Our Mandate:
To manage and deliver a national compliance and enforcement program for blood and donor semen; cells, tissues and organs; drugs (human and veterinary); medical devices and natural health products, collaborating with and across, all regions.

Health Products and Food Branch Inspectorate

Drug Establishment Licence Application:
Forms and Instructions

FRM-0033

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Disclaimer:
This document does not constitute part of the Food and Drugs Act (Act) or its associated Regulations and in the event of any inconsistency or conflict between that Act or Regulations and this document, the Act or the Regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the Regulations and the applicable administrative policies.
## INSTRUCTIONS

### TABLE 1. DRUG ESTABLISHMENT LICENCE INFORMATION (Existing DEL Holders Only)

[Drug Establishment Licence Number (DEL)] is completed by those whom already possess a Drug Establishment Licence (DEL) number.

[Application Tracking Number] is for Health Canada use only.

### TABLE 2. APPLICATION TYPE

**Note:** Select all the appropriate application types. If the application is directed towards Active Pharmaceutical Ingredients and/or Finished Dosage Forms please select one/both options, respectively.

[New Application] is completed by an applicant who does not hold a DEL and/or is applying for a new DEL.

[Amendment] is completed by any DEL holder desiring to make an amendment(s) to an existing DEL.

**Note:** Table 3 must be completed if the application includes amendments.

- **Recognized amendments**
  - Addition/removal/change of contact information,
  - Addition/removal/change of activities, categories and dosage forms of drugs,
  - Addition/removal/change of sterile fabrication of a dosage form,
  - Addition/removal/change of establishment name and/or address of the building,
  - Addition/removal/change of Alternate Sample Retention Site.

[Canadian Warehouse] is completed by any applicant desiring a Canadian Warehouse (Part C)

[Alternate Sample Retention Site Application] is completed by any applicant desiring an Alternate Sample Retention Site (Part D).

[Request Cancelation] is completed by any DEL holder desiring to cease all licensable activities. Please fill in the Drug Establishment Licence number and the date you wish to cease licensable activity.

[Request Re-instatement] is completed by any DEL holder who has had their DEL suspended / Cancelled by the Minister and desires to continue with licensable activities.

[Request Re-activation] is completed by any applicant who has withdrawn their DEL willingly.

### TABLE 3. SUMMARY OF AMENDMENT TYPE(S)

**Note:** Select all amendment types and actions (add, remove or modify) that apply for this application. Selected actions imply that there are changes to be made to the selected section.

[Establishment Information] is the location of the Head Office (Part A).

[Canadian Building Information] refers to the physical location of the building(s) in Canada where licensable activities occur (Part B).
Section 1

[Building Name] is a name which a company uses to identify a building.

[Address Information] is the physical location of the building.

[Contact Information] is the responsible individual at the Canadian building.

Section 3.0 and 3.1

[Activity] refers to licensable activities outlined in Part B, Section 3.0 and 3.1.

[Category] refers to the category of drugs outlined in Part B, Section 3.0 only.

[Class] refers to the class of Finished Dosage Form (FDF) and class of Final Active Pharmaceutical Ingredient (API) Form outlined in Part B, Section 3.0 and 3.1.

Section 4.0 and 4.1

[Product information] refers to drugs (FDF and/or API) that the applicant fabricates, packages/labels and/or distributes (Part B, Section 4.0 and 4.1).

Foreign Building Information refers to the physical location of the building(s) outside of Canada where licensable activities occur (Part B, Section 5.0 and 5.1).

Section 5.0 and 5.1

[Building Name] is a name which a company uses to identify a building.

[Address Information] is the physical location of the building.

[Activity] refers to licensable activities outlined in Part B, Section 5.0 and Table A in Section 5.1.

[Category] refers to the category of drugs outlined in Part B, Section 5.0 only.

[Class] refers to the class of FDF and class of API outlined in Part B, Section 5.0 and Table A in Section 5.1.

[Product information] refers to drugs (API and/or FDF) that the applicant fabricates and packages/labels and testing outlined in Part B, Section 5.0 and Table A in Section 5.1.

[Canadian Warehouse] refers to any Canadian location used by an establishment to store drugs (API and/or FDF).

[Alternate Sample Retention Site] refers to any foreign location used by an establishment to store drugs (API and/or FDF).

TABLE 4. FEE INFORMATION AND ATTACHEMENTS (Finished Dosage Form Only)

Note: Only applicants conducting licensable activities with regards to Finished Dosage Form products must complete this Table.
[Fee Deferral] refers to a process developed to assist in supporting small and medium-sized businesses in the deferral of the regulatory fee in support of an application until the completion of their first calendar year. Please refer to GUI-0002 Guidance on Drug Establishment Licences and Drug Establishment Licensing Fees (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/directives/gui-0002-eng.php) for Fee Deferral qualifications.

[Request Fee Remission] refers to a process developed to assist in supporting small and medium-sized businesses in the reduction of the regulatory fee in support of an application. Please refer to Guide-0002 for Fee Deferral qualifications.

[DEL Calculation Chart] is used as an aid in the calculation of DEL fees. Always provide a copy of the Calculation Chart with the application, together with any applicable fees.

