
| **Part C: Canadian warehouse:** | | ○ Add | ○ Remove | ○ Modify |
| **Part D: Alternate sample retention site:** | | ○ Add | ○ Remove | ○ Modify |

| Table 4. Fee information and attachments (select all that apply) |
|---|
| **Small business mitigation**<br>**Option 1 (both boxes must be selected):**<br>☐ 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.<br>☐ 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.<br>**Option 2:**<br>☐ I am **not** applying for the small business mitigation.<br>**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**<br>☐ I certify that I meet the definition of a Publicly Funded Health Care Institution.<br>☐ I certify that I am a branch or agency of the Government of Canada or of a province or territory.<br>See section 3 of the Fees in Respect of Drugs and Medical Devices Order at https://laws-lois.justice.gc.ca/eng/regulations/SOR-2019-124/FullText.html for more details. |
| **DEL calculation chart**<br>☐ I have attached the completed DEL calculation chart. |
| **Table 5. Other attachments (select all that apply)** |
| ☐ Cover letter for this application |
| ☐ Good Manufacturing Practices (GMP) evidence to support the addition/renewal of foreign buildings<br>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?<br>○ Yes ○ No | Drug class:<br>○ 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 (At all times or outside business hours)** | | | |
|---|---|---|---|
| Contact person and title: | | | Language: ◯ English ◯ French |
| Telephone: | Fax: | Email: | |
| **Signature of signing authority** | | | |
| Name of authorized signing official: | | | Title: |
| Telephone: | Fax: | Email: | |
| Signature: | | Date (yyyy-mm-dd): | |

| **Part B: Canadian building information** | | |
|---|---|---|
| **Section 1: 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 # and letter (if applicable): |
| Street: | | Suite or P.O. box: |
| City: | Province: | Postal code: |
| Contact Person: | | Language: ◯ English ◯ French |
| Title: | Email: | |
| Telephone: | Fax: | |
| **Section 2: Drug 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 (FDF) class information | | |
|---|---|---|
| Enter only **one** category per line. Enter all that apply. (S) is used to indicate sterile dosage. If you are requesting the removal of an FDF from your DEL, please indicate (remove) beside the applicable FDF. e.g. Activity: 1, 2 Category: 1 Class of FDF: Solution-S, powder-S, tablet, capsule, API-S, gas (remove) | | |
| **Activity** | **Category** | **Class of FDF** |
| 1 = Fabricate<br>2 = Package/Label<br>3 = Test<br>4 = Import<br>5 = Distribute<br>6 = Wholesale | 1 = Pharmaceutical<br>2 = Vaccine<br>3 = Biological<br>4 = Radiopharmaceutical<br>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. If the dosage form is an active pharmaceutical ingredient (API), bulk process intermediate (BPI) or packaging material, please indicate API, BPI or packaging material below. |
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[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 (API) information**

Enter only **one** activity per line.
e.g. Activity: 4 Category: 1 Drug class: Human = Yes / Veterinary = No Class of final API forms = 1, 2[1]

| Activity | Category | Drug class | | Class of final API forms |
|---|---|---|---|---|
| 1 = Fabricate<br>**a.** Chemical synthesis<br>**b.** Extraction<br>**c.** Cell culture/fermentation<br>**d.** Isolation/recovery from natural sources<br>**e.** Other (specify)<br>2 = Package/Label<br>3 = Test<br>**a.** Chemical<br>**b.** Microbial<br>**c.** Sterility<br>**d.** Other (specify)<br>4 = Import | 1 = API[1]<br>2 = List A API for Veterinary use[2] | H[3] | V[4] | 1 = Solid<br>2 = Liquid<br>3 = Gas |
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[1] 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).

