AmerisourceBergen
Innomar Strategies

Drug Establishment Licensing: An Industry Perspective

Wednesday November 24, 2021

Agenda

01 Overview of the current process to obtain a Drug Establishment Licence

02 Brief discussion on Health Canada inspections

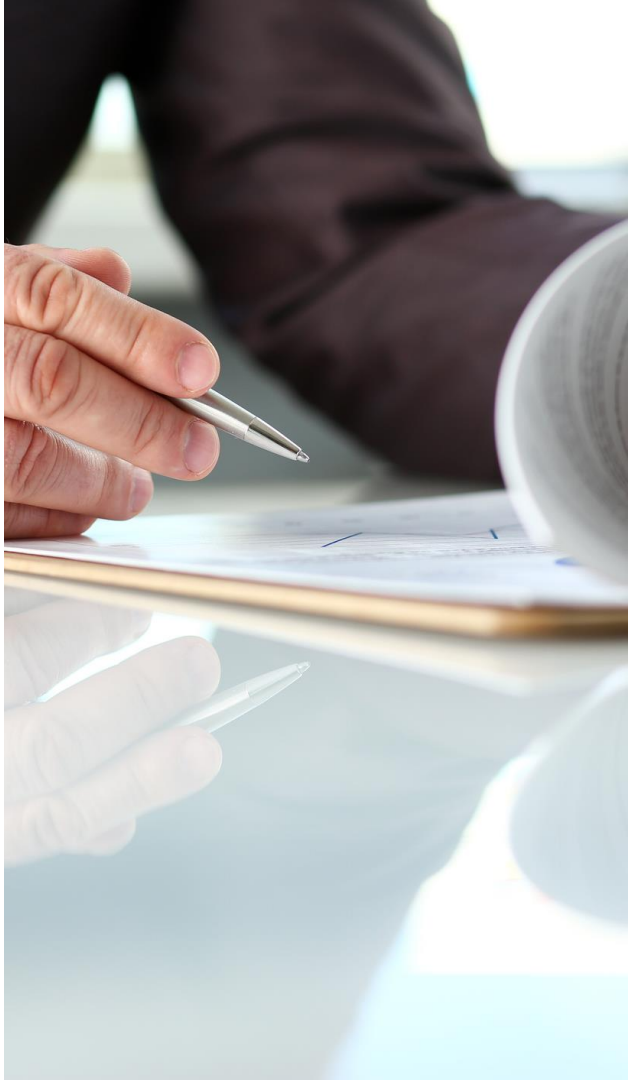
03 Review of DEL fees

04 Provide details into the Foreign Site amendment process for an Importer DEL

05 Brief discussion on DEL renewals

06 DEL management advice

07 COVID interim measures discussion



What is a Drug Establishment Licence?

A Drug Establishment Licence (DEL) is a document issued by Health Canada to an establishment in Canada to authorize that site to conduct drug related activities in compliance with Good Manufacturing Practices (GMP)

Guidance on Drug Establishment Licences can be found in GUI-0002

https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/guidance-drug-establishment-licences-drug-establishment-licensing-fees-0002/document.html

What category of drugs are governed by a DEL?

- 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 of Schedule C (radiopharmaceutical) and Schedule D (biological) drugs

DEL licensable activities

A drug establishment licence is required by any person/company conducting any of the 6 licensable activities listed with respect to a drug

01 Fabricate
02 Import
03 Package/Label
04 Distribute
05 Test
06 Wholesale

Parts of an Importer DEL

Consists of the following parts:

- Main licence to allow the importation and sale of drug products
- Foreign building annex (importers only)
- Warehouse annex
- Alternate sample retention building annex (usually for importers)
- API foreign building annex (importers only)

Drug Establishment Licence (DEL)