TABLE 5. OTHER ATTACHMENTS

[Cover Letter for this application] is a letter submitted on company letter head containing supplemental information not captured by this form.

[GMP Evidence to support the addition/renewal of foreign buildings] is submitted to support the addition/renewal of every foreign building. Required GMP evidence is outlined in Part B, Section 5.0.

[Table A] is submitted along with Section 5.1. Table A is used to list all Foreign Buildings conducting licensable activities related to API.

PART A: ESTABLISHMENT INFORMATION

Note: This Part is to be completed by all applicants.

[Establishment Name] is the legal name of the company.

[Drug Establishment Licence Number] is completed by the establishment who already possess a Drug Establishment Licence number.

[Is this Establishment a DIN owner] please select if the establishment owns any Drug Identification Numbers (DIN).

[Drug Class] please select if the drug is intended for Human and/or Veterinary use.

[Establishment Address] is the physical location of the Head Office.

[Mailing Address] is where correspondence and the licence is to be sent.

[Billing Address] is where the invoice is to be sent.

Note: the Billing Address is to be completed by all establishments dealing with FinishedDosage Form drugs. Establishments dealing with only APIs are not required to provide a billing address.

[Contact Person] is the responsible individual at the Canadian building.

[Emergency Contact Information] is contact information that can be used to reach a company representative outside of regular office hours.

[Name of Authorized Signing Official] is the individual who is responsible for the application.
PART B: CANADIAN BUILDING INFORMATION

If a company conducts activities at more than one building, then Part B of the application must be completed for each building.

SECTION 1: ADDRESS INFORMATION

This section refers to the physical location of the building(s) in Canada where licensable activities occur.

[Building Name] is a name which a company uses to identify a building.

[Building No.] is a number which a company uses to identify a building.

[Dwelling House] indicate if the building in which licensable activities are occurring is a house.

[DEL # Letter Suffix] is the letter associated to the Drug Establishment Licence. This letter is only available for buildings already included on a DEL. For new buildings, leave this box blank.

[Address Information] is the physical location of the building. This cannot be a post office box.

[Contact Person] is the responsible individual at the Canadian building.

SECTION 2: DRUG GOOD MANUFACTURING PRACTICES (GMP) INSPECTION INFORMATION

Applicants must indicate whether or not the building has been drug GMP inspected by a Regions and Programs Bureau (RAPB) inspector. If the response is yes, indicate the date of the last inspection. Other types of inspections conducted by Health Canada personnel (for example, on-site evaluations by Biologics and Genetics Therapies Directorate for New Drug Submissions) are not considered equivalent to a drug GMP inspection. For more details, refer to POL-0011 GMP Inspection Policy for Canadian Drug Establishments (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol_0011_insp_drug_ltr-doc-eng.php)

SECTION 3.0: DOMESTIC FINISHED DOSAGE FORM (FDF) INFORMATION

Note: Only applicants conducting licensable activities with regards to Finished Dosage Form products must complete this section.

This section refers to information regarding the activities, the categories, and the class of finished dosage form at the Canadian building (Part B: Section 1). For API related activities and the class of Final API Forms please refer to Part B: Section 3.1.

[Activity] When completing Section 3.0, indicate the number corresponding to the activity being performed at this Canadian building:

1 = Fabricate   4 = Import
2 = Package/Label   5 = Distribute
3 = Test 6 = Wholesale

**Note:** If the activity of import is selected, ensure that information on foreign buildings are provided using Sections 5.0 (FDF) and 5.1 (API).

**[Category]** When completing section 3.0, indicate the number corresponding to the category subject to licensable activities at this Canadian building:

- 1 = Pharmaceutical
- 2 = Vaccine
- 3 = Biological
- 4 = Radiopharmaceutical
- 5 = *Prescription Drug List (PDL) & Schedule G, Narcotic (for wholesalers only)

* Came into force December 19, 2013 (Repeal of Schedule F)

**Note:** Please enter only ONE category per line.

**[Class of Finished Dosage Form]** The appropriate class of finished dosage form must be completed for each entry. The most frequently identified classes of finished dosage forms have been coded 1-12. When completing Section 3.0, indicate the number corresponding to the class of finished dosage form. For a list of all the approved class of finished dosage forms, refer to the [Online Drug Product Database (DPD)](http://webprod5.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp).

Code 12 applies to "other" class of finished dosage form. Indicate in brackets next to the number 12 a description to code for these “other” finished dosage forms. For example, if you produce an implant and a dressing, enter 12(Implant), 12(Dressing).

Ensure that an “S” is indicated for each class of finished dosage form utilizing sterile production techniques. An example is provided on the application form.

**Note:** Sterilization (S) must be listed on the application form beside the Class of Finished Dosage Form for all buildings where the fabrication, packaging/labelling, testing, importation, distribution and wholesaling is associated with sterile drug products. In addition, ensure that third party companies who perform the activity of sterilizing packaging materials used in the preparation of aseptically filled sterile products do so in accordance with Division 1A, and section C.02.029 of Division 2 of the [Food and Drug Regulations (FDR)](http://laws.justice.gc.ca/eng/regulations/C.R.C.,_c_.870/index.html).

