



# Guidance on Drug Establishment Licences



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#### **Disclaimer**

This document does not constitute part of the *Food and Drugs Act* (the Act) or its regulations and in the event of any inconsistency or conflict between the 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.

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# About this document

## A. Purpose

This guide is for companies in the drug manufacturing industry. It will help to facilitate understanding and compliance with Part C, Division 1A of the [Food and Drug Regulations \(FDR\)](#) with regards to drug establishment licence (DEL) requirements.

## B. Scope

The scope of this document includes:

- Drug Establishment Licensing requirements outlined in Part C, Division 1A of the [\(FDR\)](#)

The scope is therefore limited to the following drugs for human and veterinary use:

- Pharmaceutical drugs (including Medical Gases)
- Active Ingredients
- Vaccines
- Biological drugs (Schedule D of the [FDA](#))
- Radiopharmaceutical drugs (Schedule C of the FDA)
- Drugs controlled under the [Controlled Drugs and Substances Act](#) and narcotics as defined in the [Narcotic Control Regulations](#)
- Drugs containing cannabis as defined in subsection 2(1) of the [Cannabis Act](#)



While this document discusses the FDR drug establishment licensing requirements that apply to drugs, including controlled drugs and narcotics, this document does not discuss the licensing requirements outlined in the *Controlled Drugs and Substances Act* and its Regulations.

This document does not cover the licensing requirements for:

- Medical devices
- Natural health products

- Whole blood for transfusion
- Tissue, cells and organs for transplantations

This document does not cover the DEL fees and payment information. Fees and payments associated with DELs are outlined in the Guidance document, [\*Fees for the Review of Human and Veterinary Drug Establishment Licence Applications\*](#).

## C. How Guidance Documents Work

Guidance documents like this one are meant to help industry and health care professionals understand how to comply with rules and regulations. They also provide guidance to Health Canada staff, so that the rules are enforced in a fair, consistent and effective way across Canada.

Guidance documents are administrative and do not have the force of law, and, because of this, they allow for flexibility in approach. This guide can be used to develop specific approaches that meet specific needs.

Health Canada endeavours to provide timely guidance. These guidelines are not the only way establishment licensing regulations can be interpreted, and are not intended to cover every possible case. In the case of a discrepancy between this guidance document and the regulations, the regulations always take precedence.

**The following icons are used in this document:**



Important: Key or cautionary information for people to know.



Information: Supplementary information like quotes and legal references.

# Application of DEL Requirements

## 1. Activities to which DEL Requirements Apply

The drug establishment licensing requirements apply to any person, with some exemptions listed in this section, who conducts any of the licensable activities listed below in Canada with respect to a drug:

- Fabricate
- Package / label
- Test
- Import
- Distribute
- Wholesale

The activities are defined as such:

### **Fabricate**

Fabricate means to prepare and preserve a drug for the purpose of sale.

### **Package / label**

Package/label means to put a drug in its immediate container or to affix the inner- or outer-label to the drug.

### **Test**

Test means to perform the tests, including examinations, required under Part C, Division 2 of the FDR.

### **Import**

Import means to import into Canada a drug for the purpose of sale.

### **Distribute**

The activity of distribute refers to distribute as a distributor referred to in section C.01A.003 of the FDR and applies to the following distributors:

- a distributor of an active ingredient
- a distributor of a drug for which the distributor holds the Drug Identification Number (DIN)



A distributor is a person, including an association or partnership, who under their own name, or under a trade, design or word mark, trade name, or other name, word or mark controlled by them, sells a drug.

### Wholesale

Wholesale means to sell, other than at retail, by a person who is not a distributor as described in section C.01A.003 of the FDR of one of the following drugs:

- a) a drug in dosage form that is listed in Schedule C or D of the FDA
- b) a drug that is a prescription drug or a controlled drug as defined in subsection G.01.001 of the FDR
- c) an active ingredient
- d) a narcotic as defined in Narcotic Control Regulations
- e) a drug containing cannabis as defined in subsection 2(1) of the Cannabis Act

## 2. Exemptions

The drug establishment licensing requirements do not apply to the following:

### Wholesaling Over-the-Counter Pharmaceutical Drugs or Non-Scheduled Drugs Including Non-Scheduled Ethical Drugs

A DEL is not required to wholesale finished dosage form drugs that are over-the-counter drugs (OTCs) or that are not listed on a Schedule of the FDA or its Regulations, and are not narcotics as defined in the *Narcotic Control Regulations*. Furthermore, a DEL is not required to wholesale unscheduled ethical drugs. However, a DEL is required to wholesale ethical drugs that are listed on a Schedule of the FDA or its Regulations (e.g. non-prescription biological or radiopharmaceutical drugs).

### Distributing or Wholesaling Active Pharmaceutical Ingredients

A DEL is not required for distributing or wholesaling active pharmaceutical ingredients (APIs), including API for veterinary use set out on [List A: List of Certain Antimicrobial Active Pharmaceutical Ingredients](#).

### Wholesaling of a Drug Premix

A DEL is not required for wholesaling a [drug premix](#).

## Conducting Activities Related to a Drug that is Used for the Purpose of a Clinical Trial Authorized by Health Canada.

Clinical trial sponsors must submit a clinical trial application (CTA) to Health Canada for authorization to sell or import a drug for the purpose of a clinical trial. Activities that comply with an authorised clinical trial do not require a DEL, except for clinical trials involving a marketed product used according to its Health Canada market authorization, sometimes referred to as a Phase IV clinical trial.

For more information on Clinical Trial Applications, please refer to the Health Canada [Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications](#).

### Storing Drugs

Drug storage is not a licensable activity and a company that only stores drugs does not need to hold a DEL. However, the storing of the drug is an integral part of regulated activities and companies that fabricate, import, package / label, test, distribute or wholesale drugs must list all Canadian buildings where they store drugs on their DEL.

### Transporting Drugs

Transporting drugs is not a licensable activity and a company that only transports drugs does not need to hold a DEL.

### Importing or Compounding a Drug not Commercially Available for Sale in Canada

With the exception of importing API for veterinary use set out on [List A: List of Certain Antimicrobial Active Pharmaceutical Ingredients](#), a DEL is not required to import or compound a drug that is not commercially available in Canada, pursuant to a prescription, if you are one of the following:

- a pharmacist
- a practitioner or
- a person who compounds a drug under the supervision of a practitioner

For more information on what activities are considered compounding versus manufacturing, please refer to Health Canada's [Policy on Manufacturing and Compounding Drug Products in Canada \(POL-0051\)](#).

As of May 17, 2018, subject to regulatory transitional provisions, a DEL is required for the import of an API for veterinary use that is for the purpose of compounding, pursuant to a prescription, if that API is set out in [List A: List of Certain Antimicrobial Active Pharmaceutical Ingredients](#), including when the API is imported by:

- a pharmacist
- a veterinary practitioner or
- a person who compounds a drug under the supervision of a veterinary practitioner

### Assembling Kits and Promotional Material

Activities such as assembling multiple already packaged drugs in a secondary package (e.g. making a kit), or adding a leaflet of promotional information, does not require a DEL except in the cases below.

The following actions require a DEL for the activity of packaging/labelling:

- Opening the drug's primary package
- Removing the drug from its primary package
- Replacing or reprinting labelling information that is required by the FDR
- Putting the drug in a package that contains information required by the FDR
- Affixing a label containing information required by the FDR to the drug's package



#### Kits

While assembling multiple drugs together to make a kit may not require a DEL, it is important to note that other requirements in Part A and Part C Division 1 of the FDR also apply.

