Health Canada Santé Canada

Our Mandate:
To promote good nutrition and informed use of drugs, food, medical devices and natural health products, and to maximize the safety and efficacy of drugs, food, natural health products, medical devices, biologics and related biotechnology products in the Canadian marketplace and health system.

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. This document is not intended to provide legal advice regarding the interpretation of the Act or Regulations. If a regulated party has questions about their legal obligations or responsibilities under the Act or Regulations, they should seek the advice of legal counsel.

Canada

INTRODUCTION

A Drug Establishment Licence (DEL) is required for any person in Canada engaged in any of the six licensable activities with respect to drugs in dosage form and bulk intermediates of Schedule C (radiopharmaceutical) and Schedule D (biological) drugs. The six licensable activities are: fabricate, package/label, test, import, distribute and wholesale. For more information, please review the **Guidance on Drug Establishment Licences (GUI-0002**) (http://web.hc-sc.gc.ca/dhp-mps/compli-conform/licences/directives/gui-0002-eng.php).

IMPORTANT CHANGES TO DEL APPLICATION PROCESS

Due to changes in the *Food and Drugs Regulations*, effective April 1 2011, an establishment licence will no longer expire on December 31 of each year. Application for Annual Review is due on April 1, of each year. Authorized foreign sites will continue to be assigned a GMP compliance expiry date which will appear on the foreign site annex of the licence. If applicable, terms and conditions on a DEL will continue to have expiration date.

IMPORTANT CHANGES REGARDING FEES

Payment for a drug establishment licence is due upon receipt of the application with the exception of establishments who have not completed their first calendar year of conducting licensable activities. Their payment is deferred for one calendar year. In order to apply for a fee remission, a completed Fee Form, a Certified Statement, and a DEL Calculation Chart must be submitted with the application. For more information on fees and fee remission, please refer to the following:

1) HPFB Inspectorate website – (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/index-eng.php)
2) Section 10 of the *Drug Establishment Licensing and Fee Guide*
3) *DEL Fee Form* for calculating fee

IMPORTANT NOTE: Money will not be refunded to applicants that are found not to require a DEL, not ready for first inspection, have received a non-compliant rating, or cancel their licence.

NEW APPLICATIONS

New applications should be submitted once the establishment is ready to be inspected and to begin licensable activities. At this point in time, the applicant should also have received their Drug Identification Number (DIN) or is in the process of obtaining their DIN.

NOTE: A new building added to a preexisting licence will be treated as a new application.

AMENDMENT APPLICATION

Amendments are to be submitted within 15 days of making the change or as part of the annual review process if the change is within 15 days of submitting the application for annual review. Amendments with respect to the establishment licence application are required to be submitted in order add or change any of the following:

- change of contact information,
- activities, categories and dosage forms of drugs,
- sterile fabrication of a dosage form,
- change of establishment name and/ or address of the building,

- change of Alternate Sample Retention Site.

Amendment to Change a Company Name
Companies may submit a letter on company letterhead detailing the name change. This is permitted when there are no operational or personnel changes. The letter must indicate that there are no operational or personnel changes and should be signed by the authorized signing official.

Company Buy-Out/Merger
Companies may submit a letter on company letterhead detailing the name change of the merged establishment. A new application form must be submitted for the newly merged company.

Amendment to Add or Change a Foreign Site
Changes to activities, categories, dosage forms or whether any drugs will be in a sterile dosage form at an existing foreign site, or a new foreign site on an importer's licence (see instructions for completing Section 5 for more information).

INSTRUCTIONS

This document contains instructions, important definitions, and key notes to assist applicants in the completion of their DEL Application. For convenience, the **Alternate Sample Retention Site Application Form** (more information at: (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/form/site_retention_tc-tm-eng.php), the **Intention to Invoke Section 37 of the Canada *Food and Drugs Act* for Products Being Exported** form (more information at: (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/frm_0038_tc-tm-eng.php), and the **DEL Fee Form** are included at end of the DEL Application Form.

APPLICATION TYPE

If applying for a new Drug Establishment Licence, select "**New**". If requesting an amendment to a previously issued Drug Establishment Licence, select "**Amendment to Licence #**" and specify the complete licence number (e.g. 100999-C).

PART A: COMPANY INFORMATION

[Company Name] is the legal name of the company.
[Mailing Address] is where correspondence and the licence is to be sent.
[Billing Address] is where the fee statement is to be sent.