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**SECTION 3.1: DOMESTIC ACTIVE PHARMACEUTICAL INGREDIENT (API) INFORMATION**

**Note:** Only applicants conducting licensable activities with regards to Active Pharmaceutical Ingredients (API) products must complete this section.

This section refers to information regarding the activities, and the class of API at the Canadian building (Part B: Section 1).

**[Activity]** When completing Section 3.1, indicate the number corresponding to the activity:

**Note:** Enter only ONE activity per line.

1 = Fabricate
[Manufacturing process] Select a manufacturing process only if the activity of Fabricate is selected. Indicate next to the number 1 the letter associated to the manufacturing used. For example, if you perform chemical synthesis, enter 1a. For multiple processes, simply add the corresponding letters (for example, 1ac).

Manufacturing processes

a. Chemical Synthesis
b. Extraction
c. Cell Culture/Fermentation
d. Isolation/Recovery from natural sources
e. Other (specify)

2 = Package/Label

3 = Test

[Testing process] Select a testing process only if the activity of test is selected. Indicate next to the number 3 the letter associated to the testing used. For example, if you perform chemical testing, enter 3a. For multiple processes, simply add the corresponding letters (for example, 3bc).

Testing processes

a. Chemical
b. Microbial
c. Sterility
d. Other (specify)

4 = Import

[Class of Final API Forms] The appropriate class of final API form must be completed for each entry. The most frequently identified class of final API forms have been coded 1-5. When completing Section 3.1, indicate the number corresponding to the class of final API form.

Code 5 applies to "other" class of final API forms. Indicate next to the number 5 in brackets a description to code these "other" final API forms. For example, if you produce granules, enter 5(Granules).

Please ensure that an “S” is indicated for each dosage form class utilizing sterile production techniques. An example is provided on the application form. For example, if you produce sterile granules, enter 5(S) (Granules).

Note: Sterilization (S) must be listed on the application form beside the Class of Final API form for all buildings where the fabrication, packaging/labelling, testing and importation is associated with sterile drug products. In addition, ensure that the third party companies who perform the activity of sterilizing packaging materials used in the preparation of aseptically filled sterile products do so in accordance with Division 1A, and section C.02.029 of Division 2 of the Food and Drug Regulations.
SECTION 4.0: DOMESTIC FINISHED DOSAGE FORM (FDF) PRODUCT INFORMATION

Note: Only applicants conducting licensable activities with regards to Finished Dosage Form products must complete this section.

Section 4.0 contains information only about the Finished Dosage Forms that the applicant fabricates, packages/labels and/or distributes (Part B: Section 1).

For the section related to Active Pharmaceutical Ingredients that the applicant fabricates, packages/labels at the Canadian building, refer to Part B: Section 4.1.

Section 4.0 does not apply to the establishments:

- Engaged solely in testing or wholesaling; and
- Importing finished dosage form products, as this information will be captured under Section 5.0 product information of the form.

[Product Name] is the name under which the product is sold.

[Drug Class] Select the drug class – Product for Human or Veterinary use.

[Schedule/PDL] Indicate the schedule or Prescription Drug List (PDL)* to which the drug belongs (for example schedule D for biologicals). This information can be found at Online Drug Product Database (DPD).

*Comes into force on December 19, 2013 (Repeal of Schedule F)

[Drug Identification Number (DIN)] is an eight digit number assigned to a drug product. It must be included unless not required by regulation (for example, active ingredients).

[Activity] For each product, select all activities that apply to it [fabricate (F), package/ Label (P/L), and/or distribute (D)].

SECTION 4.1: DOMESTIC ACTIVE PHARMACEUTICAL INGREDIENT (API) PRODUCT INFORMATION

Note: Only applicants conducting licensable activities with regards to API products must complete this section.

Section 4.1 contains information only about the API that the applicant fabricates and packages/labels (Part B: Section 1).

Section 4.1 does not apply to the establishments:

- Engaged solely in testing or wholesaling; and
- Importing API products, as this information will be captured in Table A of Section 5.1 under API product information.

[Product Name] is the name under which the product is sold.
[**Associated Drug Identification Number (DIN)**] is the eight digit drug identification number of the product in which the API will be used to fabricate a Finished Dosage Form Product.

[**Activity**] For each product, select all activities that apply to it [fabricate (F) and package/Label (P/L)].

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**SECTION 5.0: FINISHED DOSAGE FORM (FDF) FOREIGN BUILDING INFORMATION**

**Note:** Complete Section 5.0 only if the foreign building is conducting any licensable activities related to Finished Dosage Form products.

**Adding foreign Building:**

**New importers**

If applying for the activity of import (Section 3.0), please complete a Section 5.0 for each foreign fabricator, packager/labeller, and/or tester from which the product(s) will be imported into Canada.

**Licensed importers**

Licensed importers may amend foreign buildings by completing only Section 5.0 of the DEL Application Form, for each fabricator, packager/labeller, and/or tester. A cover letter from the importer describing the actions should accompany the Section 5.0(s).

**Foreign Building Name and Address Information**

**[Foreign Company Name]** is the legal name of the foreign company which is engaged in licensable activities; not necessarily the DIN owner.