Health Canada / Santé Canada

Establishment Licence / **Licence d'établissement**

Licence No. / No. de la licence
101487-C

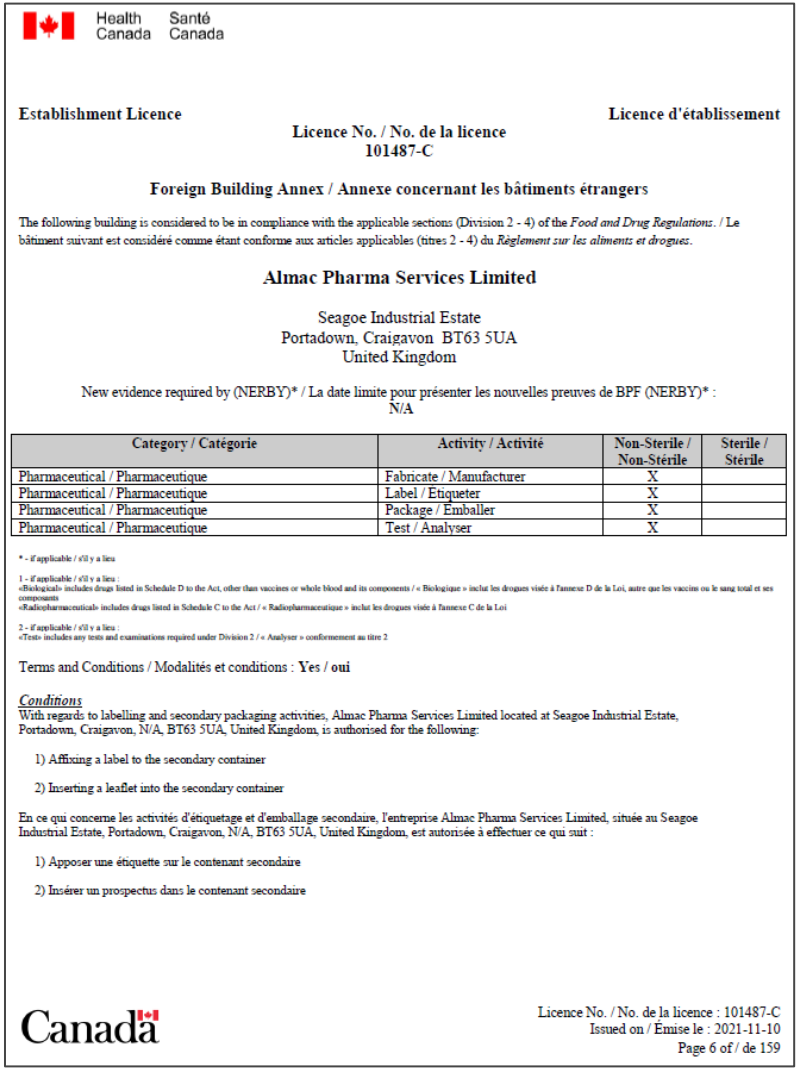
Innomar Strategies Inc

8030 Esquesing Line
Unit B
Milton ON L9T 6W3

This licence is issued in accordance with the *Food and Drugs Act and Regulations* (Division 1A) for the following activities /
Cette licence est délivrée conformément à la *Loi et au Règlement sur les aliments et drogues* (titre 1A) pour les activités et les catégories de drogues suivants :

Category / Catégorie	Activity / Activité	Non-Sterile / Non-Stérile	Sterile / Stérile
Pharmaceutical / Pharmaceutique	Distribute / Distribuer	X	
Active Pharmaceutical Ingredients / Ingrédient actif pharmaceutique	Import / Importer	X	
Biological / Biologique	Import / Importer	X	X
Pharmaceutical / Pharmaceutique	Import / Importer	X	X
Vaccine / Vaccin	Import / Importer	X	X
Biological / Biologique	Label / Étiqueter	X	X
Pharmaceutical / Pharmaceutique	Label / Étiqueter	X	X
Vaccine / Vaccin	Label / Étiqueter	X	X
Biological / Biologique	Package / Emballer	X	X
Pharmaceutical / Pharmaceutique	Package / Emballer	X	X
Vaccine / Vaccin	Package / Emballer	X	X
Biological / Biologique	Wholesale / Vendre en gros	X	X
Prescription Drug List, Schedule G, Narcotics, and/or Drug containing Cannabis / Liste des drogues sur ordonnance, l'Annexe G, Stupéfiants et/ou Drogue contenant du Cannabis	Wholesale / Vendre en gros	X	X
Vaccine / Vaccin	Wholesale / Vendre en gros	X	X

Foreign Building Annex



Health Canada Santé Canada

Establishment Licence **Licence d'établissement**

Licence No. / No. de la licence
101487-C

Foreign Building Annex / Annexe concernant les bâtiments étrangers

The following building is considered to be in compliance with the applicable sections (Division 2 - 4) of the *Food and Drug Regulations*. / Le bâtiment suivant est considéré comme étant conforme aux articles applicables (titres 2 - 4) du *Règlement sur les aliments et drogues*.

Almac Pharma Services Limited

Seagoe Industrial Estate
Portadown, Craigavon BT63 5UA
United Kingdom

New evidence required by (NERBY)* / La date limite pour présenter les nouvelles preuves de BPF (NERBY)* :
N/A

Category / Catégorie	Activity / Activité	Non-Sterile / Non-Stérile	Sterile / Stérile
Pharmaceutical / Pharmaceutique	Fabricate / Manufacturer	X	
Pharmaceutical / Pharmaceutique	Label / Étiqueter	X	
Pharmaceutical / Pharmaceutique	Package / Emballer	X	
Pharmaceutical / Pharmaceutique	Test / Analyser	X	

