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Drug Establishment Licence Developments

June 17, 2025

Agenda

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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

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

Where We Stand

Over the course of the pandemic, Health Canada introduced temporary measures in response to challenges created by the COVID-19 pandemic.

One of these measures was to provide an indefinite extension to the “new evidence required by” (NERBY) dates assigned to foreign buildings on the foreign building (FB) annex. This was lifted on December 31, 2024.

DEL holders who relied on this temporary measure should have submitted DEL amendment applications (with updated good manufacturing practices (GMP) evidence) to renew the foreign buildings before January 1, 2025.

Source: DEL Bulletin 174

What's Next?

Health Canada has been contacting DEL holders regarding:

1. Non-MRA sites with expired NERBY dates to begin the process of removing the site from the DEL.

2. MRA sites that do not have an updated CoC to submit a DEL amendment application, along with full GMP evidence, to maintain the building on the DEL. A NERBY date will then be assigned to the MRA site by Health Canada.

What should DEL holders do?

1. Renew sites with new GMP evidence as soon as possible

2. If no updated GMP evidence is available, DEL holders may
   - Request Health Canada to conduct an inspection of the foreign building
   - Submit an amendment to request a risk-based NERBY extension.

Source: DEL Bulletin 181

Requesting a NERBY Extension Date

- DEL holders can request for an extension of the NERBY date by submitting the following to el.applications-le@hc-sc.gc.ca :
    1. Cover letter
    2. “Drug Establishment Licence Application Form” (FRM-0033)
    3. “Risk-based New Evidence Required By (NERBY) date extension request form” (FRM-0559)

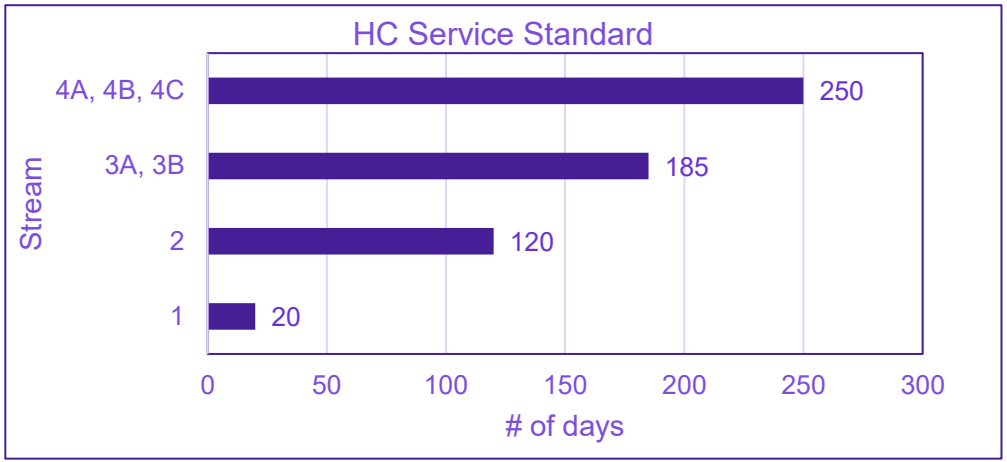
- HC will consider the risk profile of the foreign site to confirm eligibility for a NERBY extension, for example:
    - compliance history of the foreign building
    - the activities and the categories and dosage forms being handled at the foreign building
    - nature of the drugs (medical necessity, real or imminent drug shortage)
    - inspection method of the most recent Health Canada inspection (onsite or remote inspection)
    - eligibility to be supported by the submission of a corporate or consultant audit
    - assurance that GMP operations and any changes made to quality assurance management, equipment or manufacturing processes meet GMP requirements

Requesting Health Canada conduct an Inspection

- DEL holders can request HC for an inspection of a Foreign Building by submitting the following to el.applications-le@hc-sc.gc.ca :
  1. Cover letter
  2. “Request for Inspection of a Foreign Site Form” (FRM-0213)

- HC will assess the information provided. HC prioritizes foreign inspections using a risk based approach, including but not limited to:
  - The nature of the product (e.g. urgent need for the product)
  - Compliance history of the foreign building
  - Whether other trusted regulatory authorities are planning to inspect the foreign building

Health Canada Review Streams



Stream	Description	Examples
1	Administrative	Change: Contact info, warehouse annex, API Annex, Canadian building info
2	Abbreviated GMP compliance verification	Remove: FB, activity, category or dosage form from a FB Amend: CoC already reviewed by HC, domestic building inspection not required, Alternate Sample Retention site
3A, 3B	Leveraging existing GMP compliance review	Amend: CoC in Eudra, MHRA Database, GMP evidence already reviewed by HC (LoA from another importer) NERBY date extension-abbreviated review
4A, 4B, 4C	Comprehensive GMP review	New DEL Amend: domestic building and inspection is required, FB GMP evidence package has not been reviewed by HC NERBY date extension-full review

Source: GUI-0127

Scope or Review Type Change during DEL Amendments

With the introduction of the application streams, any changes to the scope and review type may lead to an application being rejected.

Example: A non-MRA site submitted full GMP evidence for review (Stream 4) however, the inspection was conducted by an MRA partner and EJCoC is available. Health Canada should have been requested to review the EJCoC (Stream 3) instead of the full GMP review. The application may be rejected due to review type change.

Source: GUI-0127

Foreign Building Name or Address Changes

If the foreign building name or address changes you must submit a DEL amendment.

- Non MRA foreign buildings or MRA foreign buildings for which a CoC is not available, submit:
  - a DEL application listing the foreign building name and address as it appears on the SMF (or equivalent)
  - the SMF (or equivalent) to support the change

- MRA foreign buildings for which a CoC is available submit:
  - a DEL application listing the foreign building name and address as it is listed on the CoC

  or

  - include an explanatory note in the cover letter accompanying the DEL application if a revised CoC listing the new name or address has not been issued. Health Canada will confirm the name and address with the applicable MRA regulatory authority before updating the DEL

Source: DEL Bulletin 166

Flexibilities for Packaging Component Sterilization Sites

Health Canada has announced additional flexibility for DEL holders when renewing or adding a foreign building performing sterilization of packaging materials to their DEL.

Health Canada will now accept third party audit reports based on the appropriate ISO standard, in situations where there is no GMP inspection report available.

When submitting applications with ISO audit reports, DEL holders should ensure the following:

- The ISO audit report should be completed against ISO 13485:2016 – Medical devices and the ISO standard covering the applicable type of sterilization being performed by the foreign building (for example, ISO 11137-3:2017 Sterilization of health care products for sites performing gamma irradiation).
- All of the information described under Section 5.3.1 - Corporate/consultant audits of GUI-0080 should also be submitted with the application.
- The auditor's resumé should demonstrate their knowledge and experience in ISO standards and conducting ISO audits.
- An ISO certificate, if available, should also be submitted but it should not be the only evidence submitted

Source: Communication to DEL holders further to DEL Bulletin 181

Thank you

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