For additional information about drug labelling requirements you can consult the Guidance Document: [Labelling of Pharmaceutical Drugs for Human Use](#) and [Guidance Document on Post-Drug Identification Number \(DIN\) Changes](#).

### Conducting Activities Related to Antimicrobial Agents

[Antimicrobial agents](#) are exempt from the DEL requirements.

### Activities Related to Biologicals for Veterinary Use

The DEL requirements apply to veterinary biologic drugs that require a DIN to be sold in Canada.

In Canada, not all veterinary biologic drugs require a DIN under the FDR. Those Veterinary biologicals that do not require a DIN are regulated by the Canadian Food Inspection Agency (CFIA), and include animal health products such as vaccines, antibody products, and in vitro diagnostic test kits that are used for the prevention, treatment, or diagnosis of infectious diseases in animals. These drugs are not subject to the DEL requirements.

For additional details, refer to the [Veterinary Biologics CFIA web page](#).

### 3. Inclusions

For further clarity, the activities below are subject to the DEL requirements.

#### Third Party Performing Testing Required by Part C, Division 2 of the FDR

Third party companies that are testing or examining drugs as required by Part C, Division 2 of the FDR, including but not limited to, raw material testing (C.02.009), packaging material testing (C.02.016), finished product testing (C.02.018) and stability testing (C.02.027, C.02.028) must hold a DEL for the activity of test.

#### Sterilization of Raw Materials and Packaging Material

Companies that perform raw material or packaging material sterilization functions are considered to be conducting a finished drug fabrication step if the raw material and/or packaging components are used in the production of sterile drugs and do not undergo a subsequent sterilization step (e.g. terminal sterilization). Companies that perform such activities in Canada require a DEL for the activity of fabricate. In the case of a third party company that only performs sterilization, the DEL must include the activity of fabricate for the drug category associated with the finished drug (e.g. pharmaceuticals) for the dosage form “raw materials” or “packaging materials” as applicable. It is the responsibility of the company providing the sterilization services to validate with its clients whether raw materials and packaging components will undergo subsequent sterilization steps. When the company cannot demonstrate that all of its client will conduct a subsequent sterilization step, the company requires a DEL.

Foreign buildings performing sterilization of raw materials or packaging material that do not undergo subsequent sterilization step, need to be listed on the foreign building annex of importers. In the case of a third party company that only performs sterilization, the DEL must authorize the activity of fabricate, for the drug category associated with the finished drug (e.g. pharmaceuticals) for the dosage form “raw materials” or “packaging materials” as applicable.

## Medical Gas Trans-Filling and Curbside Filling

Trans-filling of medical gas, whether performed onsite or curbside, is considered a packaging activity, pursuant to Section C.01A.001(1) of the FDR, which defines the term "package" as "to put a drug in its immediate container", and section C.01.001, which defines the term "immediate container" as "the receptacle that is in direct contact with a drug".

Curbside filling is authorised when performed in compliance with the FDR. The company must hold a DEL for packaging/labelling for the building where the vehicles used in curbside filling or the containers (e.g. cylinders) are replenished.



Fire departments, ambulance services, hospitals or health care facilities packaging medical gases for their own use or administration to a patient do not require a DEL.

## Export

For the purpose of the FDR, exporting a drug product to another country is considered a sale in Canada. The requirements under Part C, Division 1A of the FDR are the same for domestic sale and for a sale for the purpose of export. As such, to export a drug, a DEL that authorizes the sale of the drug in Canada is required (e.g. distribute or wholesale).



### Section 37 of the Food and Drugs Act

Section 37 of the [FDA](#) includes an exemption for the exportation of Drugs manufactured in Canada for export. For more information about section 37 you can consult Health Canada's [Import and Export Policy for Health Products under the Food and Drugs Act and its Regulations \(POL-0060\)](#).

## 4. Combination Products

The [Policy on Drug/Medical Device Combination Products](#) defines a combination product as:

a therapeutic product that combines a drug component and a device component (which by themselves would be classified as a drug or a device), such that the distinctive nature of the drug component and device component is integrated into a singular product.

It is Health Canada's policy that a combination product will be subject to either the Medical Devices Regulations or the FDR according to the principal mechanism of action by which the claimed effect or purpose is achieved.

As such, combination products classified as drugs will be subject to the DEL requirements of Part C Division 1A of the FDR. Depending on the products, the medical device component can become a packaging material (e.g. when the medical device such as a syringe becomes the drug's immediate container).

For more information on combination products, consult the [Policy on Drug/Medical Device Combination Products](#).

For more information on combination product classification decisions, consult the [Policy on Drug/Medical Device Combination Products - Decisions](#).

# Prohibition and Interpretation

## 5. Prohibition

No person shall, except in accordance with a DEL:

- Fabricate, package / label, import or test a drug in dosage form or an active ingredient
- Distribute a bulk process intermediate (BPI) or a drug in dosage form for which they hold the DIN
- Wholesale a drug in dosage form that is:
  - Listed in Schedule C (radiopharmaceutical drug) or D (biologic drug) of the FDA
  - A prescription drug
  - A controlled drug as defined in subsection G.01.001
  - A narcotic as defined in the Narcotic Control Regulations
  - A drug containing cannabis as defined in subsection 2(1) of the Cannabis Act
- Wholesale an active ingredient that is listed in Schedule D (biologic drug) of the FDA

### Exception - Test:

Licensed fabricators, packagers/labellers, distributors and importers do not require the activity of test on their DEL to perform tests, including examinations under Part C, Division 2 of the FDR for the drugs they fabricate, package/label, distribute, or import.

Similarly, foreign buildings listed on an importer's DEL as a fabricator or packager/labeller are not required to be listed on the importer's DEL as testers for the drugs the foreign buildings fabricates or packages/labels.

#### Exception – Package/Label for Fabricator:

When a licensed drug fabricator packages/labels a bulk drug or in-process drug they have fabricated, the packaging and labelling of the bulk containers are considered an integral part of the activity of fabrication and do not require a DEL for package/label when the drug is:

- Packaged in bulk, in a package not suitable or intended for retail sale; and,
- For sale to a drug fabricator or packager/labeler.

#### Exception – Label for Importers:

Labelling activities conducted by drug importers to satisfy the requirements of Part C Division 2 of the FDR are considered an integral part of the activity of importation and do not require a DEL for the activity of label when the drug is:

- Imported and sold in bulk, in a package not suitable or intended for retail sale; and,
- Sold in the same container it was imported in; and
- For sale to a drug fabricator or packager/labeler.

## 6. Drug Establishment Licensing Requirements

In Canada, licensable activities subject to DEL requirements can only be conducted in accordance with a valid DEL. Activities cannot be conducted with a suspended or cancelled DEL. For more information on suspension and cancellations please see [section 20](#) and [section 21](#) of this guide.

To fabricate, package / label, test, import, distribute or wholesale a drug in Canada, the company must hold a valid DEL that includes:

- The Canadian building where the activity is authorized
- The activity that is authorized to be conducted at the building
- The category of drugs for which the activity is authorized
- In the case of a sterile drug, the DEL must authorize sterile dosage form for the drug category

To import a drug into Canada, a company must comply with the above, including holding a DEL for the activity of import, and additionally have the following on their DEL:

- For each Canadian building authorized to import drugs, a foreign building annex including all the foreign buildings involved in the fabrication, packaging/labelling and/or testing of the finished dosage form drug, including finished dosage form intermediates, that is being imported by the Canadian building. For each foreign building, the foreign building annex must include:
  - The activity that is authorized
  - The category of drugs for which the activity is authorized
  - In the case of a sterile drug, the DEL must authorize sterile dosage form for the drug category.
  