* - if applicable / s'il y a lieu

1 - if applicable / s'il y a lieu :
«Biological» includes drugs listed in Schedule D to the Act, other than vaccines or whole blood and its components / « Biologique » inclut les drogues visée à l'annexe D de la Loi, autre que les vaccins ou le sang total et ses composants
«Radiopharmaceutical» includes drugs listed in Schedule C to the Act / « Radiopharmaceutique » inclut les drogues visée à l'annexe C de la Loi

2 - if applicable / s'il y a lieu :
«Test» includes any tests and examinations required under Division 2 / « Analyser » conformement au titre 2

Terms and Conditions / Modalités et conditions : **Yes / oui**

Conditions
With regards to labelling and secondary packaging activities, Almac Pharma Services Limited located at Seagoe Industrial Estate, Portadown, Craigavon, N/A, BT63 5UA, United Kingdom, is authorised for the following:

1) Affixing a label to the secondary container

2) Inserting a leaflet into the secondary container

En ce qui concerne les activités d'étiquetage et d'emballage secondaire, l'entreprise Almac Pharma Services Limited, située au Seagoe Industrial Estate, Portadown, Craigavon, N/A, BT63 5UA, United Kingdom, est autorisée à effectuer ce qui suit :

1) Apposer une étiquette sur le contenant secondaire

2) Insérer un prospectus dans le contenant secondaire

Canada

Licence No. / No. de la licence : 101487-C
Issued on / Émise le : 2021-11-10
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Warehouse Annex

Health Canada / Santé Canada

Establishment Licence / **Licence d'établissement**

Licence No. / No. de la licence
101487-C

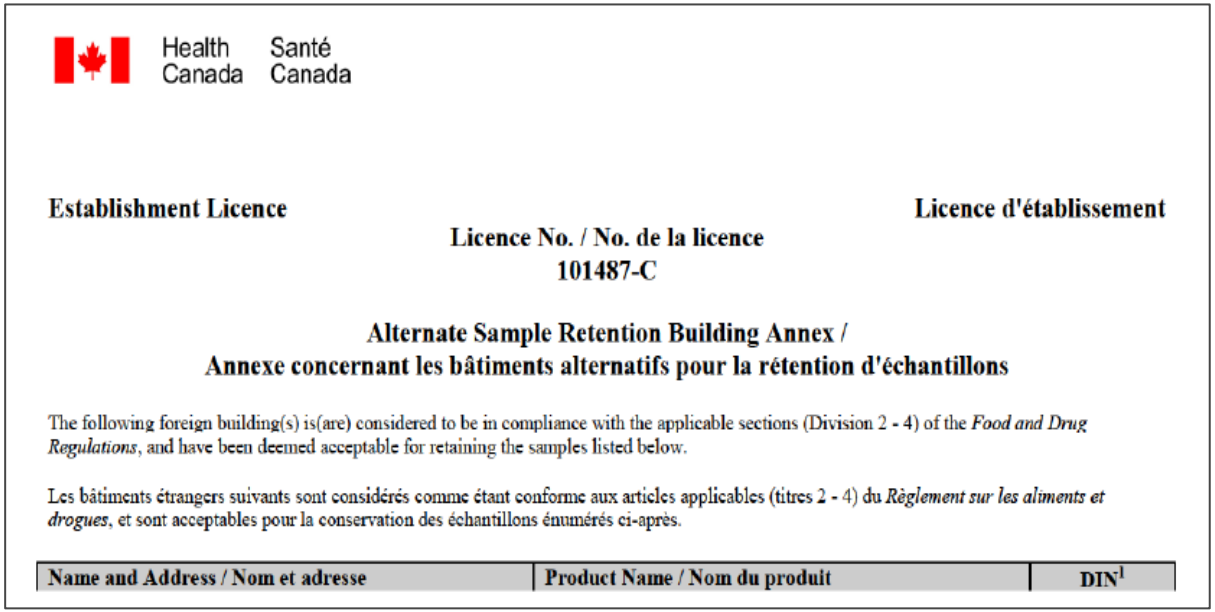
Warehouse Annex / Annexe des entrepôts

Pursuant to C.01A.008(2)(b) of the *Food and Drug Regulations*, the holder of this establishment licence is authorized to store the category(ies) of drugs, as approved on the first page of this licence, at the following Canadian building(s).

En vertu de l'article C.01A.008(2)(b) du *Règlement sur les aliments et drogues*, le détenteur de cette licence est autorisé d'entreposer les catégories de drogues, tel qu'approuvé à la première page de cette licence, dans les bâtiments canadiens suivants.