[Name of Authorized Signing Official] is the individual who is responsible for preparing the application

Note: A signature MUST be provided in order for the submitted DEL Application to be processed.

PART B: CANADIAN BUILDING INFORMATION

If applicable, please indicate the DEL number on the provided line. If a company conducts activities at more than one building, then Part B of the application must be completed for each building.

SECTION 1: LOCATION

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

Building Identification

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] is a house where licensable activities are occurring.

[Address Information] is the address where the building is located, if it differs from the mailing or billing address. This cannot be a post office box.

[**Contact Person]** is the individual at the Canadian building, who will be contacted regarding the inspection.

[Good Manufacturing Practices (GMP) Records Maintenance Address] is where the records required for compliance under Division 2 (GMP) of the *Food and Drugs Regulations* are maintained.

[**Contact Person]** is the individual responsible to receive communication regarding the GMP Records Maintenance building

SECTION 2: GMP INSPECTION INFORMATION

Applicants are asked to indicate whether or not the building has been GMP inspected by a Regions and Programs Branch (RAPB) inspector. If the response is yes, please indicate the date of the last inspection. Other types of inspections conducted by Health Canada personnel (e.g. on-site evaluations by Biologics and Genetics Therapies Directorate for New Drug Submissions) are not considered equivalent to a GMP inspection. For more details, please refer to **GMP Inspection Policy for Canadian Drug Establishments (POL-0011):** (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol_0011_tc-tm-eng.php)

SECTION 3: ACTIVITY, CATEGORY AND DOSAGE FORM CLASS INFORMATION

This section refers to information regarding the activities, the categories, and the dosage form classes of the drug products at the Canadian building (Part B: Section 1).

[Activity] When completing Section 3, indicate the number corresponding to the activity:

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

[Category] When completing Section 3, indicate the number corresponding to the category:

1 = Pharmaceutical	4 = Biological
2 = Vaccine	5 = Radiopharmaceutical
3 = Blood & Blood Components	6 = Schedule F & G, Narcotic (for wholesalers only)

Note: Please enter only ONE activity and ONE category per line.

[Dosage Form Classes] The appropriate dosage form box(es) must be completed for each entry.
The possible dosage form classes have been coded 1-14. When completing Section 3, indicate the number corresponding to the dosage form class. For a listing of all the approved dosage form classes, please refer to the **Drug Product Database (DPD) Online**: (http://webprod.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp).

Code 14 applies to "other" dosage form classes. At the bottom of Section 3, there is an area to code these "other" dosage forms. For example, if you produce an implant and a dressing, enter A = Implant, B = Dressing and insert "A" and "B" in the appropriate fields/boxes in Column 14 of the table.

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

Note: Sterilization is considered the activity of fabrication. All buildings where the activities of fabrication, packaging/labelling, importation and distribution of sterile drug products must be listed on the application form. In addition, please 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 *Division 2 (section C.02.029).*

SECTION 4: PRODUCT INFORMATION

This section contains information about the drugs that the applicant fabricates, packages/labels and/or distributes. This section is not applicable for the following establishments:

- those engaging solely in testing or wholesaling do not have to complete Section 4.
- those importers of finished products do not list such products in Section 4 since that information is captured in the product information in Section 5.

[Product Name] is the name under which the product is sold.
[Class] Select the drug class – Human or Veterinary.
[Schedule] Indicate the schedule to which the drug belongs (e.g. schedule D for biologicals). This information can be found at **Drug Product Database (DPD) Online**: (http://webprod.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp)
[DIN] is the drug identification number assigned to a product. It must be included unless not required by regulation (e.g., blood).
[Activity] For each product, select all activities that apply to it [fabricate (F), package (P), and/or distribute (D)].

Note: If additional space is needed to list product information, an attachment may be submitted with the application.

SECTION 5: FOREIGN SITE INFORMATION

Adding foreign sites: new importers

If applying for the activity of import, please complete a Section 5 for each foreign fabricator, packager/labeller, and/or tester from which the product(s) will be imported into Canada.

Adding foreign sites: licensed importers

Licensed importers may add foreign sites by completing only Section 5 of the DEL Application Form, for each fabricator, packager/labeller, and/or tester they wish to add. A cover letter from the importer should accompany the Section 5(s).