**[Foreign Building Address]** is the physical location of the foreign company at which the licensable activity is being conducted.

**[Building in an MRA Country]** is selected if the foreign building is located in a Mutual Recognition Agreement country.

**[Are Activities Covered by MRA?]** is selected if all the licensable activities conducted at this foreign building are covered under the Mutual Recognition Agreement.

**Note:** If the answer to both questions [Building in an MRA Country], and [Are Activities Covered by MRA], is yes then the [Required GMP Documents] section do not require to be completed.

**Reason for Submission** select the reason(s) for submission that apply from the available predetermined list.

**[Renew]** select if the foreign building is currently on your DEL and would like to update the GMP expiry.

**[Add]** select if you would like to add a new foreign building that is currently not on your DEL.

**[Remove]** select if you would like to remove an existing foreign building that is currently on your DEL.

**[DIN Submission]** select if in support of any drug submission. If the addition of the foreign building is also desired, please select the add option.
**Canadian Building Information** is completed when Section 5.0 is submitted separately as part of an amendment or when the contact is unique for the foreign building.

- **[Establishment Name]** is the legal name of the Canadian company importing from this foreign building.
- **[Drug Establishment Licence Number]** is the DEL number of the importer. Only applicants who possess a Drug Establishment Licence number are required to record this information.
- **[Contact Person]**: is designated to receive feedback about the foreign building and is the person to whom foreign building correspondences will be sent.
- **[Name of Authorized Signing Official]** is the individual who is responsible for the application.

**Activity, Category and Class of Dosage Form Class Information** refers to information regarding the activities, the categories, and the class of finished dosage forms of the drug products at the indicated foreign building.

- **[Activity]** is limited to fabricate, package/label and/or test. When completing Section 5.0, indicate the number corresponding to the activity being conducted at this foreign building:
  
  1 = Fabricate  
  2 = Package/Label  
  3 = Test

  - **[Testing process]** Please select a testing process only if the activity of test is selected. Please indicate next to the number 3 the letter associated to the testing used. For example, if you perform stability testing, enter 3g. For multiple processes, simply add the corresponding letters (For example, 3bce).

  Testing processes
  
  a. Biological  
  b. Chemistry  
  c. In-process  
  d. Microbiological – Sterility  
  e. Microbiological  
  f. Physicochemical  
  g. Stability  
  h. Other (specify)

- **[Category]** When completing Section 5.0, indicate the number corresponding to the category subject to licensable activities at this foreign building:

  - **Note:** Enter only ONE Category per line

  1 = Pharmaceutical  
  2 = Vaccine  
  3 = Biological  
  4 = Radiopharmaceutical  
  5 = Prescription Drug List (PDL)* & Schedule G, Narcotic (for wholesalers only)
[Class of Finished Dosage Form] The appropriate class of finished dosage form must be completed for each entry. The most frequently identified class of finished dosage forms have been coded 1-12. When completing Section 5.0, indicate the number corresponding to the class of finished dosage form. For a list of all the approved classes of dosage forms, please refer to the Online Drug Product Database (DPD).

Code 12 applies to "other" class of finished dosage form. Indicate in brackets next to the number 12 a description to code these “other” finished dosage forms. For example, if you produce an implant and a dressing, enter 12(Implant), 12(Dressing).

Please ensure that an “S” is indicated for each class of finished dosage form utilizing sterile production techniques. An example is provided on the application form.

**Note:** Sterilization (S) must be listed on the application form beside the class of Finished Dosage Form for all buildings where the fabrication, packaging/labelling, and testing is associated with sterile drug products. In addition, ensure that third party companies who perform the activity of sterilizing packaging materials used in the preparation of aseptically filled sterile products do so in accordance with Division 1A, and section C.02.029 of Division 2 of the Food and Drug Regulations.

Finished Dosage Form (FDF) Product Information section refers to information regarding the finished dosage form drug products handled at the indicated foreign building.

[Product Name] is the name under which the product is sold.

[Drug Class] Select the drug class – Product for Human or Veterinary use.

[Schedule/PDL] Indicate the Schedule or Prescription Drug List (PDL)* to which the drug belongs (for example Schedule D for biologicals). This information can be found at Online Drug Product Database (DPD).

*came into force December 19, 2013 (Repeal of Schedule F)

[DIN] is the eight digit drug identification number assigned to a product. It must be included unless not required by regulation (for example, active ingredients).

[Activity] For each product, select all activities that apply to it [fabricate (F), package/label (P/L), and/or test (T)].

[Required GMP Documents] refers to all the Good Manufacturing Practices documentation required with any foreign building submission.

**Note:** All documents listed in this section must be provided; otherwise the application will be considered incomplete and will be screened out. The foreign building is only exempted from this section when the country and all the activities are covered under the MRA.

Required Supplemental Documents for Foreign Site Submissions

Refer to GUI-0080 Guidance on Evidence to Demonstrate Drug GMP Compliance of Foreign Sites (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui-0080-eng.php) for a list of required GMP documents. These documents are also required upon request for extension of GMP compliance expiry for existing foreign building.