- For each Canadian building authorized to import drugs (including FDF and API), an API foreign building annex including all the foreign buildings involved in the fabrication, packaging/labelling and/or testing of the APIs and/or List A APIs for veterinary use, including API intermediates, that are being imported by the Canadian building, or that are used in the fabrication of the finished drugs that are being imported by the Canadian building. For each foreign building, the API foreign building annex must include:
  - The authorized activity
  - The category of drugs for which the activity is authorized (API or List A API for veterinary use)

## 7. Category of Drugs

This section provides further clarifications with respect to drug categories to help understand what drug categories are required on a DEL.

The categories of drugs are:

- Active pharmaceutical ingredients
- Pharmaceuticals
- Vaccines
- Drugs that are listed in Schedule D of the FDA, other than vaccines
- Drugs listed in Schedule C of the FDA
- Drugs that are prescription drugs, controlled drugs as defined in subsection G.01.001, narcotics as defined in the [Narcotic Control Regulations](#) and drugs



containing cannabis as defined in subsection 2(1) of the [Cannabis Act](#) - Sometimes called “Category 6 drugs”

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

Unless specified, the categories of drugs apply to both human and veterinary drugs.

### Active Pharmaceutical Ingredients (API)

Companies conducting activities with respect to APIs require the drug category “active pharmaceutical ingredients” on their DEL for the domestic building conducting activities.

Importers of APIs and importers of pharmaceutical drugs are required to have the following foreign buildings listed on their DEL API foreign building annex under the drug category “API”:

- Foreign building(s) involved in fabrication, packaging/labeling and/or testing of the API and/or their intermediates they import
- Foreign building(s) involved in fabrication, packaging/labeling and/or testing of the API and their intermediates used in the fabrication of the finished dosage form pharmaceutical drugs they import



#### Atypical APIs

Importers of atypical APIs and finished dosage form importers of products formulated using listed atypical APIs are subject to the requirements above. For more information on atypical APIs you can consult the [Notice to Stakeholders - Implementation of Establishment Licensing Requirements for Atypical Active Pharmaceutical Ingredients](#).

The drug category “Active Pharmaceutical Ingredients” includes:

- Active ingredients used in the manufacture of finished dosage form drugs that are pharmaceutical drugs and their intermediates
- Active ingredients used in the manufacture of finished dosage form drugs that are listed on Schedule C (radiopharmaceutical drugs) of the FDA that are not of biological origin and their intermediates

The drug category “Active Pharmaceutical Ingredients” does not include:

- Sterile active ingredients
- Active pharmaceutical ingredients set out in List A that are for veterinary use
- Active ingredients of biological origin used in the manufacture of finished dosage form drugs that are listed on Schedule C (radiopharmaceutical drugs) or Schedule D (biologic drugs) of the FDA



**Important:**

If a company fabricates an API and then uses the API in the fabrication of a finished pharmaceutical drug by either:

- Fabricating a drug into its finished dosage form
- Partially fabricating a finished drug (i.e. fabricating a finished dosage form intermediate)
- Sterilizing the API

The company is required to hold a DEL for the activity of fabricate APIs **and** fabricate pharmaceuticals.

## Pharmaceuticals

Companies conducting activities with respect to pharmaceutical drugs in their finished dosage form and their intermediates require the drug category “Pharmaceuticals” on their DEL for the domestic building conducting activities.

Importers of pharmaceutical drugs in their finished dosage form or their intermediates are required to have the foreign buildings that are involved in the fabrication, packaging/labeling and/or testing of the finished dosage form drugs or finished dosage form intermediate listed on the foreign building annex of their DEL under the drug category “Pharmaceuticals”.

The drug category “Pharmaceuticals” includes:

- Finished dosage form drugs and their intermediates other than drugs listed in Schedule C or D to the FDA
- Finished dosage form narcotic drugs and controlled drugs and their intermediates that are not listed in Schedule C or D of the FDA



### Test

For the activity of test when the test performed is used to satisfy the GMP requirements associated with an activity related to finished dosage form pharmaceutical drugs, the tester, including third party tester, requires a DEL with the drug category “Pharmaceuticals”.

As an example, the tests performed by a third party tester on an API prior to its use in the fabrication of a finished dosage form drug to satisfy C.02.009(1) require a DEL including Test Pharmaceuticals.

### Sterile Active Pharmaceutical Ingredients

Activities performed on sterile active pharmaceutical ingredients require the drug category “Pharmaceuticals” to be listed on the DEL.

The sterilisation of active pharmaceutical ingredients is considered as a step in the fabrication of the finished drug and requires a licence for the fabrication of pharmaceuticals. Also, the importation of sterile APIs is considered importation of a finished pharmaceutical drug. In both cases, the drug category “Pharmaceuticals” is required to be listed on the DEL.



### Wholesale

Health Canada does not issue a DEL for wholesale within the drug category of pharmaceuticals. For more information on the drug category applicable for the wholesale of pharmaceutical drugs, see the information provided under the drug category Prescription Drug List, Schedule G, Drugs Containing Cannabis and/or Narcotics below.

## Biologics

Companies conducting activities with respect to biologic drugs require the drug category “Biologics” on their DEL for the domestic building conducting activities.

Importers of biologic drugs are required to have the foreign buildings that are involved in the fabrication, packaging/labeling and/or testing of the biologic drugs listed on the foreign building annex of their DEL under the drug category “Biologics”.

The drug category “Biologics” includes:

- Drugs listed in Schedule D of the FDA

- Narcotics and controlled drugs that are listed in Schedule D of the FDA
- Active ingredients of biological origin that are used in the fabrication of a drug that is listed on Schedule C of the FDA
- Active ingredients that are used in the fabrication of a drug that is listed on Schedule D of the FDA

## Vaccines

Companies conducting activities with respect to vaccines or vaccine active ingredients require the drug category “Vaccines” on their DEL for the domestic building conducting activities.

Importers of vaccines or vaccine active ingredients are required to have the foreign buildings that are involved in the fabrication, packaging/labeling and/or testing of the vaccine and/or vaccine active ingredients listed on the foreign building annex of their DEL under the drug category “Vaccines”.

## Radiopharmaceuticals

Companies conducting activities with respect to finished dosage form radiopharmaceutical drugs and their intermediates require the drug category “Radiopharmaceutical” on their DEL for the domestic building conducting activities.

Importers of finished dosage form radiopharmaceutical drugs and their intermediates are required to have the foreign buildings that are involved in the fabrication, packaging/labeling and/or testing of the finished dosage form radiopharmaceutical drugs and their intermediates listed on the foreign building annex of their DEL under the drug category “Radiopharmaceuticals”.

The drug category “Radiopharmaceuticals” includes:

- Finished dosage form drugs and their intermediates listed in Schedule C of the FDA
- Finished dosage form narcotics and controlled drugs and their intermediates that are listed in Schedule C of the FDA

The drug category “Radiopharmaceuticals” excludes:

- Active ingredients used in the manufacture of finished dosage form drugs that are listed on Schedule C (radiopharmaceutical drugs) of the FDA that are not of biological origin (see category of drug: active pharmaceutical ingredients)

## Prescription Drug List, Schedule G, Drugs Containing Cannabis, and/or Narcotics

The activity of wholesale does not apply to all pharmaceutical drugs. It only applies to pharmaceutical drugs that:

- are listed on the [Prescription Drug List](#)
- are controlled drugs as defined in Schedule G of the FDR
- are narcotics as defined in the Narcotic Control Regulations
- are drugs containing cannabis as defined in subsection 2(1) of the [Cannabis Act](#)

As such, wholesalers of prescription drugs, controlled drugs, drugs containing cannabis or narcotics are required to have the drug category “Prescription Drug List, Schedule G, Cannabis, and/or Narcotics” on their DEL under the wholesale activity.