[Foreign Site Name and Address Information]

> **[Foreign Company Name]** is the legal name of the foreign company which is engaging in a licensable activity; not necessarily the DIN owner.
> **[Foreign Site Address]** is the address of the foreign company at which the licensable activity is being conducted.

[Importer Information] is completed when Section 5 is submitted separately as part of an amendment or when the contact is unique for the foreign site.

> **[Contact (foreign site correspondence)]:** is designated to receive feedback about the foreign site and is the person to whom foreign site correspondence will be sent.

[Activity, Category and Dosage Form Class Information] refers to information regarding the activities, the categories, and the dosage form classes of the drug products at the indicated foreign site.

> **[Activity]** is limited to fabricate, package/label and/or test. When completing Section 5, indicate the number corresponding to the activity:
>
> 1 = Fabricate
> 2 = Package/Label
> 3 = Test
>
> **Note: Please enter only ONE activity and ONE category per line.**

[Product Information]
This section refers to information regarding the drug products handled at the indicated foreign site.

> **[Product Name]** is the name under which the product is sold.
> **[Class]** Select the drug class – Human or Veterinary.
> **[Schedule]** Indicate the schedule to which the drug belongs (e.g. schedule D for biologicals). This information can be found at **Drug Product Database (DPD) Online**: (http://webprod.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp)
> **[DIN]** is the Drug Identification Number assigned to a product; to be included unless not required by regulation (e.g., blood).
> **[Activity]** For each product, select all activities that apply to it [fabricate (F), package (P), and/or test (T)].
> **Note: If additional space is needed to list product information, an attachment may be submitted with the application.**

Required Supplemental Documents for Foreign Site Submissions
Please 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 sites. Please note that if these documents are not provided in their entirety, the Drug GMP Inspections Unit will screen out the foreign site addition request.

SUBMIT THE COMPLETED APPLICATION FORM(S) TO:

Establishment Licence Invoicing Unit
Health Products and Food Branch Inspectorate
250 Lanark Avenue
Graham Spry Building – 2nd Floor
Address Locator 2002C
Ottawa, ON
K1A 0K9

USEFUL CONTACT INFORMATION

For inquiries related to DELs:

Establishment Licence Unit (ELU)
Tel: 613-954-6790
Fax: 613-957-4147
Email: DEL_questions_LEPPP@hc-sc.gc.ca

For inquiries related to GMP inspections, foreign site submissions, Section 37, and alternate sample retention sites:

Drug GMP Inspections Unit
Tel: 613-957-1492
Fax: 613-957-6709
Email: GMP_questions_BPF@hc-sc.gc.ca
Email: foreign_site_etranger@hc-sc.gc.ca

For inquiries related to DEL fees:

Establishment Licence Invoicing Unit (ELIU)
Tel: 613-946-5141
Fax: 613-957-6711
Email: ELIU_UFLE@hc-sc.gc.ca

CHECKLIST FOR DEL APPLICANTS

	DEL Application Form (completed and signed where applicable)
	Valid foreign site GMP Compliance Evidence (see GUI-0080 for more information)
	Alternate Sample Retention Site Application Form (if applicable)
	Intention to Invoke Section 37 of the Canada *Food and Drugs Act* for Products Being Exported (if applicable)
	DEL Fee Form
	Fee Calculation (DEL Calculation Chart)
	Payment (if applicable)

Health Canada Santé Canada

Application Tracking #: _____
(For internal use only)

DRUG ESTABLISHMENT LICENCE APPLICATION FORM

Application Type: ☐ **New**
☐ **Amendment to licence #:** _____

PART A: COMPANY INFORMATION

Company Name:		
Mailing Address		
Street:	Suite:	Post Office Box:
City:	Province:	Postal Code:
Contact Person:		Language: ☐ English ☐ French
Telephone:	Fax:	Email:
Billing Address ☐ same as mailing address		
Street:	Suite:	Post Office Box:
City:	Province:	Postal Code:
Contact Person:		Language: ☐ English ☐ French
Telephone:	Fax:	Email:

Name of Authorized Signing Official	**Title**	**Signature**	**Date (yyyy-mm-dd)**