Warehouse Name / Nom d'entrepôt	Address / Adresse
Innomar Strategies Inc	101-5898 Trapp Avenue, Burnaby, BC, V3N 5G4
Innomar Strategies Inc	26 Akerly Boulevard, Unit 1, Dartmouth, NS, B3B 0K4
Innomar Strategies Inc	8030 Esquesing Line, Unit B, Milton, ON, L9T 6W3
Lynden International Logistics Co.	10 Corrine Court, Vaughan, ON, L4K 4T7
Lynden International Logistics Co.	4441 76th Avenue S.E., West Building, Calgary, AB, T2C 2G8
Lynden International Logistics Co.	7403 Progress Way, Delta, BC, V4G 1E7
McKesson Specialized Distribution Inc.	8449 Lawson Road, Unit 102, Milton, ON, L9T 9L1

Alternate sample – Retention Building Annex



Health Canada / Santé Canada

Establishment Licence / **Licence d'établissement**

Licence No. / No. de la licence
101487-C

Alternate Sample Retention Building Annex /
Annexe concernant les bâtiments alternatifs pour la rétention d'échantillons

The following foreign building(s) is(are) considered to be in compliance with the applicable sections (Division 2 - 4) of the *Food and Drug Regulations*, and have been deemed acceptable for retaining the samples listed below.

Les bâtiments étrangers suivants sont considérés comme étant conforme aux articles applicables (titres 2 - 4) du *Règlement sur les aliments et drogues*, et sont acceptables pour la conservation des échantillons énumérés ci-après.

Name and Address / Nom et adresse	Product Name / Nom du produit	DIN[1]

Alternate Sample Retention Site Guidelines (GUI-0014):
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/forms/alternate-sample-retention-site-guidelines-0014.html

API Foreign Building Annex

Health Canada / Santé Canada

101487-C

Innomar Strategies Inc

8030 Esquesing Line
Unit B, Milton, ON, L9T 6W3, Canada

Active Pharmaceutical Ingredient Foreign Building Annex /
Annexe concernant les bâtiments étrangers d'ingrédients pharmaceutiques actifs

This is an annex to the Drug Establishment Licence #101487-C which contains all foreign buildings conducting regulated activities for active pharmaceutical ingredients (API). The information included in this annex supersedes the information in any previous API Foreign Building Annex. The buildings listed below are subject to ongoing assessment of compliance with the Good Manufacturing Practices pursuant to Part C, Division 2 of the *Food and Drug Regulations*.

La présente annexe concerne la licence d'établissement de produits pharmaceutiques no 101487-C, et traite de tous les bâtiments étrangers où on effectue des activités réglementées comportant des ingrédients pharmaceutiques actifs (IPA). L'information contenue dans cette annexe remplace celle de toute autre annexe soumise précédemment sur des bâtiments étrangers comportant des IPA. Les bâtiments de la liste ci-dessous sont sujets à des évaluations continues de la conformité à l'égard des bonnes pratiques de fabrication en vertu de la partie C, titre 2, du *Règlement sur les aliments et drogues*.

The API category authorized by this annex are / Les classes d'IPA autorisée par la présente annexe sont les suivants:

API / IPA

API Name / Nom de l'IPA	Activity[1] / Activité[1]	Foreign Building Name[2] / Nom du bâtiment étranger[2]	Street, City, Postal Code / Rue, Ville, Code postal	Province / State / État	Country / Pays

Overview of DEL fees

Fees for Examination of an Application for an Establishment Licence – Drugs for Human Use

https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/fees-drugs-medical-devices.html

Example:

If on March 31, 2022 you are an importer and have 20 foreign sites on your DEL, your Fee will be:

$ 29,033 + 20 x $ 918

= $ 47,393

Fees for Examination of an Application for an Establishment Licence – Drugs for Human Use

Item	Name of Fee	Description	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Performance Standard
-	Drug Establishment Licence	Application for new licence, annual review of licence, or amendment to a licence to add a new building in Canada	-	-	-	-	250 calendar days to issue decision
Activity							
1	Fabrication — sterile dosage form	-	$41,626	$41,730	$41,834	$41,937	
2	Importation	-	$27,359	$29,033	$30,707	$32,380	
3	Fabrication — nonsterile dosage form	-	$27,000	$28,364	$29,727	$31,091	
4	Distribution	-	$12,560	$13,882	$15,205	$16,527	
5	Wholesaling	-	$4,937	$6,171	$7,715	$9,644	
6	Packaging/labelling	-	$6,061	$6,061	$6,061	$6,061	
7	Testing	-	$2,560	$3,200	$4,001	$5,002	
8	Foreign building (Each)	-	$918	$918	$918	$918	

Process for obtaining a new DEL

- Apply at least 250 days prior to needing authorization to perform your activity.
- You will have an inspection no later than day 190 after your application date. This provides HC with 30 days to inspect your site and finalize their report and also allows 30 days for your site to respond to any observations.
- In reality, the inspection usually occurs 3-4 months after the DEL application, but theoretically it can be scheduled anytime.