**Note:** If these documents are not provided in their entirety the application will be considered incomplete and the Drug GMP Inspections Unit will screen out the request.
SECTION 5.1: ACTIVE PHARMACEUTICAL INGREDIENTS FOREIGN BUILDING INFORMATION

Note: This section applies to importers importing APIs from a foreign building. In addition, this section is also used by the importers of Finished Dosage Forms, to list their foreign API Fabricators, Packagers/Labellers, and Testers, who supply Finished Dosage Form Foreign buildings.

Adding Foreign Buildings:

New importers

If applying for the activity of import (Section 3.0 and/or 3.1), complete Table A of the DEL Application form for each foreign fabricator, packager/labeller and tester from which the API products will be imported into Canada, and complete the Attestation set out in Section 5.1.

Licensed importers

Licensed importers may amend foreign buildings by completing Table A of the DEL Application form for each foreign fabricator, packager/labeller, and/or tester they wish to list on their DEL, and complete the Attestation set out in Section 5.1. A cover letter from the importer describing the actions should accompany the Section 5.1(s).

Canadian Building Information is completed to confirm the attestation stated in Section 5.1.

[Canadian Drug Establishment name] is the legal name of the Canadian company importing products into Canada.

[Drug Establishment Licence Number] is only completed by the establishments who already possess a Drug Establishment Licence number.

[Contact Person]: is designated to receive feedback about the foreign building and is the person to whom foreign building correspondences will be sent.

Attestation and Undertaking

[Name of Senior Official] is the individual who is responsible for the application.

[Name of Quality Assurance Official] is the individual who is responsible for Quality Assurance.

TABLE A: FOREIGN BUILDINGS CONDUCTING API-RELATED LicensABLE ACTIVITIES

Complete this Table for all Active Pharmaceutical Ingredients imported into Canada from foreign API buildings and/or for all Active Pharmaceutical Ingredients intended for the fabrication, packaging/labelling, and/or testing of finished dosage forms in the foreign country, intended for import into Canada.

Import Information refers to information related to the activity of import via Active Pharmaceutical Ingredient or Finished Dosage Form.

[DEL #] (Column A) is completed by those who already possess a Drug Establishment Licence number. This number includes the letter suffix (10XXXX-X)

[Imported As] (Column B) indicates whether the Active Pharmaceutical Ingredients at this foreign location are used for import into Canada and/or intended for the foreign fabrication, packaging/labelling, and/or testing of finished dosage forms intended for import into Canada. Select a type from the available predetermined list.
**API** implies the imported product is an API. **Dosage Form** implies the API is imported via finished dosage form.

**Note:** If the [Dosage Form] option from column B is selected in Table A, then columns Q and R are not applicable at this time.

**[API Name]** (Column C) is the name under which the API is sold.

**API Foreign Building Information** refers to the name and address of the foreign API fabricator, packager/labeller, and/or tester from whom the product(s) will be imported into Canada or used by a foreign fabricator, packager/labeller, and/or tester of finished dosage forms who intends to import Finished Dosage Form products into Canada.

**[Foreign Building Name]** (Column D) is the legal name of the foreign company that is engaged in a licensable activity related to APIs; not necessarily the DIN owner.

**[Foreign Building Address]** (Columns E, F, G and H) is the physical location of the foreign building at which the licensable activity related to APIs is being conducted.

**API Foreign Building GMP Status** refers to the status of the Good Manufacturing of the building of the foreign source API fabricator, packager/labeller or tester.

**[Building complies with applicable GMP requirements set out in Part C Div. 2, FDR]** (Column I) select [Yes] if the building is compliant with *Part C, Division 2 of the FDR* or *ICH Q7*. Select [Exception] only if the API is used in a product part of the selected consumer health products pilot.

**Note:** If the API is used in a product part of the selected consumer health products pilot and the [Exception] option from column I is selected in Table A, then columns J, K, L, M, N, O, P, Q, R, U, V, W and X are not applicable at this time.

**[Date First Used as an API Source Site]** (Column J) refers to the first date the foreign API fabricator, packager/labeller and tester was used for importation into Canada and/or for the foreign fabrication, packaging/labelling, and/or testing of finished dosage forms intended for import into Canada.

**[Date of Last Inspection]** (Column K) refers to the latest GMP inspection of the API source site conducted by the regulatory authority.

**[Inspection Type]** (Column L) refers to the regulatory authority who conducted the last inspection. Select an option from the available predetermined list.

**Note:** If other type of inspection is selected, specify in the [Specify Other] field. (Column M)

**[Date of Renovations]** (Column N) is to be completed if the foreign API source building was renovated since the last GMP inspection. Please note that renovations of interest are those which were performed to ensure that drug quality is not compromised. Please use “None” if no renovations have occurred.

**[Has This Building Been Issued A Non-Compliant Rating In The Last 5 Years]** (Column O) please select “Yes” or “No” from the available list to identify if a Non-Compliant rating has been issued to the foreign API building by a regulatory authority in the last 5 years.

**[Years Conducting API-related Activities]** (Column P) refers to the duration that the foreign API source building has been conducting API related activities in accordance to *Division 2 of the FDR*. 
**API Product Information** refers to information related to the API products handled at the foreign API source building.

*Class of Final API Form* (Column Q) is the final state of the API. Select a final API form class from the available predetermined list. Multiple selections are possible.