PART B: CANADIAN BUILDING INFORMATION

Drug Establishment Licence # (if applicable): _____

SECTION 1: LOCATION		
Building Name:	Building No:	Dwelling-house: ☐ Yes ☐ No
Address Information: ☐ same as mailing address ☐ same as billing address		
Street:		Suite:
City:	Province:	Postal Code:
Contact Person:		Language: ☐ English ☐ French
Telephone:	Fax:	Email:
GMP Records Maintenance Address: ☐ same as location address ☐ same as mailing address ☐ same as billing address		

Street:	Suite:	Post Office Box:
City:	Province:	Postal Code:
Contact Person:		Language: ☐ English ☐ French
Telephone:	Fax:	Email:

SECTION 2: GMP INSPECTION INFORMATION

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

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

SECTION 3: ACTIVITY, CATEGORY AND DOSAGE FORM CLASS INFORMATION

Activity	Category	Dosage Form Class
1 = Fabricate 2 = Package/Label 3 = Test 4 = Import 5 = Distribute 6 = Wholesale	1 = Pharmaceuticals 2 = Vaccine 3 = Blood & Blood Components 4 = Biological 5 = Radiopharmaceutical 6 = Schedule F & G, Narcotic (for Wholesalers only)	1 = Powder for solution 2 = Tablet 3 = Capsule 4 = Solution 5 = Suspension 6 = Aerosol 7 = Powder 8 = Suppository 9 = Medical Gas 10 = Veterinary Premix 11 = Bulk Intermediates (biological only) 12 = Active Pharmaceutical Ingredient (API) 13 = Packaging Material 14 = Other [2]

Enter only ONE activity and ONE category per line		1	2	3	4	5	6	7	8	9	10	11	12	13	14
e.g. 1	1		x		Sx[1]										A

[1] An "S" should be placed in front of the "X" to indicate that the product is sterile

[2] Other dosage forms: A = _____ B = _____ C = _____ D = _____

SECTION 4: PRODUCT INFORMATION (Complete only if applying for: fabricate, package/label and/or distribute)

Product Name	Class		Schedule	Drug Identification Number (DIN)	Activity		
	Human	Vet.			F	P	D

SECTION 5: FOREIGN SITE INFORMATION

FOREIGN SITE NAME AND ADDRESS INFORMATION

Foreign Company Name:		
Foreign Site Address		
Street:		
City:	Province/ State:	
Country:	Postal Code / Zip Code:	

IMPORTER INFORMATION (Complete only if Section 5 submitted separately)

Canadian Drug Establishment Name:			
Drug Establishment Licence Number:			
Contact (foreign site correspondence):			
Telephone:	Fax:	Email:	
Name of Authorized Signing Official	**Title**	**Signature**	**Date (yyyy-mm-dd)**

ACTIVITY, CATEGORY AND DOSAGE FORM CLASS INFORMATION

Activity	Category	Dosage Form Class
1 = Fabricate 2 = Package/Label 3 = Test	1 = Pharmaceuticals 2 = Vaccine 3 = Blood & Blood Components 4 = Biological 5 = Radiopharmaceutical 6 = Schedule F & G, Narcotic (for Wholesalers only)	1 = Powder for solution 2 = Tablet 3 = Capsule 4 = Solution 5 = Suspension 6 = Aerosol 7 = Powder 8 = Suppository 9 = Medical Gas 10 = Veterinary Premix 11 = Bulk Intermediates (biological only) 12 = Active Pharmaceutical Ingredient (API) 13 = Packaging Material 14 = Other [2]

Enter only ONE activity and ONE category per line		1	2	3	4	5	6	7	8	9	10	11	12	13	14
e.g. 1	1		x		Sx[1]										A

[1] An "S" should be placed in front of the "X" to indicate that the product is sterile

[2] Other dosage forms: A = _____ B = _____ C = _____ D = _____

PRODUCT INFORMATION*

Product Name	Class		Schedule	Drug Identification Number (DIN)	Activity		
	Human	Vet.			F	P	T

Health Canada Santé Canada

Alternate Sample Retention Site Application Form
Formulaire de demande de site alternatif pour la rétention d'échantillons

***Once completed, please fax this application form to the Health Products and Food Branch Inspectorate at 613-952-9805 or email it to GMP_Questions_BPF@hc-sc.gc.ca.**
Une fois complété, veuillez faire parvenir ce formulaire de demande à l'Inspectorat de la Direction générale des produits de santé et des aliments par télécopieur au 613-952-9805 ou par courriel à l'adresse suivante GMP_Questions_BPF@hc-sc.gc.ca.