Initial inspection

1. HC inspection of the following:
   - Quality System (SOPs)
   - Quality Agreements
   - Training
   - Facility Inspection (if applicable)
2. Receive Inspection Exit Notice (usually within 20 days of the inspection)
3. The observations will be posted on the HC website
4. Respond to observations within 30 days
5. Receive Close out Letter

Periodic Health Canada inspections

Based on your activity you will be re-inspected by Health Canada on a periodic basis or when there is a major change to the activity on your DEL.

This inspection will include all aspects of the initial inspection as well as verification that the quality system is being followed and is in compliance to Canadian GMPs.

Items typically reviewed after the initial inspection:

- Quality System (SOPs)
- Quality Agreements
- Training
- Facility Inspection (if applicable)
- Release and distribution records
- Deviations
- Change controls
- Complaints
- Recalls and mock recalls
- Annual requirements
- Self-inspection reports
- Master documents
- Table A GMP evidence

Inspection frequency

Table 2.0 Domestic Establishment Inspection Frequency

Activity[1]	Sterile	Non-Sterile	Inspection Frequency (target - years)
Sterile Fabrication (includes sterile packaging)	✔	N/A[3]	2
Non-sterile Fabrication	N/A[3]	✔	3
Primary Packaging/Labelling	N/A[3]	✔	3
Testing	✔	✔	3
Medical Mixed Gases — All Licensable Activities	N/A[3]	✔	3
Secondary Packaging/Labelling	✔	✔	4
Importation	✔	✔	4
Distribution[2]	✔	✔	4
Wholesale[2]	✔	✔	4
Medical Single Gases — All Licensable Activities	N/A[3]	✔	4

[1] If an establishment is conducting multiple activities at the same time, the higher risk activity may dictate the inspection cycle.
[2] Distribution and wholesale are not licensable activities for APIs.
[3] Not applicable

What is required for a DEL application?

- Cover letter
- FRM-0033 (Application form)
  - Part A: Company information
  - Part B: Canadian building information
  - Section 2: Date of last HC GMP inspection
  - Section 3.0: Domestic Dosage Form
  - Section 3.1: Domestic API Information
- GMP evidence (if the foreign site is not covered by an MRA)
- Table A Excel Spreadsheet (if API suppliers are being added)
- Section 4.0: Domestic FDF
- Section 4.1: Domestic API FDF
- Section 5.0: FDF foreign building information
- Section 5.1: API foreign building information
- Part C: Canadian warehouse information
- Past D: Alternate sample retention application

Drug Establishment Licence application form (FRM-0033)

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

Mutual Recognition Agreements (MRA)

- Health Canada is a partner in several mutual recognition agreements covering GMP compliance programs for drug products
- Apply only to foreign buildings located within the MRA partners jurisdiction for products and categories covered by the MRA
- Due to established equivalency Health Canada will accept reduced GMP evidence –Certificate of Compliance

Detailed List of all Sites with a signed MRA with Canada:

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

DEL (Importation) – Foreign Site Amendment

In addition to the application that is submitted for any activity an importer must have any foreign site performing licensable activities added to their license.

This is done in the same way as a Canadian site is added to a DEL: Health Canada audits the compliance of the site against the Canadian GMPs.

If you are filing an NDS, any site listed as conducting GMP activities must be considered GMP compliant.
If the site is a foreign manufacturer, packager or tester then that site must either be on the DEL associated with the importation of the new drug product or an amendment to add that site to the DEL must have been submitted at least 90 days prior to the NDS.

Documentation requirements to add a Foreign Site to a DEL

GMP evidence for a finished product manufacturing, packager or release tester:

1. Inspection Report (<3 years old), Observations and Responses
2. Site Master File (a Quality Manual is acceptable for a test site)

Note: If a site is in an MRA country then you do not submit GMP information, you ask HC to request a CofC for the site.

Inspections:
must be conducted by a member of PIC/S
https://picscheme.org/en/members

Foreign Sites:
provide the name and address of each DP and DS manufacturer, packager, and test site

Description of Finished Product:
must include strengths and dosage form

Information requirements to add a foreign test site to a DEL

For any site conducting drug product or drug substance

Specify the type of testing as per the following:

a) Biological
b) Chemical
c) In process
d) Microbiological – sterility
e) Microbiological
f) Physicochemical
g) Stability
h) Other (specify)

Documentation requirements to add an API site to Table A

01 Evidence of GMP compliance (e.g. Inspection report, Certificate of Compliance)

02 API Name

03 API form (solid, liquid or gas)

04 Activity performed at the site (A: manufacture, B: package, C: label, D: test)

05 Date of last inspection and by what agency

06 Has the building been found non-compliant in the last 5 years?

Submitted the application ? Now what?