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

[3] Drug for human use

[4] Drug for veterinary use

## Section 4.0: Domestic 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] |
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[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) or each drug containing cannabis as defined in subsection 2(1) of the Cannabis Act

| Section 4.1: Domestic API information (complete only if applying to fabricate and package/label) | | | |
|---|---|---|---|
| API name | Associated DIN | Activity | |
| | | F[1] | P/L[1] |
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[1] F=Fabricate, P/L=Package/Label

| **Section 5.0: 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 a Mutual Recognition Agreement (MRA) country? ○ Yes ○ No | Are activities covered by an MRA? ○ Yes ○ No |
| Reason for submission: ○ Renew ○ 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** | | |
|---|---|---|
| Enter only one category per line. Enter all that apply. (S) is used to indicate sterile dosage. If you are requesting the removal of a dosage form from your DEL, please indicate (remove) beside the applicable dosage form.<br>e.g. Activity: 1, 2 Category: 1 Class of FDF: Solution-S, powder-S, tablet, capsule, API-S, gas (remove) | | |
| **Activity** | **Category** | **Class of FDF** |
| 1 = Fabricate<br>2 = Package/Label<br>3 = Test<br>**a.** Biological<br>**b.** Chemical<br>**c.** In process<br>**d.** Microbiological<br>**e.** Microbiological - Sterility<br>**f.** Physicochemical<br>**g.** Stability<br>**h.** Other (specify) | 1 = Pharmaceutical<br>2 = Vaccine<br>3 = Biological<br>4 = Radiopharmaceutical | Please use the FDF 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. If the dosage form is an active pharmaceutical ingredient (API), bulk process intermediate (BPI) or packaging material, please indicate API, BPI or packaging material below. |
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| **FDF product information** (Complete only if applying for: fabricate, package/label and/or test) | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Product name** | **Drug class** | | **Schedule / PDL**[3] | **DIN**[4] | **Activity** | | |
| | H[1] | V[2] | | | F[5] | P/L[5] | T[5] |
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[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

| **Required GMP evidence documents (select and complete all that apply)** | |
|---|---|
| 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: API 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 authorized signing official: | Title of authorized signing official: |
| Signature of authorized signing 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 del.questions-leppp@hc-sc.gc.ca) will be treated as incomplete.

| Section 5.2 API – 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** | | |
|---|---|---|
| Enter only **one** category per line.<br>e.g. Activity: 1,2 Category: 1 Class of Final API Form: 1,2 | | |
| **Activity** | **Category** | **Class of Final API Form** |
| 1 = Fabricate<br>2 = Package/Label<br>3 = Test | 1 = Active pharmaceutical ingredient<br>2 = List A API for veterinary use[1] | 1 = Solid<br>2 = Liquid<br>3 = Gas |
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[1] 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 | DIN |
|---|---|---|
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**Privacy notice**

The personal information you provide to Health Canada will be used by the Drug Establishment Licencing regimen, under the authority of the *Food and Drugs Act*, section 23(1)(c) and handled in accordance with the *Privacy Act*.

**Why are we collecting your personal information?** The personal information is used to support Health Canada's compliance and enforcement activities, including inspections and investigations, related to human or veterinary drugs.

**Will we use or share your personal information for any other reason?** In limited and specific situations, your personal information may be shared internally or with other regulators through international agreements, without your consent in accordance with subsection 8(2) of the *Privacy Act*.

**What are your rights**? You have the right to access and request a correction and/or notation to your personal information. You also have a right to complain to the Privacy Commissioner of Canada if you feel your personal information has been handled improperly. For more information about these rights, or about how we handle your personal information, please contact the Health Canada's Privacy Management Division at 613-948-1219 or privacy-vie.privee@hc-sc.gc.ca.

**For more information:** The collection of your personal information is described in Info Source at https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/access-information-privacy/info-source-federal-government-employee-information.html. Refer to the personal information bank (PIB) for these collections are described in HC PPU 407 Compliance and Enforcement Pharmaceutical Drugs and HC PPU 408 Compliance and Enforcement – Biologics & Radiopharmaceuticals.

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