Ensure that “Sterile” is indicated for each final API form class utilizing sterile production techniques.

**Note:** If “Other” type of Final API form is selected, specify in the *Specify Other* field (Column R).

*DIN associated with API* (Column S) is the eight digit drug identification number issued to the Finished Dosage Form product intended to be sold in Canada, in which the API will be used to fabricate the Finished Dosage Form product (if known).

**API Activity Information** refers to information regarding the activities conducted at the foreign building.

*Activity* (Column T) activities are limited to fabricate, package/label and/or test. Multiple selections are possible.

F = Fabricate

*Manufacturing process* (Column U) is the type of process used in the fabrication of the API. Select a manufacturing process from the available predetermined list. Multiple selections are possible.

**Note:** If other types of manufacturing processes are required select “Other” and specify in the *Specify Other* field (Column V).

P/L = Package/Label

T = Test

*Testing process* (Column W) is the type of testing conducted on the APIs. Select a testing process from the available predetermined list. Multiple selections are possible.

**Note:** If other types of testing processes are required select “other” and specify in the *Specify Other* field (Column X).

**PART C: CANADIAN WAREHOUSE INFORMATION**

**Note:** Complete Part C only if applying for a Canadian storage facility for FDF and/or API which is not already recorded in Part B.

*Warehouse Company Name* is the name of the Canadian building where the FDF and/or API will be stored.

*Building Name* is completed only if the name of the building differs from the name of the warehouse.

*Date of Last Drug GMP Inspection* is the date of the most recent Health Canada drug GMP inspection conducted for the listed warehouse.

**Note:** Building must be compliant with *Division 2 Good Manufacturing Practices of the FDR.*
Note: If more warehouses need to be listed than the space provided, additional Part C: Canadian Warehouse Information pages must be used.

PART D: ALTERNATE SAMPLE RETENTION SITE INFORMATION

Note: Complete Part D only if a foreign storage facility for FDF and/or API is being used as an alternate sample retention building.

[Site where samples are to be retained] refers to the foreign building name and address.

Note: Site must be outside of Canada, and must be compliant with Division 2 of the FDR.

[Product Name] The name of the product as it is associated to its Drug Identification Number (DIN).

[Drug Identification Number] an eight digit DIN must be provided for each product listed.

# DRUG ESTABLISHMENT LICENCE (DEL) APPLICATION FORM

## APPLICATION INFORMATION

### TABLE 1. DRUG ESTABLISHMENT LICENCE INFORMATION (Existing DEL Holders Only)

<table>
<thead>
<tr>
<th>Drug Establishment Licence (DEL) # (if applicable):</th>
<th>Application Tracking # (for internal use only):</th>
</tr>
</thead>
</table>

### TABLE 2. APPLICATION TYPE

- [ ] Active Pharmaceutical Ingredients (API)
- [ ] Finished Dosage Forms (FDF)

- [ ] 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) ________________ 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

### TABLE 3. SUMMARY OF AMENDMENT TYPE(S)

<table>
<thead>
<tr>
<th>SECTION</th>
<th>ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Add</td>
</tr>
<tr>
<td>PART A: Establishment Information</td>
<td>[ ]</td>
</tr>
<tr>
<td>PART B: Canadian Building Information</td>
<td>[ ]</td>
</tr>
<tr>
<td>Section 1</td>
<td>Building Name</td>
</tr>
<tr>
<td></td>
<td>Address Information</td>
</tr>
<tr>
<td></td>
<td>Contact Information</td>
</tr>
<tr>
<td>Section 3.0/3.1</td>
<td>Activity</td>
</tr>
<tr>
<td></td>
<td>Category</td>
</tr>
<tr>
<td></td>
<td>Class</td>
</tr>
<tr>
<td>Section 4.0/4.1</td>
<td>Product Information</td>
</tr>
<tr>
<td>Foreign Building Information</td>
<td>[ ]</td>
</tr>
<tr>
<td>Section 5.0/5.1</td>
<td>Building Name</td>
</tr>
<tr>
<td></td>
<td>Address Information</td>
</tr>
<tr>
<td></td>
<td>Activity</td>
</tr>
<tr>
<td></td>
<td>Category</td>
</tr>
<tr>
<td></td>
<td>Class</td>
</tr>
<tr>
<td></td>
<td>Product Information</td>
</tr>
<tr>
<td>PART C: Canadian Warehouse</td>
<td>[ ]</td>
</tr>
<tr>
<td>PART D: Alternate Sample Retention Site</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

### TABLE 4. FEE INFORMATION AND ATTACHMENTS (Finished Dosage Form Only)
- **Fee Deferral** (for new applications only)
  “I certify that I have not completed my first calendar year of conducting activities under an establishment licence”.

- **Request Fee Remission**
  - Certified Statement of Revenue included (Note: This must be included in order for Health Canada to consider a request for Fee Remission).