- Receive Health Canada auto reply to indicate they received your application (immediate)
- Receive Acknowledgment of Application Acceptance and App# (usually within 5 days, up to 20 days)
- First Clarification Request (Screening)
- Receive screening deficiency notices
- Respond to deficiency notices
- Re-submit your section 5 to make your address match what Health Canada has in their database
- DEL Screening Completion Notice
- Wait… Wait… Wait… (90 -250 days)
- Foreign Building GMP Compliance Notification
- Receive signed DEL from Health Canada

DEL Issuance

- This will occur prior to the 250 days
- You will be invoiced the DEL charge after the license has been issued
- Once you have the signed licence you are authorized to perform the activity on your DEL

Expedited Review

- If you have a drug considered as medically necessary or if the NDS has a priority review, then the DEL approval process can be as fast as 60–90 days
- COVID-19 DEL sites can be approved within days.

DEL Renewal

Prior to April 1st of every year, you must submit a renewal, or your DEL will be cancelled. (A renewal package will be sent in January)

This is when you confirm that you are still using your DEL and that you are complying with GMPs. This is also your opportunity to remove any foreign sites that are no longer needed so that you avoid being charged for the upcoming year.

Health Canada will issue an invoice for you DEL activities based on your renewal

Note: If your initial DEL is issued prior to April 1st, you will be required to renew this DEL before April 1st. The renewal will also be charged the DEL fee.

Example:

If your DEL is issued March 1st and has a charge of $30,000, in April you will renew and be charged an additional $30,000.

I had an experience with this where the DEL office contacted me and suggested they hold off on issuance of the DEL until April 1st. I would not be using the DEL until later in the year, so I agreed and avoided the double charge.

DEL Renewal

DEL Main Licence – Renewal (Annually)

For importers this is the time where any API and DP foreign sites are confirmed as being still in use and GMP compliant. Each site is then linked to the specific DIN that they are performing activities for.

DEL (Importation) – Foreign Site Renewal (Based on NERBY Date)

Sites located in non-MRA countries are assigned a NERBY (New Evidence Required By) date. This is the date when the process for adding a foreign site is repeated so that Health Canada can once again review the site's status and authorize its use by applying a new NERBY date or by rejecting the site and having removed from your DEL.

Note: Currently no sites expire due to COVID

DEL management

Currently Innomar manages 10 DELs (each with their own quality system), which include:

- 2 Innomar DELs
- 8 Client importer DELs where Innomar acts as the QA Unit and fully manages all quality activities on behalf of the client
- Requires management of ~450 foreign sites
- The key to DEL management is a good tracking system