Health Canada does not issue DELs with the drug category “Prescription Drug List, Schedule G, Cannabis, and/or Narcotics” for any other activities. For activities other than wholesale, another drug category listed in this section that applies to your drug is required. In most cases, this would be the drug category “Pharmaceuticals”.

The licensing requirements under the [Controlled Drugs and Substances Act](#) and its regulations – including Part G and J of the FDR are not discussed in this guide.

### List A API for Veterinary Use

Companies conducting activities with respect to List A APIs for veterinary use require the drug category “List A API for veterinary use” on their DEL for the domestic building conducting activities.

Importers of List A API for veterinary use and importers of pharmaceutical drugs for veterinary use containing List A API are required to have the following foreign buildings listed on their API foreign building annex with the drug category “List A API for veterinary use”:

- Foreign buildings involved in fabrication, packaging/labeling and/or testing of the List A API for veterinary use and/or their intermediates they import
- Foreign buildings involved in fabrication, packaging/labeling and/or testing of the List A API and or their intermediates used in the fabrication of the finished dosage form pharmaceutical drugs for veterinary use they import

The drug category “List A API for veterinary use” includes:

- API set out in [List A](#) that are for veterinary use and their intermediates

## 8. Storing Drugs as a DEL Holder

Canadian fabricators, importers, packagers/labelers, distributors, wholesalers, or testers are required to hold a DEL for the activities they conduct. In addition, their DEL must include every building in Canada where they store drugs. Buildings where drugs are being stored and where no licensable activities are being conducted are listed on the DEL Warehouse Annex.

## 9. Alternate Sample Retention

Every distributor and importer of drugs is required to retain in Canada a sample of each lot or batch of the packaged/labelled drug for a period of at least one year after the expiration date of the label of the drug.

All buildings outside of Canada where an importer or distributor is authorized to store samples (as per section C.02.025 of the FDR) are listed on the Alternate sample retention Annex of the DEL.

For more information, please refer to [GUI-0014: Alternate Sample Retention Site Guidelines](#).

# DEL Application

## 10. Application Types

This section provides a high level description of the various application types.

### New DEL Application (C.01A.005)

This type of application is to be submitted by companies that do not hold a DEL. This includes applications submitted by companies that are requesting the re-activation of a cancelled DEL.

### Amendment Application (C.01A.006)

This type of application is to be submitted by companies that hold a DEL and wish to make a change to their DEL, including but not limited to the addition, modification or removal of:

- A building in Canada where regulated activities are conducted
- A foreign building from which a drug is imported
- An activity for a specific building
- A category of drugs for a specific activity

- The authorization of sterile dosage forms for a specific category of drugs
- A building in Canada where drugs are stored (Canadian warehouse)
- An alternate sample retention site (ASR)
- Terms and Conditions

### Annual Licence Review (ALR) Application (C.01A.009)

This type of application is to be submitted each year before April 1<sup>st</sup> by companies that hold a valid DEL. This application is required for Health Canada to conduct the annual review of the DEL.



#### New Licence Holders

Every DEL holder is required to submit an ALR application by April 1<sup>st</sup> of every year. Companies that are issued a DEL close to April 1<sup>st</sup> (e.g. March), are still required to submit an ALR application by April 1<sup>st</sup>.

### NERBY Application (C.01A.009/C.01A.006)

In lieu of submitting GMP evidence as part of the ALR application for all foreign buildings listed on a DEL holder's licence, DEL holders are provided as part of their [ALR package](#) the option of signing "Undertaking B" form, thereby committing to submit GMP evidence prior to the New Evidence Required By (NERBY) date indicated on their DEL. A NERBY application is an amendment application intended to meet the commitment that the DEL holder made as part of their ALR application and to request the amendment of the DEL to update the NERBY date.

The NERBY amendment application must include valid and current evidence to demonstrate that each of the foreign fabricator's, packager/labeller's and tester's buildings, equipment, practices and procedures meet the applicable GMP requirements of Part C, Division 2 of the FDR. For more information about NERBY, please consult: [How to demonstrate foreign building compliance with drug good manufacturing practices \(GUI-0080\)](#).

### Reinstatement Application (C.01A.018)

When a company's DEL has been suspended in full or in part by Health Canada and the company wishes to request the reinstatement of the DEL, a reinstatement request may be submitted to Health Canada via [FRM-0033: Drug Establishment Licence Application: Forms and Instructions](#).

The processing of the request is subject to an inspection and associated performance standard.

**Important:**

When a DEL has been suspended for a period of more than 12 months, regardless of whether a reinstatement request was submitted to Health Canada, the DEL cannot be reinstated as the DEL is cancelled pursuant to C.01A.018.1 of the FDR.

Health Canada's authority to reinstate a DEL is limited to suspended DELs. If a DEL is cancelled and the company wishes to resume activities, an application for a new DEL pursuant to C.01A.005 or an amended DEL pursuant to C.01A.006 of the FDR must be submitted as applicable.

To avoid situations where a DEL would be cancelled before a reinstatement decision can be made by Health Canada, Health Canada accepts applications under C.01A.005/C.01A.006 from the holder of suspended DELs who have taken adequate steps to correct the situation on which the suspension was based.

By submitting a new DEL application or an application to amend a DEL rather than an application for reinstatement, Health Canada can process the application irrespective of whether the DEL becomes cancelled pursuant to C.01A.008.1.

### Cancellation Application

If a company wishes to cancel their DEL, the company must send a cover letter or e-mail stating the intention to cancel their DEL. The requestor must be a contact currently on file with Health Canada. Once the request has been processed, confirmation will be sent by Health Canada.

## 11. Submitting a DEL Application other than ALR

All application types listed below must be submitted by completing the most current version of the application form established by the Minister – FRM-0033 and Table A when applicable:

- Application for a new DEL (C.01A.005)
- Application to amend a DEL (C.01A.006)
- NERBY application (C.01A.006/C.01A.009)
- Application to request the reinstatement of a DEL after the situation on which the suspension was based has been rectified

It is recommended that applicants also include a cover page to provide further information with regards to the application or provide clarifications.

Complete applications must be submitted to [Hc.el.applications-le.sc@canada.ca](mailto:Hc.el.applications-le.sc@canada.ca).



When completing an application for a new DEL or for a reinstatement, all the information below must be provided. For amendment applications and NERBY applications, only the information relevant to the change being made or the foreign building that is being renewed is required.

## FRM-0033

[FRM-0033](#) is the form prescribed by the Minister to submit DEL applications. A complete [FRM-0033](#) must be submitted with every application and include the following information:

- Applicant Information
- Canadian Building Information
- Foreign Building Information

## Table A

The Table A form is an Annex to the FRM-0033 that must be submitted, in addition to FRM-0033, when submitting an application requesting to:

- amend the Active Pharmaceutical Ingredient (API) Foreign Building annex of your DEL
- add an API Foreign Building Annex to your DEL or
- add an API Foreign Building Annex as part of a New DEL application



### Table A Form

The Table A form is used to list all foreign buildings conducting licensable activities with regards to APIs imported into Canada and/or for all APIs used in the fabrication of finished dosage forms drugs for import into Canada. Interested stakeholders who wish to obtain the form may send a request to the [Drug Establishment Licence Unit](#).