1. Importer or Distributor / *Importateur ou distributeur*

Name / *Nom* :
Address / *Adresse* :
Telephone number / *Numéro de téléphone* :
Fax number / *Numéro de télécopieur* :

2. Product / *Produit*

Name / *Nom* :
DIN (if applicable) / *DIN (le cas échéant)* :

3. Fabricator / *Manufacturier*

Name / *Nom* :
Address / *Adresse* :
Telephone number / *Numéro de téléphone* :
Fax number / *Numéro de télécopieur* :

4. Site where samples are to be retained / *Établissement où les échantillons seront conservés*

Name / *Nom* :
Address / *Adresse* :
Telephone number / *Numéro de téléphone* :
Fax number / *Numéro de télécopieur* :

*Please note that if the alternate site is located outside of Canada, it must be listed as a foreign site on a Canadian establishment's Drug Establishment Licence. If the alternate site is located in Canada, the Canadian establishment must hold a Drug Establishment Licence.
**Veuillez prendre note que si le site alternatif est situé à l'extérieur du Canada, il doit être inscrit en tant que site étranger sur la licence d'établissement pharmaceutique d'un établissement canadien. Si le site alternatif est situé au Canada, l'établissement canadien doit détenir une licence d'établissement pharmaceutique.*

5. Criteria for assessment (complete as applicable) / *Critères d'évaluation (remplir selon le cas)*

a. The testing of this product requires specialized product-specific methodology that is not available in Canada :
L'analyse de ce produit exige une méthode spécialisée, spécifique au produit, qui n'est pas disponible au Canada :

Yes/Oui ☐ No/Non ☐

If yes, please specify (e.g. unique bioassay involving the use of cell lines or animals) :
Dans l'affirmative, veuillez préciser (p. ex. dosage biologique particulier exigeant le recours à des lignées cellulaires ou à des animaux) :

Alternate Sample Retention Site Application Form (…continued)
Formulaire de demande de site alternatif pour la rétention d'échantillons (…suite)

b. This product is subject to Health Canada's lot release programme :
Le produit est visé par le programme d'autorisation de mise en circulation des lots de Santé Canada :
Yes/Oui ☐ No/Non ☐

c. Estimated Canadian utilization :
Consommation canadienne estimative :
i. Approximate number of lots sold annually in Canada :
Nombre approximatif de lots vendus annuellement au Canada :
ii. Approximate number of units sold annually in Canada :
Nombre approximatif d'unités vendues annuellement au Canada :

d. Average batch size imported to Canada / *Taille moyenne d'un lot de fabrication importé au Canada* :

e. Approximate unit cost/value per sample / *Coût/valeur unitaire approximatif par échantillon* :

f. Shelf life of perishable drug / *Durée de vie de la drogue périssable* :

g. Radiopharmaceuticals / *Produits radiopharmaceutiques* :
Yes/Oui ☐ No/Non ☐

h. Non-prescription drug (see Category IV product monographs) :
Drogues en vente libre (voir les monographies de produit de la catégorie IV):
Yes/Oui ☐ (Specify below/*Spécifier ci-dessous)* No/Non ☐

☐ Acne therapies / *produits contre l'acné (topique)*
☐ Anti dandruff products / *produits antipelliculaires*
☐ Antiperspirants / *produits antisudorifiques*
☐ Antiseptic skin cleansers / *nettoyants antiseptiques pour la peau*
☐ Athletes foot treatments / *traitements contre le pied d'athlète*
☐ Fluoride-containing anti-caries products / *produits contre la carie dentaire contenant du fluorure*
☐ Medicated skin care products / *produits médicamenteux pour le soin de la peau*
☐ Sunburn protectants / *agents de protection solaire*

i. Hard surface disinfectants / *désinfectants pour surface dure* :
Yes/Oui ☐ No/Non ☐

j. The fabricator of the drug is located in Canada and is responsible for keeping the retained samples.
Le manufacturier du médicament est situé au Canada et est responsable de la rétention d'échantillons.
Yes/Oui ☐ (Complete section 4 / Remplir la section 4) No/Non ☐

Alternate Sample Retention Site Application Form (…continued)
Formulaire de demande de site alternatif pour la rétention d'échantillons (…suite)

6. Attestation / *Attestation*

We have formally arranged with the storage site to maintain sufficient numbers of samples of lots and retained as per storage conditions indicated on the label, with the same container-closure sold in Canada to allow access by all pertinent regulatory authorities including Health Canada.
Nous avons pris des dispositions officielles avec l'établissement d'entreposage pour qu'il conserve, conformément aux conditions d'entreposage indiquées sur l'étiquette, des nombres suffisants d'échantillons de lots doté du même système contenant-fermeture vendus au Canada de manière à ce que toutes les autorités réglementaires concernées, y compris Santé Canada, puissent y avoir accès.