DEL management

Sample portion of DEL Tracker

Foreign Site Name	Foreign Site Address	Category	MRA or Non-MRA	Activity (FP)	Release Testing of API?	Table A Activity (API)	Testing Categories (a-h)	GMP Expiry	Renew By (-60 Days for non-MRA)	Date Submitted to HC	Status	Response Due Date
Aesica Pharmaceuticals Limited	Windmill Industrial Estate, Cramlington, UK, NE23 3JL	Pharmaceutical	MRA	None	No	A, B, C, D		March 23, 2021	January 22, 2021		Expired	
AGC Biologics	21501 23rd Dr. SE Bothell, WA, 98021, USA	Vaccine	Non-MRA	Mnf, Test	Yes	None	DS: b,c,e,f			June 3, 2021	Pending	February 8, 2022
AGC Biologics A/S	Vandtaarnsvej 83B, DK-2860, Soeborg, Copenhagen, Denmark	Vaccine	MRA	Mnf, Test	Yes	None	DS: b,c,e,f			June 3, 2021	Pending	February 8, 2022
AGES GmbH IMED	Beethovenstraße 6, 8010, Graz, Austria	Pharmaceutical	MRA	None	Yes	None	DS: e	N/A	No Renewal		Good	
Agilent Technologies Inc.	5555 Airport Blvd, Boulder, CO, 80301, USA	Pharmaceutical	Non-MRA	None	Yes	A, B, C, D	DS: b,e,f	February 13, 2022	December 15, 2021	February 12, 2021	Submitted	October 20, 2021
Ajinomoto Althea, Inc.	11030 Roselle Street, San Diego, California, 92121, USA (Building 3)	Pharmaceutical	Non-MRA	Manufacture	No	None	N/A	May 23, 2021	March 24, 2021	May 13, 2021	Submitted	January 18, 2022
Ajinomoto Althea, Inc.	11040 Roselle Street, San Diego, California, 92121, USA (Building 1)	Pharmaceutical	Non-MRA	Test	No	None	c,d	December 16, 2023	October 17, 2023		Good	
Albemarle Corporation	1421 Kalamazoo St., South Haven, MI 49090, USA	Pharmaceutical	Non-MRA	None	Yes	A, B, C, D		December 4, 2021	October 5, 2021		Overdue	
ALCALIBER S.A.U.	Avenida Ventalomar, 1-Polígono Industrial de Toledo, 45007, Toledo, Spain	Pharmaceutical	MRA	None	No	A		N/A	No Renewal		Good	
Alkaloid AD Skopje	Blvd. Aleksandar Makedonski 12, 1000, Skopje, Republic of Macedonia	Pharmaceutical	Non-MRA	Mnf, Pck, Lbl, Test	No	None		September 23, 2023	July 25, 2023		Good	
Almac Pharma Services Limited	Seagoe Industrial Estate, Portadown, Craigavon, BT63 5UA, United Kingdom	Pharmaceutical	MRA	Mnf, Pck, Lbl, Test	No	None		N/A	No Renewal		Good	
Alpha-Pharma-Service GmbH	Badstr. 36-38, 74072, Heilbronn, Germany	Pharmaceutical	MRA	None	Yes	None	DS: b,c,f,g	N/A	No Renewal		Good	
ALS Food and Pharmaceutical	2 Bartholomew's Walk, Angel Drove, Cambridgeshire Business Park, Ely, Cambridgeshire, CB7 4ZE, England, UK	Biologic	MRA	Test	No	None		N/A	No Renewal		Good	
Amoli Organics Private Limited	Plot No 522/4, 40 Shed Area, GI.D.C., Vapi, 396 195, Gujarat, India	Pharmaceutical	Non-MRA	None	No	A, B, C, D		March 30, 2020	January 30, 2020		Expired	
Ampac Fine Chemicals	1100 Windfield Way, El Dorado Hills, CA, 95762, USA	Pharmaceutical	Non-MRA	None	Yes	None	DS: b,f			July 9, 2021	Pending	March 16, 2022
Ampac Fine Chemicals	Highway 50 and Hazel Avenue, Rancho Cordova, CA, 95670, USA	Pharmaceutical	Non-MRA	None	Yes	A, B, C, D	DS: b,g			July 9, 2021	Pending	March 16, 2022
AMRI SSCI, LLC	3065 Kent Avenue, West Lafayette, IN 47906, USA	Pharmaceutical	Non-MRA	None	Yes	None		November 4, 2023	September 5, 2023		Good	
Anderson Brecon Inc DBA PCI of Illinois	4545 Assembly Drive, Rockford, IL, 61109-3081, USA	Pharmaceutical	Non-MRA	Package/Label	No	None	N/A	October 30, 2023	August 31, 2023		Good	
Arevipharma GmbH	Meissner Strasse 35, 01445 Radebeul, Germany	Pharmaceutical	MRA	None	Yes	A, B, C, D		N/A	No Renewal		Good	
AS Grindeks	53 Krustpils Street, Riga, LV-1057, Latvia	Pharmaceutical	Non-MRA	Test	No	None		June 6, 2021	April 7, 2021		Expired	

DEL management

- The tracker Innomar uses is a simple Excel spreadsheet with data for approx. 25 information types
- There are built in formulas to warn when sites are expiring and to estimate Health Canada completion dates
- Choose what works for you based on the complexity of the sites you need to maintain

Recommended items to track

- Foreign Site name and address
- Category of Drug
- Dosage Form
- Activity at site
- Testing categories
- GMP expiry date
- GMP Renewal date
- Submission Date
- Tracking #
- Status of site
- Expected approval date
- Actual approval date
- etc...

ISAD interim order expiry – records

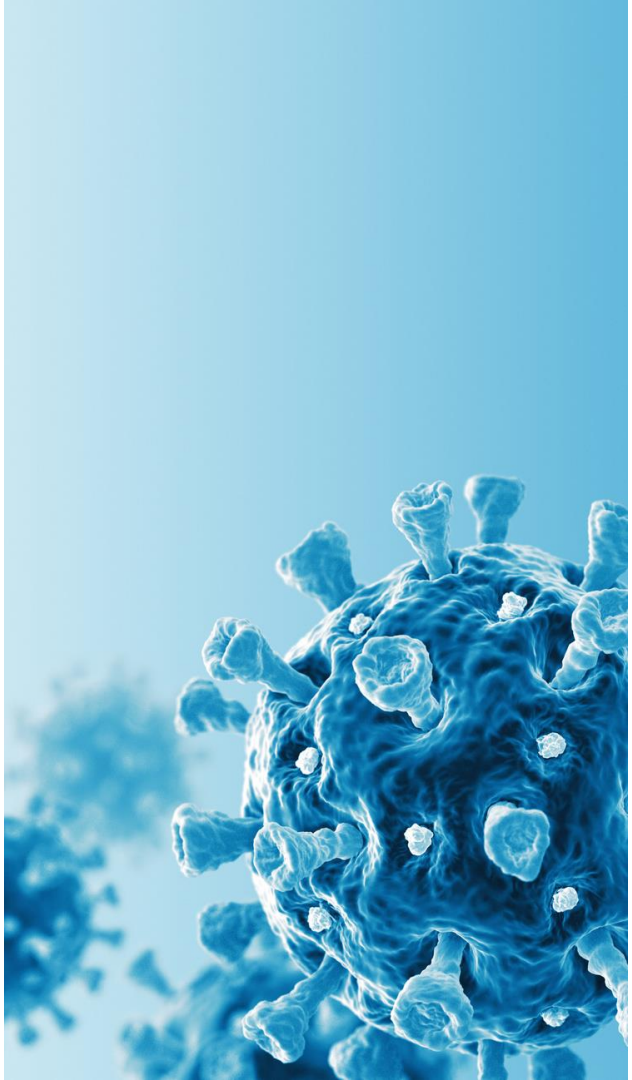
In relation to COVID-19 drugs, an importer is required to maintain the following (previously exempt) records on-site as outlined in C.02.020 upon expiry of the ISAD interim order.