## Evidence of Compliance with GMP – Domestic Buildings

- Evidence of compliance with GMP of Canadian buildings is not required to be submitted with an application. GMP evidence will be requested by Health Canada as part of the processing of the application. An onsite inspection by Health Canada Inspectors may also be performed.

## Evidence of Compliance with GMP – Foreign Buildings

- Guidance related to the type of GMP evidence to be submitted as part of a DEL application for foreign buildings is available in [GUI-0080 – How to demonstrate foreign building compliance with drug good manufacturing practices.](#)

## 12. Authority to Request Additional Information, Inspect and Request Samples

### Additional Information

When receiving an application, Health Canada may request additional information from the applicant to enable Health Canada to make a licensing decision. Failure to provide the information requested within the allotted timeframe may result in a refusal to issue, amend or reinstate the DEL.

### Inspection

Health Canada has the authority to inspect any building in Canada subject to an application where the applicant proposes to conduct a licensable activity, store drugs or maintain records. The inspection may occur at any time and date as determined by Health Canada within normal business hours. While Health Canada will try to accommodate the company's schedule when possible, Health Canada reserves the right to select the inspection date unilaterally. Should an applicant refuse to be inspected at the date selected by Health Canada for any reason, including because they are not ready for an inspection, this may result in Health Canada not issuing, amending or reinstating the DEL, thereby closing the applications associated with the inspection. Therefore, it is recommended that companies only submit a DEL application once they are ready for an inspection.

Health Canada considers the observations made during the inspection when making licensing decisions on the application.

The following are guidelines and policies that help an applicant prepare for a GMP inspection:

- [Drug Establishment Good Manufacturing Practices—Pre-Application Package \(Importers, Distributors and Wholesalers\)](#)
- [Good manufacturing practices guide for drug products \(GUI-0001\)](#)
- [Annex 1 to the Good manufacturing practices guide - Manufacture of sterile drugs \(GUI-0119\)](#)
- [Risk classification guide for drug good manufacturing practices observations \(GUI-0023\)](#)

- [Guidance on Good Manufacturing Practices for Active Pharmaceutical Ingredients \(APIs\) \(GUI-0104\)](#)
- [Good manufacturing practices for medical gases \(GUI-0031\)](#)
- [GMP Inspection Policy for Canadian Drug Establishments \(POL-0011\)](#)

## Samples

Health Canada has the authority to require that an applicant applying for the activity of fabrication, packaging/labelling, testing, distribution, or importation supply samples of any material to be used in the fabrication, packaging/labelling or testing of a drug. Health Canada considers the information obtained from these samples when making licensing decisions on the application.

## 13. Refusal to Issue or Amend or Reinstate

Health Canada may refuse to issue or amend an establishment licence in respect of any or all matters subject to an application if:

- The applicant had an establishment licence suspended in respect of the matter.

Health Canada may refuse to issue, amend or reinstate an establishment licence in respect of any or all matters subject to an application if:

- The applicant made a false or misleading statement in relation to the application for the licence.

Health Canada will refuse to issue, amend or reinstate an establishment licence in respect of any or all matters subject to an application if:

- Health Canada has reasonable grounds to believe that issuing or amending an establishment licence would constitute a risk to the health of the consumer.

## 14. Issuance

Health Canada issues DELs pursuant to section C.01A.008 of the regulations. Unless Health Canada has grounds to refuse the application under C.01A.010, a licence will be issued when C.01A.008 is met.

In order to meet the requirements of C.01A.008, all application requirements set out in C.01A.005 to C.01A.007 must be satisfied, including demonstrating compliance with GMP, and

compliance with any information request, inspection request and sample request made by Health Canada.

### Issuance with Terms and Conditions

When making a licensing decision, Health Canada may issue an establishment licence that includes terms and conditions to help prevent injury or ensure drugs are not unsafe for use. DEL holders must comply with all terms and conditions listed on their DEL. DEL holders found to be in contravention of the terms and conditions of their licence will be subject to compliance and enforcement actions. Health Canada will take compliance and enforcement actions considering the particularities of each situation while adhering to the legislative framework and the principles of [POL-0001: Compliance and Enforcement Policy for Health Products](#).

## 15. The DEL and its Annexes

When issuing a DEL for the first time, Health Canada issues a full DEL with all applicable sections and annexes. When issuing an amended DEL, only the section subject to the amendment will be issued and will replace the previously issued section or annex.

### Domestic Buildings

A DEL lists each domestic building on its own section (usually one page). For each domestic building the following information is provided:

- The DEL number including the domestic building letter identifier (e.g. 3-001234-A for building A)
- The name of the licence holder
- The address of the Canadian building where licensable activities are authorized
- The licensable activities authorized to be conducted in each building
- The categories of drugs
- Whether sterile dosage forms are authorized for each activity and drug category
- Date of the last GMP inspection
- A list of all the annexes applicable for the domestic building
- The Minister's designate's signature
- The date of issuance or amendment

### DEL Annexes

The annexes below are not part of every DEL. They will be present if applicable, based on the application or Health Canada's licensing decision. Each annex is associated with a specific Canadian building. Companies with multiple Canadian buildings on their DEL may have each type of annex for each domestic building.



### Example of a DEL with Multiple Buildings

An importer with DEL 100000 including building A (100000-A) and building B (100000-B) where both buildings are licenced for import will have a Foreign Building Annex and an API Foreign Building Annex for 100000-A and another Foreign Building Annex and an API Foreign Building Annex for 100000-B. The 2 Foreign Building Annexes may have different foreign buildings listed if the drugs imported by building A are not the same as the drugs imported by building B. The same applies for the API Foreign Building Annex.

**Terms and Conditions Annex:** This annex is where Health Canada will list the terms and conditions associated with a particular Canadian building. This annex contains the DEL number and the building letter to which the terms and conditions apply (e.g. 3-001234-A for building A). This annex may also include terms and conditions regarding an API foreign building associated with this domestic building. When the terms and conditions apply to an API foreign building, the terms and conditions will specifically mention the foreign building.

Terms and conditions are also listed on the Foreign Building Annex.

DEL holders are required to comply with the terms and conditions listed in this annex.

**Foreign Building Annex:** This annex lists all of the foreign buildings which fabricate, package/label and test the drugs imported by the DEL holder to the associated Canadian building. The annex authorizes the DEL holder to import drugs from those foreign buildings.

Each foreign building will have its own section within the annex (usually one page). For each authorized foreign building, Health Canada will include the following information on the Foreign Building Annex:

- The DEL number including the domestic building letter identifier (e.g. 3-001234-A for building A)
- The name of the foreign company
- The address of the foreign building

- The new evidence required by (NERBY) date before which updated GMP evidence must be submitted
- The activities authorized to be conducted at the foreign building
- The categories of drugs
- Whether sterile dosage forms are authorized for each activity and drug category
- Applicable terms and conditions associated with the foreign building

DEL holders are required to comply with the terms and conditions listed on this annex.

**Alternate Sample Retention Annex:** This annex applies to distributors and importers of drugs and is where Health Canada will list all buildings outside of Canada where the importer/distributor is authorized to store samples. For full details, see [Alternate Sample Retention Site Guidelines \(GUI-0014\)](#).