- **DEL Calculation Chart**

<table>
<thead>
<tr>
<th>Method of Payment:</th>
<th>Payment Amount:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payment is included with this application.</td>
<td></td>
</tr>
<tr>
<td>This application is being submitted electronically, and payment will follow by mail.</td>
<td></td>
</tr>
</tbody>
</table>

### 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**

---

**PART A: ESTABLISHMENT INFORMATION**
### Establishment Name:

<table>
<thead>
<tr>
<th>Drug Establishment Licence (DEL) # (if applicable):</th>
</tr>
</thead>
</table>

#### Is this Establishment a DIN Owner?

- [ ] Yes  
- [ ] No

#### Drug Class:

- [ ] Human  
- [ ] Human and Veterinary  
- [ ] Veterinary Only

### Establishment Address

<table>
<thead>
<tr>
<th>Building Name or No. (if applicable):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street:</td>
</tr>
<tr>
<td>City:</td>
</tr>
<tr>
<td>Contact Person and Title:</td>
</tr>
<tr>
<td>Telephone:</td>
</tr>
</tbody>
</table>

#### Mailing Address

- [ ] same as Establishment Address

<table>
<thead>
<tr>
<th>Company Name (if different from Establishment Name):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street:</td>
</tr>
<tr>
<td>City:</td>
</tr>
<tr>
<td>Contact Person and Title:</td>
</tr>
<tr>
<td>Telephone:</td>
</tr>
</tbody>
</table>

#### Billing Address

- [ ] same as Establishment Address  
- [ ] same as Mailing Address

<table>
<thead>
<tr>
<th>Company Name (if different from Establishment Name):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Street:</td>
</tr>
<tr>
<td>City:</td>
</tr>
<tr>
<td>Contact Person and Title:</td>
</tr>
<tr>
<td>Telephone:</td>
</tr>
</tbody>
</table>

### Emergency Contact Information (24/7 or outside business hours)

<table>
<thead>
<tr>
<th>Contact Person and Title:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Language: [ ] English [ ] French</td>
</tr>
<tr>
<td>Telephone:</td>
</tr>
</tbody>
</table>

### SIGNATURE OF SIGNING AUTHORITY

<table>
<thead>
<tr>
<th>Name of Authorized Signing Official</th>
<th>Signature</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Title</th>
<th>Date (yyyy-mm-dd)</th>
</tr>
</thead>
</table>

### PART B: CANADIAN BUILDING INFORMATION

Drug Establishment Licence Application: Form and Instructions (FRM-0033) / October 23, 2014  
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**SECTION 1: ADDRESS INFORMATION**

- ☐ same as Establishment Address
- ☐ same as Mailing Address
- ☐ same as Billing Address

<table>
<thead>
<tr>
<th>Building Name or No. (if applicable):</th>
<th>Dwelling-house:</th>
<th>DEL # letter suffix (10XXXX-X) (if applicable):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>☐ No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Street:</th>
<th>Suite:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>City:</th>
<th>Province:</th>
<th>Postal Code:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Contact Person and Title:</th>
<th>Language:</th>
<th>Telephone:</th>
<th>Fax:</th>
<th>Email:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐ English</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ French</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SECTION 2: DRUG GOOD MANUFACTURING PRACTICES (GMP) INSPECTION INFORMATION**

This building has undergone a Drug GMP inspection by a Health Canada Inspector: ☐ Yes ☐ No

Date of last Drug GMP inspection (yyyy-mm-dd): _____________________

**SECTION 3: DOMESTIC FINISHED DOSAGE FORM (FDF) INFORMATION**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Category</th>
<th>Class of Finished Dosage Forms</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 = Fabricate</td>
<td>1 = Pharmaceuticals</td>
<td>1 = Powder for solution</td>
</tr>
<tr>
<td>2 = Package/Label</td>
<td>2 = Vaccine</td>
<td>2 = Tablet</td>
</tr>
<tr>
<td>3 = Test</td>
<td>3 = Biological</td>
<td>3 = Capsule</td>
</tr>
<tr>
<td>4 = Import</td>
<td>4 = Radiopharmaceutical</td>
<td>4 = Solution</td>
</tr>
<tr>
<td>5 = Distribute</td>
<td>5 = (for Wholesalers only) =</td>
<td>5 = Suspension</td>
</tr>
<tr>
<td>6 = Wholesale</td>
<td>Prescription Drug List (PDL)*, Schedule G, and/or Narcotic</td>
<td>6 = Aerosol</td>
</tr>
</tbody>
</table>

Enter only ONE category per line. Enter all that apply. (S) is used to indicate sterile dosage form.

e.g. 3 1 2, 3, 5(S), 12 (cream)

*Comes into force December 19, 2013 (Repeal of Schedule F)

**SECTION 3.1: DOMESTIC ACTIVE PHARMACEUTICAL INGREDIENT (API) INFORMATION**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Class of Final API Forms</th>
</tr>
</thead>
</table>

Drug Establishment Licence Application: Form and Instructions (FRM-0033) / October 23, 2014

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### SECTION 4.0: DOMESTIC FINISHED DOSAGE FORM (FDF) PRODUCT INFORMATION
(Complete only if applying for: fabricate, package/label and/or distribute)

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Drug Class</th>
<th>Schedule/PDL*</th>
<th>Drug Identification Number (DIN)</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Human</td>
<td>Vet.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Comes into force December 19, 2013 (Repeal of Schedule F)*