Yes/Oui ☐ No/Non ☐

7. Commitment / *Engagement*

We have a written commitment with the responsible person at the storage site that samples will be provided within 48 hours of receiving a request from Health Canada.
Nous avons un engagement écrit avec la personne responsable de l'établissement d'entreposage pour qu'il fournisse des échantillons dans les 48 heures qui suivent la réception d'une demande provenant de Santé Canada.

Signature, Responsible Officer / *Signature de l'agent responsable* :
Title / *Titre* :
Emergency Telephone Number / *Numéro de téléphone en cas d'urgence* :

INTENTION TO INVOKE SECTION 37 OF THE CANADA FOOD AND DRUGS ACT FOR PRODUCTS BEING EXPORTED

Section 37 of the Food and Drugs Act states as follows:

"This Act does not apply to any packaged food, drug, cosmetic or device, not manufactured for consumption in Canada and not sold for consumption in Canada, if the package is marked in distinct overprinting with the word <<Export>> or <<Exportation>> and a certificate that the package and its contents do not contravene any known requirement of the law of the country to which it is or is about to be consigned has been issued in respect of the package and its contents in prescribed form and manner."

The Export Certificate that must accompany the packaged food, drug, cosmetic or device can be found on the Health Canada website Establishment Licensing page at :

http://hc-sc.gc.ca/dhp-mps/compli-conform/licences/index_e.html

You are asked to inform us of the packages and contents of products that are exported in compliance with Section 37 of the Food and Drug Act at the time of Drug Establishment Licence renewal. This form must be used when you intend to invoke Section 37 for any drug products fabricated in Canada that you are to export. Please complete the following and return this document to the Health Products and Food Branch Inspectorate at fax (613) 957-6709 or e-mail it to GMP_Questions_BPF@hc-sc.gc.ca .

Drug Establishment Licence Number: _____

Name of Establishment: _____

☐ The above establishment does not intend to invoke Section 37 for any products that they are exporting.

☐ As the above establishment intends to invoke Section 37 for exportation, I ensure that the Export Certificate has been duly signed by the Commissioner of Taking Oaths, that the Export Certificate is kept on the premises and covers the following products: **(An attached list is acceptable.)**

Please provide a copy of the duly signed Export Certificate for these packages.

Product name	DIN (if any)	Dosage Form	Strength	Lot number	Expiry Date	Sterile (Y) or (N)

If you intend to market the same products for consumption in Canada, please provide a statement of confirmation that the manufacturing of the packages for consumption in Canada meets all Good Manufacturing Practices.

Be advised that evidence of Good Manufacturing Practices compliance is required to rescind Section 37.

Name of Regulatory Person: _____

Signature of Regulatory Person:_____

Date: _____

Drug Establishment Licence Fee Form

Company Name:		**DEL #:**
Mailing Address		
Street:	Suite:	Post Office Box:
City:	Province:	Postal Code:
Contact Person:		Language: ☐ English ☐ French
Telephone:	Fax:	Email:
Billing Address ☐ same as mailing address		
Street:	Suite:	Post Office Box:
City:	Province:	Postal Code:
Contact Person:		Language: ☐ English ☐ French
Telephone:	Fax:	Email:

ONLY for applicants who have not completed their first calendar year:

"I certify that I have not completed my first calendar year of conducting activities under an establishment licence".

Name of Authorized Signing Official	**Title**	**Signature**	**Date (yyyy-mm-dd)**

For all applicants

"I certify that the information given on this form and in any documents attached is correct, complete, and fully discloses the total Canadian revenue from the sales of products covered by the establishment licence"

Name of Authorized Signing Official	**Title**	**Signature**	**Date (yyyy-mm-dd)**