This annex includes the following information:

- The DEL number including the domestic building letter identifier (e.g. 3-001234-A for building A)
- The name and address of the foreign building where samples are authorized to be stored
- The name and the DIN of the drug for which samples are authorized to be stored at the foreign building

**Warehouse Annex:** This annex lists all the Canadian buildings where the DEL holder is authorized to store drugs.

This annex includes the following information:

- The DEL number including the domestic building letter identifier (e.g. 3-001234-A for building A)
- The name and address of the domestic building where the DEL holder is authorized to store drugs

**Active Pharmaceutical Ingredient Foreign Building Annex:** This annex lists all the foreign buildings authorised to fabricate, package/label and test:

- Non-sterile APIs imported by the DEL holder
- Non-sterile APIs used in the fabrication of the finished drugs imported by the DEL holder

API importers are authorized to import APIs from any foreign building listed on this annex.

This annex includes the following information:

- The DEL number including the domestic building letter identifier (e.g. 3-001234-A for building A)
- API Name
- Activity
- Foreign Building Name
- Foreign Building address
- The category of drug (API or List A API for veterinary use)

## 16. Submitting an ALR Application

### ALR Package

ALR applications do not require the use of FRM-0033. Every year, Health Canada will send an ALR package to all companies holding a DEL that is not suspended. The package will include instructions on how to submit and what revisions are permitted in an ALR application and which ones are not. Companies must submit their ALR application to Health Canada before April 1.

Companies that do not receive their ALR application package by January 1 of each year must request one by contacting Health Canada at [Hc.del.questions-leppp.sc@canada.ca](mailto:Hc.del.questions-leppp.sc@canada.ca).

Companies that have been issued a DEL for the first time after December of a given year will receive an ALR application package soon after they have received their DEL. The ALR application must be submitted to Health Canada before April 1.

### ALR GMP Evidence Requirements

As part of their ALR application, companies are required to provide all applicable information and documents outlined under C.01A.005 including evidence of compliance with GMP. However, Health Canada aims to reduce this burden at ALR by the following:

#### Domestic GMP Requirements

When submitting an ALR application for a Canadian building inspected by Health Canada, GMP evidence is not required, unless specifically requested by Health Canada. Health Canada monitors the GMP compliance of domestic buildings via its GMP inspection program and additional evidence is not required to be submitted as part of an ALR application.

## GMP Requirements for Foreign building located in MRA

GMP evidence is not required as part of an ALR application for foreign buildings listed on a DEL that are located in a Mutual Recognition Agreement (MRA) country and where all the activities, category of drugs and dosage forms associated with the foreign building are recognized by the MRA regulatory authority as being in compliance with GMP.

### Other foreign buildings that require GMP evidence include:

- Foreign buildings located in a non-MRA country listed on a DEL, or
- Foreign buildings located in a MRA country, where not all the activities, categories, and dosage forms are covered by the Certificate of Compliance (CoC)

However, Health Canada has implemented the NERBY process to reduce the burden on importers and prevent requesting the same evidence multiple times from year to year. In lieu of the requirement to provide GMP evidence for the foreign building every year as part of ALR, importers can sign and submit Undertaking B as part of their ALR thus allowing for the submission of GMP evidence by the NERBY date associated with the buildings on the DEL. If Undertaking B is not signed GMP evidence for every foreign building listed on the DEL is required with the ALR application.

Importers that sign and submit Undertaking B as part of their ALR application will be notified via a letter that the foreign building has been cancelled from the DEL when they fail to do either of the following:

- submit GMP evidence before the NERBY date
- apply for an extension of the current NERBY date

For more information on NERBY, including the assignment of NERBY date and extension of NERBY date, consult [GUI-0080](#).

## 17. ALR Review Outcomes

Where the review of an ALR application identifies the application as incomplete, Health Canada will follow up with the DEL holder to address the deficiencies. Where the deficiencies are not addressed within the allotted timeframe, the part of the DEL associated with the deficiency will be **cancelled**.

If Health Canada does not receive your ALR application before April 1, Health Canada will take steps to cancel your DEL.



When a DEL is cancelled in full or in part, the company is no longer authorized to conduct the cancelled activities.

To resume activities, the company must obtain a new DEL or an amended DEL that includes the activity the company intends to conduct. To request a new DEL or an amended DEL, an application must be submitted and the application will be subject to the regular service standard.

## 18. Notification Requirements

### MRA Permits

Importers must notify Health Canada **immediately** if a MRA foreign building listed on the importer's DEL no longer holds a valid permit, licence, or authorisation from the MRA regulatory authority.

### Contravention to GMP that may affect quality, safety or efficacy of a drug

DEL holders must notify Health Canada in writing within 15 calendar days after an event occurs that results in their being in contravention of any of the applicable requirements of Divisions 2 to 4 of the FDR, where it may affect the quality, safety or efficacy of a drug fabricated, packaged/labelled, tested as required under Division 2 or stored by them.

Notifications, pursuant to C.01A.013 (b) of the Regulations are to be sent to [Hc.el.applications-le.sc@canada.ca](mailto:Hc.el.applications-le.sc@canada.ca) using the subject "C.01A.13 Notification". The notification should include a description of the contravention, a description of the impact the contravention may have on quality, safety and/or efficacy. If available at the time of notification, any action that has been taken or is planned to address the contravention and mitigate the health risk the drug may pose to the consumer should also be submitted to Health Canada.

Quality, safety or efficacy incidents resulting in a recall decision must be reported to the applicable Health Product Compliance Regional Office in line with the requirements and processes outlined in the [POL-0016: Recall Policy](#).

It is recommended that bankruptcies be notified to Health Canada under C.01A.013 (b).

### Notifiable Changes

DEL holders must notify Health Canada in writing within 15 calendar days of making the following changes:

- Changes to the licence holder's name, address or contact information
- Changes to the emergency contact's name or contact information

- Change of address for a building in Canada where records will be maintained



### Change of Address

When the city or municipality where a building is located changes the address of the building by renaming the street or making any other change to the building address, the change is a notification. However, when a company moves its operations into a different building, this is a change that requires an amendment to the DEL before conducting activities at the new location.

Health Canada recommends that notifications that pertain to a matter that appears on the DEL be submitted using FRM-0033 as an amendment. This does not change the requirement to submit the application within 15 calendar days of the changes but will allow Health Canada to make the change to the DEL (e.g. amend the address of a building) and will meet the notification requirements.

## 19. Amalgamations and Changes of Ownership

Whenever a business transaction is being planned, it is recommended that Health Canada be contacted at [Hc.del.questions-leppp.sc@canada.ca](mailto:Hc.del.questions-leppp.sc@canada.ca) for more information with respect to the regulatory requirements and associated processes. Business transactions include, but are not limited to:

- mergers/amalgamations
- acquisition of assets, particularly acquisitions of buildings where regulated activities are conducted

# Compliance and Enforcement

## 20. Suspension Authority

Health Canada can suspend a DEL in full or in part when:

- Health Canada has reason to believe that the DEL holder has contravened the FDA or FDR, including when a GMP inspection results in a Non-Compliant rating
- it is found that the DEL holder made false or misleading statements when applying for the licence or an amendment to an existing DEL

- it is necessary to do so to prevent a risk to the health of consumers
- the licensee fails to comply with an order to assess, issued under section 21.31 of the FDA, to demonstrate that the licensee’s buildings, equipment or practices meet GMP requirements
- the licensee complies with an order to assess, issued under section 21.31 of the FDA, but fails to demonstrate that the licensee’s buildings, equipment or practices meet GMP requirements

When a DEL is suspended, the DEL holder must cease all suspended activities.