Master Batch Records

- **Finished Product and stability specifications**
- **Master Manufacturing Instructions**
- **Master Packaging Instructions**
- **Analytical Methods**
- **API specifications**

Stability Data

Evidence of Validation



COVID interim measures

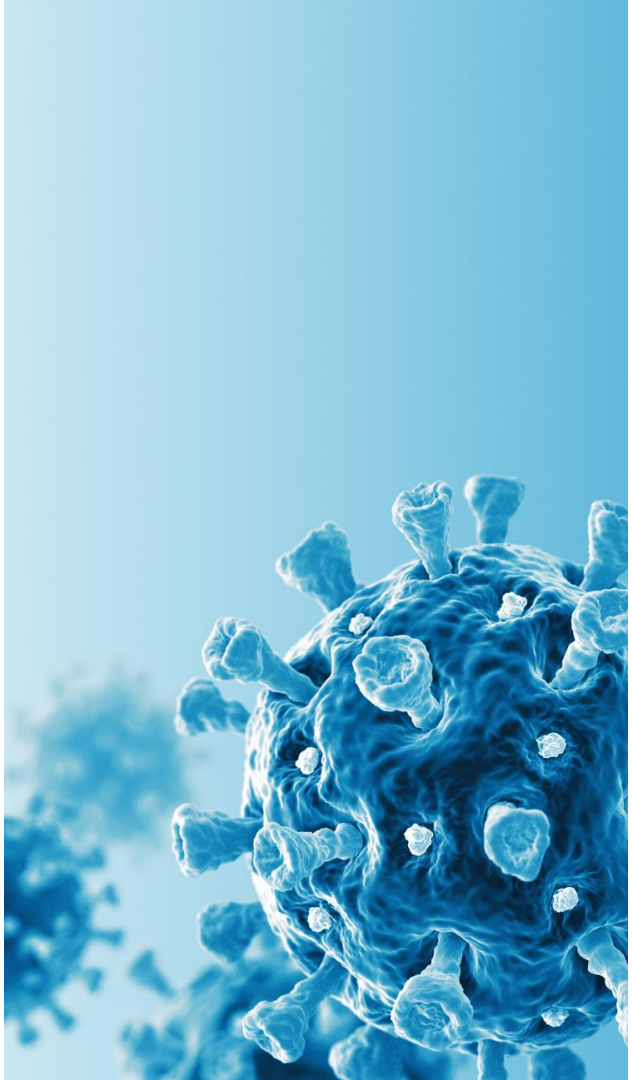
Testing - Flexibilities related to identity testing and confirmatory testing as outlined in DEL bulletin 76 continue to apply.

Apply expanded use of unique identifiers to allow for confirmation of identity based on physical verification in lieu of chemical ID.

- visual inspection of the labelling on samples of product taken from each batch received against approved product labelling
- visual comparison of the drug in dosage form against that of previously retained samples or other comparative information
- application of physical measurements (e.g. dimensions, volume, etc.) of a sample of the drug in dosage form.

Defer confirmatory testing when required.

Health Canada will accept deferment of confirmatory testing requirements if companies are not able to conduct such tests. As per GUI-0001 “Good manufacturing practices guide for drug products” requirements, product may be released for sale before the completion of confirmatory testing provided all other product release requirements are met.



COVID interim measures

Inspections

At this time, foreign on-site inspections are limited to regions where safe travel is ensured, or in cases where an on-site visit is critical for facilitating responses to the COVID-19 pandemic, or preventing a shortage of a medically necessary drug

Remote assessments are being considered on a case-by-case basis using a risk-based criteria, including but not limited to:

- The nature of the product
  i.e., urgent need for the product, medical necessity of the product
- Compliance history of the foreign building
- Whether other trusted regulatory authorities are planning to inspect the foreign building

Information regarding Health Canada's approach to on-site inspections during COVID-19 can be found in this notice: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/onsite-inspections-notice.html

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Questions?

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thank
you