### SECTION 4.1: DOMESTIC ACTIVE PHARMACEUTICAL INGREDIENTS (API) PRODUCT INFORMATION
(Complete only if applying for: fabricate and package/label)

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Associated Drug Identification Number (DIN)</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### SECTION 5.0: FINISHED DOSAGE FORM (FDF) FOREIGN BUILDING INFORMATION
FOREIGN BUILDING NAME AND ADDRESS INFORMATION
### Foreign Company Name:  
**Street:**  
**Province/State:**  
**Postal Code/Zip Code:**  
**Country:**  
**Building in an MRA country?**  
**Are activities covered by MRA?**  

### GPS Coordinates:  

**City:**  

### CANADIAN BUILDING INFORMATION (Complete only if submitting Section 5 separately)

### Canadian Drug Establishment Name:

### Drug Establishment Licence Number (10XXXX-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

<table>
<thead>
<tr>
<th>Activity</th>
<th>Category</th>
<th>Class of Dosage Form</th>
</tr>
</thead>
</table>
| 1 = Fabricate  
2 = Package/Label  
3 = Test  
  a. Biological  
  b. Chemistry  
  c. In-process  
  d. Microbiological – Sterility  
  e. Microbiological  
  f. Physicochemical  
  g. Stability  
  h. Other (specify) | 1 = Pharmaceuticals  
2 = Vaccine  
3 = Biological  
4 = Radiopharmaceutical  
5 (for Wholesalers only) = Prescription Drug List (PDL)*, Schedule G, and/or Narcotic | 1 = Powder for solution  
7 = Powder  
2 = Tablet  
3 = Capsule  
4 = Solution  
5 = Suspension  
6 = Aerosol  
8 = Suppository  
9 = Medical Gas  
10 = Veterinary Premix  
11 = Bulk Intermediates (biological only)  
12 = Other (specify) |

Enter only ONE category per line.  
Enter all that apply. (S) is used to indicate sterile dosage form.

Example: e.g. 3a,b,h  
1  
2, 3, 5(S), 12 (cream)

### FINISHED DOSAGE FORM (FDF) PRODUCT INFORMATION

(Complete only if applying for: fabricate, package/label and/or Test)

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Drug Class</th>
<th>Schedule/PDL*</th>
<th>Drug Identification Number (DIN)</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Human</td>
<td>Vet.</td>
<td></td>
<td>F</td>
</tr>
<tr>
<td></td>
<td>P/L</td>
<td>T</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Comes into force December 19, 2013 (Repeal of Schedule F)*

### REQUIRED GMP DOCUMENTS

[ ] the most recent (within the last 3 years) signed inspection report issued by:  
[ ] Regulatory Authority for a site outside of its jurisdiction or,  
**Specify Authority:**
<table>
<thead>
<tr>
<th>Qualitative Authority for a site within its jurisdiction or,</th>
<th>Specify Authority:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qualified Authority for a site outside of its jurisdiction</td>
<td>Specify Authority:</td>
</tr>
</tbody>
</table>

☐ 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 copy of the site’s procedures for handling deviations and out of specification test results

☐ a copy of the out of specification test results

☐ a copy of the site’s procedure for finished product release

☐ a copy of the quality agreement between the foreign site and the Canadian site, including a list of the specific products for supply in Canada

☐ if cross-referencing GMP package of another importer, provide letter of access, and all quality agreements

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**SECTION 5.1: ACTIVE PHARMACEUTICAL INGREDIENTS FOREIGN BUILDING INFORMATION**

**CANADIAN BUILDING INFORMATION** (Complete only if submitting Section 5.1 separately)
I _____________ <name> attest to the following statements:

1. I have signing authority for ________________________<drug establishment licence applicant/company name> and I am the contact person with respect to this application and any subsequent related matters that may arise;
2. all the information relating to 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 column I in 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.

FOREIGN BUILDINGS CONDUCTING API-RELATED LICENSABLE ACTIVITIES

Please complete Table A for all Foreign Buildings that fabricate, package/label and test active pharmaceutical ingredients.

Note: If Table A is not completed, the application will be treated as incomplete. Submit Table A along with FRM-0033 electronically.
<table>
<thead>
<tr>
<th>Warehouse Company Name:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Building Name (if applicable):</td>
<td></td>
</tr>
<tr>
<td>Date of last Drug GMP inspection (yyyy-mm-dd):</td>
<td></td>
</tr>
<tr>
<td>This warehouse is used for storage of products from DEL # (10XXXX-X):</td>
<td></td>
</tr>
<tr>
<td>Street Address:</td>
<td>Appt./Suite:</td>
</tr>
<tr>
<td>City:</td>
<td>Province:</td>
</tr>
<tr>
<td>Contact Person and Title:</td>
<td>Language:</td>
</tr>
<tr>
<td>Telephone:</td>
<td>Fax:</td>
</tr>
</tbody>
</table>

**PART D: ALTERNATE SAMPLE RETENTION SITE APPLICATION**
<table>
<thead>
<tr>
<th>Site where samples are to be retained (Establishment Name &amp; Address)</th>
<th>Product Name</th>
<th>Drug Identification Number (DIN)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</table>