## 21. Cancellation

The minister must cancel a DEL when:

- the licence has been suspended for a period of more than 12 months
- the licence holder has failed to submit an application for the review of their licence in accordance with subsection C.01A.009(1)

## 22. Authority to Add or Amend Terms and Conditions

Health Canada can add or modify terms and conditions to a DEL at any time when Health Canada determines that restrictions are necessary to ensure that the drug is not unsafe for use, or to prevent injury to the health of consumers.

# Contact Information

Generic email accounts have been set up to provide subject specific guidance. These generic email accounts are regularly monitored by trained and knowledgeable staff.

Please send questions to the following generic email accounts based on the subject.

- General enquiries: [Hc.del.questions-leppp.sc@canada.ca](mailto:Hc.del.questions-leppp.sc@canada.ca)
- Fee-related enquiries: [HC.CRIU-UFRC.SC@canada.ca](mailto:HC.CRIU-UFRC.SC@canada.ca)
- API-related enquiries: [hc.api.questions-ipa.sc@canada.ca](mailto:hc.api.questions-ipa.sc@canada.ca)
- Foreign building GMP enquiries: [hc.foreign.site-etranger.sc@canada.ca](mailto:hc.foreign.site-etranger.sc@canada.ca)
- General GMP enquiries: [hc.drug.gmp.questions-bpf.medicaments.sc@canada.ca](mailto:hc.drug.gmp.questions-bpf.medicaments.sc@canada.ca)

# Appendix A - Glossary

## Acronyms

ALR	Annual Licence Review
API	Active Pharmaceutical Ingredient
ASR	Alternate Sample Retention
BPI	Bulk Process Intermediate
CDSA	Controlled Drugs and Substances Act
CFIA	Canadian Food Inspection Agency
CoC	Certificate of Compliance
CTA	Clinical Trial Application
DEL	Drug Establishment Licence
DIN	Drug Identification Number
FDA	Food and Drugs Act
FDR	Food and Drug Regulations
GMP	Good Manufacturing Practices
MRA	Mutual Recognition Agreement
NC	Non-Compliant
NERBY	New Evidence Required By
OTC	Over-the-Counter drugs

## Terms



These definitions explain how terms are used in this document. If there is a conflict with a definition in the FDA or any of the regulations cited in this document, the definition in the FDA or regulations prevails.

**Active ingredient** – A drug that, when used as a raw material in the fabrication of a drug in dosage form, provides its intended effect. (FDR C.01A.001)

**Active pharmaceutical ingredient (API)** – An active ingredient that is used in the fabrication of a pharmaceutical. (FDR C.01A.001)

**Alternate sample retention (ASR)** – An alternate site specified on a DEL for the storage of samples pursuant to section C.02.025 (1) of the FDR.

**Alternate sample retention (ASR) site annex** – A listing of the ASR sites that have been assessed

against good manufacturing practices. This annex is a part of the DEL.

**Antimicrobial agent** – Antimicrobial agent means a drug that is capable of destroying pathogenic micro-organisms and that is labelled as being for use in the disinfection of environmental surfaces or medical devices, as defined in the [Medical Devices Regulations](#), that

- (a) are not invasive devices as defined in those Regulations; and
- (b) are intended to come into contact with intact skin only.

Antimicrobial agents include environmental hard surfaces disinfectants used to clean surfaces such as desks and benches.

**Active pharmaceutical ingredient Intermediate** – A material (isolated or not) produced during steps of the processing of an API that undergoes further molecular change or purification before it becomes a final API.

**Biological drug** – Any drug that is listed in Schedule D of the FDA that is in dosage form. This also includes any drug that is a bulk process intermediate that can be used to prepare a drug listed in Schedule D of the FDA.

**Bulk process intermediate** – Any intermediate form of a Schedule C or D drug (e.g. final bulk intermediate, bulk material, bulk concentrate, drug substance) that must undergo further processing before it becomes a final product.

**Clinical trial** – An investigation in respect of a drug for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug. (FDR C.05.001)

**Controlled drug** – A substance included in Schedule I, II, III, IV or V of the *Controlled Drugs and Substances Act*.

**Distributor** – A person, including an association or partnership, who under their own name, or under a trade, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug.

Divisions 1A and 2 to 4 of the FDR apply to the following distributors:

- a) a distributor of an active ingredient
- b) a distributor of a drug for which the distributor holds the DIN (FDR C.01A.003)

**Drug** – Any substance or mixture of substances manufactured, sold or represented for use in (a) the diagnosis, treatment, mitigation or prevention of a disease, a disorder, an abnormal physical state or the symptoms thereof, in humans or animals; (b) restoring, correcting or modifying organic functions in humans or animals; or (c) "disinfection" in premises in which food is manufactured, prepared or kept. (Section 2 of the FDA)

In Division 1A and Division 2 of the FDR, “drug” does not include any of the following:

- (a) a dilute drug premix;
- (b) a medicated feed as defined in subsection 2(1) of the [Feeds Regulations, 1983](#);
- (c) an active ingredient that is for veterinary use and that is not an active pharmaceutical ingredient;
- (d) an active pharmaceutical ingredient for veterinary use that is not required to be sold pursuant to a prescription and that is also a natural health product as defined in subsection 1(1) of the [Natural Health Products Regulations](#);
- (e) a drug that is used only for the purposes of an experimental study in accordance with a certificate issued under section C.08.015 of the FDR. (C.01A.001(2))

**Drug establishment licence (DEL)** – A licence that allows a person to conduct licensable activities in a building in Canada.

**Drug identification number (DIN)** – A drug identification number (DIN) is an eight (8)-digit numerical code assigned by Health Canada to each drug product marketed under the FDA and Regulations. A DIN uniquely identifies the following product characteristics: manufacturer, brand name, medicinal ingredient(s), strength of medicinal ingredients(s), pharmaceutical form, route of administration.

**Drug premix** – A drug for veterinary use to which a drug identification number has been assigned, where the directions on its label specify that it is to be mixed with feed as defined in section 2 of the *Feeds Act*. (FDR C.01A.001)

**Ethical drug** – a drug that, in accordance with Federal Legislation, does not require a prescription, but that is generally prescribed by a medical practitioner (e.g. nitroglycerine).

**Fabricate** – To prepare and preserve a drug for the purposes of sale. (FDR C.01A.001). This definition applies to Division 1A, 2, 3 and 4 of the FDR.

**Finished Dosage Form (FDF) Intermediate** – Any physical mix, starting when any 2 ingredients (e.g., active ingredient, anti-oxidant, preservative, filler, binder, solvent, etc.) are first added to the drug lot being manufactured, and before it becomes a drug in dosage form. Partially processed drug product intermediate, in-process drugs or bulk drug are examples of drug in

dosage form intermediates

**Foreign building** – A building outside of Canada where the following licensable activities are conducted for drugs that are sold in Canada: fabrication, packaging/labelling, and/or testing.

**Import** – To import into Canada a drug for the purpose of sale. (FDR C.01A.001(1))

**Inspection** – Assessment of compliance against any of the applicable requirements of the FDA and its associated regulations by a designated inspector.

**Invasive devices** – means a medical device that is intended to come into contact with the surface of the eye or penetrate the body, either through a body orifice or through the body surface.

**Label** – Any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package. (Section 2 of the FDA). The action of labelling refers to affixing the inner or outer label to the drug. (FDR C.01A.001)

**Licensable activity** – Activities that require a licence (DEL). The six activities are fabricating, packaging/labelling, importing, distributing, wholesaling and testing.

**List A APIs** - List A names certain antimicrobial APIs that are important in human medicine.

**Medical gas** – Any gas or mixture of gases manufactured, sold or represented for use as a drug. (FDR C.02.002).

**Mutual recognition agreement (MRA)** – An international agreement that provides for the mutual recognition of compliance certification for good manufacturing practices for drugs. (FDR C.01A.001)

**Natural health product** – A substance set out in Schedule 1 of the Natural Health Products Regulations or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine that is manufactured, sold or represented for use in:

- a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans
- b) restoring or correcting organic functions in humans
- c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health

However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.

Also, in accordance with subsection 2(2) of the NHPR, a substance or combination of substances or a traditional medicine is not considered to be a natural health product if its sale, under the FDR, is required to be pursuant to a prescription when it is sold other than in accordance with section C.01.043 of the FDR.

**Over-the-counter drug** – drugs that do not appear on a schedule or the [Prescription Drug List](#) or are not recommended to appear on any schedule.

**Package/label** – To put a drug in its immediate container or to affix the inner or outer label to the drug. (FDR C.01A.001)

This definition also applies to the replacement of packaging or labelling of previously packaged and labelled products (i.e. re-packing/re-labelling).

**Pharmaceutical** – A drug other than a drug listed in Schedule C or D to the FDA. (FDR C.01A.001)

This definition applies to Division 1A, 2, 3 and 4 of the FDR.

**Pharmacist** – An individual who (a) is registered or otherwise authorized under the laws of a province to practise pharmacy; and (b) is practising pharmacy in that province. (FDR C.01.001)

**Practitioner** – A person who (a) is entitled under the laws of a province to treat patients with a prescription drug; and (b) is practising their profession in that province. (FDR C.01.001)

**Radiopharmaceutical** – A drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons. (FDR C.03.201)

These drugs are listed in Schedule C to the FDA.

**Retail sale** – The sale of goods to the public for use or consumption rather than for resale.

**Regulatory authority** – A government agency or other entity in an MRA country that has a legal right to control the use or sale of drugs within that country and that may take enforcement action to ensure that drugs marketed within its jurisdiction comply with legal requirements. (FDR C.01A.001)

**Sell** – To offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration. (Section 2 of the FDA)

**Sterile** – Free from viable microorganisms.

**Test** – To perform the tests, including examinations, required under Part C, Division 2 of the FDR.

**Vaccine** – A preparation of a weakened or killed pathogen (such as a bacterium or virus) that,



upon administration, stimulates antibody production or cellular immunity against the pathogen. Vaccines are listed in Schedule D to the FDA.

**Wholesaler** – A person who is not a distributor described in section C.01A.003 of the FDR and who sells any of the following drugs other than at retail sale:

- a) a drug in dosage form that is listed in Schedule C or D of the FDA, a drug that is a prescription drug or a controlled drug as defined in subsection G.01.001
- b) an active ingredient
- c) a narcotic as defined in Narcotic Control Regulations
- d) drugs containing cannabis as defined in subsection 2(1) of the Cannabis Act

# Appendix B - References

## Laws

### [Controlled Drugs and Substances Act](#)

<http://laws-lois.justice.gc.ca/eng/acts/C-38.8/>

### [Food and Drugs Act](#)

[laws-lois.justice.gc.ca/eng/acts/f-27](http://laws-lois.justice.gc.ca/eng/acts/f-27)

### [Food and Drug Regulations](#)

[laws-lois.justice.gc.ca/eng/regulations/c.r.c.,\\_c.\\_870/index.html](http://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/index.html)

### [Narcotic Control Regulations](#)

[http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,\\_c.\\_1041/](http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._1041/)

### [Prescription Drug List](#)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list/list.html>

## Guidelines

### [GUI-0001: Good manufacturing practices guide for drug products](#)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/gmp-guidelines-0001.html>

### [GUI-0014: Alternate Sample Retention Site Guidelines](#)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/forms/alternate-sample-retention-site-guidelines-0014.html>

### [GUI-0023: Risk classification guide for drug good manufacturing practices observations](#)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/risk-classification-drug-gmp-observations-0023.html>

### [GUI-0031: Good Manufacturing Practices for Medical Gases](#)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/gmp-guidelines-0031/document.html>

[GUI-0080: How to demonstrate foreign building compliance with drug good manufacturing practices](#)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/guidance-evidence-demonstrate-drug-compliance-foreign-sites-0080.html>

[GUI-0104: Good Manufacturing Practices Guidelines for Active Pharmaceutical Ingredients](#)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/guidelines-active-pharmaceutical-ingredients-0104.html>

[GUI-0119: Annex 1 to the Good manufacturing practices guide - Manufacture of sterile drugs](#)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/gmp-guidelines-annex-1-manufacture-sterile-drugs-0119.html>

[Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications](#)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/clinical-trials/clinical-trial-sponsors-applications.html>

[Fees for the Review of Human and Veterinary Drug Establishment Licence Applications](#)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/funding-fees/review-drug-establishment-licence.html>

## Policies

[POL-0001: Compliance and Enforcement Policy for Health Products](#)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/compliance-enforcement-policy-0001.html>

[POL-0004: Drug Good Manufacturing Practices and Establishment Licensing Enforcement Directive](#)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/drug-good-manufacturing-practices-establishment-licensing-enforcement-directive-0004.html>

*POL-0011: GMP Inspection Policy for Canadian Drug Establishment*

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/inspection-policy-canadian-drug-establishments.html>

*POL-0016: Recall Policy*

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/recall-policy-0016.html>

*POL-0051: Policy on Manufacturing and Compounding Drug Products in Canada*

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/policy-manufacturing-compounding-drug-products.html>

*POL-0060: Import and Export Policy for Health Products under the Food and Drugs Act and its Regulations*

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/policy-health-products-under-food-drugs-act-regulations-0060.html>

*Policy on Drug/Medical Device Combination Products*

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/policies/drug-medical-device-combination-products.html>

*Policy on Drug/Medical Device Combination Products – Decisions*

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/policies/policy-drug-medical-device-combination-products-decisions.html>

## Forms

### [FRM-0033: Drug Establishment Licence Application: Form and Instructions](https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/forms/drug-establishment-licence-application-instructions-0033.html)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/forms/drug-establishment-licence-application-instructions-0033.html>

## Other related documents and tools

### [Drug Establishment Good Manufacturing Practices – Pre-Application Package \(Importers, Distributors and Wholesalers\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/application-package-importers-distributors-wholesalers.html)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/application-package-importers-distributors-wholesalers.html>

### [List A: List of Certain Antimicrobial Active Pharmaceutical Ingredients](https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/veterinary-antimicrobial-sales-reporting/list-a.html)

<https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/veterinary-antimicrobial-sales-reporting/list-a.html>

### [Mutual Recognition Agreement Regulatory Authorities](https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/international/mutual-recognition-agreements/updates/regulatory-authorities.html)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/international/mutual-recognition-agreements/updates/regulatory-authorities.html>

### [Notice to Stakeholders - Implementation of Establishment Licensing Requirements for Atypical Active Pharmaceutical Ingredients](https://www.canada.ca/en/health-canada/services/drugs-health-products/public-involvement-consultations/compliance-enforcement/notice-stakeholders-implementation-establishment-licensing-requirements-atypical-active-pharmaceutical-ingredients.html)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/public-involvement-consultations/compliance-enforcement/notice-stakeholders-implementation-establishment-licensing-requirements-atypical-active-pharmaceutical-ingredients.html>

### [Veterinary Biologics CFIA web page](http://www.inspection.gc.ca/animals/veterinary-biologics/eng/1299159403979/1320545281259)

<http://www.inspection.gc.ca/animals/veterinary-biologics/eng/1299159403979/1320545281259>