Health Canada Santé Canada

**Protected B** When Completed

# Proposal for adding a foreign-authorized drug on the List of Drugs for Exceptional Importation and Sale (FRM-0522)

Through sections C.10.005 to C.10.011 of the *Food and Drug Regulations*, Health Canada may allow the importation and sale of certain foreign-authorized drugs in order to mitigate drug shortages. Health Canada prioritizes drugs that are in critical shortage (for example, a Tier 3 shortage). Companies may submit proposals for a drug to be added to the List of Drugs for Exceptional Importation and Sale by completing the form below and emailing it to drugshortages.prop.notif-penuriesmedicaments@hc-sc.gc.ca.

| **Part I: Importing Company Identifier** | | |
|---|---|---|
| Importing company name: | | |
| Importing company address: | | |
| Drug establishment license (DEL) number: | | |
| Are you licensed for this activity, category of drugs and dosage form? | O Yes | O No |
| Storage address in Canada: | | |
| **Key contact details (if a third party is involved in importation, please advise)** | | |
| Name: | | |
| Phone number: | | |
| Email address: | | |

| **Part II: Product Identifiers** | | | |
|---|---|---|---|
| **Product to be imported** | | | |
| Brand name: | | | |
| Medicinal ingredient(s): | | | |
| Dosage form: | | Strength: | |
| Is the finished product sterile? | O Yes O No | Is the API sterile? | O Yes O No |
| Route of administration: | | | |
| Storage conditions: | | | |
| Identifying code in authorizing country: | | Batch number (if available): | |

Canada

| **Name of Approved Canadian Product (if available)** | |
|---|---|
| Brand name: | |
| Medicinal ingredient(s): | |
| Dosage form: | Strength: |
| Route of administration: | |
| Identifying code: | |
| Status: | |
| **Please note** that importers should fill this section out even if they are not the authorization holder. | |
| **Tabular Comparison: Complete Annex A**<br>Where possible, provide as much information as possible regarding the product being imported in comparison to the Canadian-approved product. | |
| **Country and building where product is being exported to Canada from** | |
| Country name: | |
| Company name: | |
| Building address: | |

If different from any of the buildings listed in Part III below, indicate the activities performed by this site for the product being exported:

☐ Fabrication ☐ Primary packaging (for instance, filling drug into primary container)

☐ Labelling only (for instance, affixing a label with information to meet Division 1A Labelling requirements)

☐ Testing ☐ **Only** Storage and shipping

How are these products non-compliant with Canadian requirements?

Please provide a detailed description of the conditions of use of the drug. Where possible, the description should be a comparison between the foreign-labelled product and Canadian-authorized product that contains significant, clinically important differences between product label with respect to indications, dosing, preparation (e.g., dilution priming), administration and warnings and precautions.

| Condition | Foreign-labelled Product | Canadian-approved Product |
|---|---|---|
| Indications | | |
| Dosing | | |
| Preparation | | |
| Administration | | |
| Warnings and precautions | | |

Please provide a description of the actions being taken to ensure safe use of the product, and indicate in what form for example, letter to health care professionals or customers) the information is being made available. Please indicate the language in which the product is labelled and provide copies of the label, packaging and information that will accompany the product. *Similarly, please outline how adverse drug events would be reported.*

Is your product a high alert medication? O Yes O No

If it is a high alert medication, does the packaging conform to Canadian standards for high alert medications?
O Yes O No

Please identify any regulatory actions taken with respect to safety, efficacy or quality of this product by another regulatory agency.

**Part III: Foreign Fabricator, Packager/Labeller, Tester Identification (please attach additional information as required to include each building in which the drug is fabricated, packaged, labelled or tested)**

**Finished Dosage Form**

**Fabrication Building**

Country name:

Company name:

Building address:

**Packaging/Labelling Building (N/A if same as fabrication building)**

Country name:

Company name:

Building address:

| |
|---|
| **Testing Building (N/A if same as fabrication building)** |
| Country name: |
| Company name: |
| Building address: |
| **Active Pharmaceutical Ingredient** |
| **Fabrication Building** |
| Country name: |
| Company name: |
| Building address: |
| **Packaging/Labelling Building (N/A if same as fabrication building)** |
| Country name: |
| Company name: |
| Building address: |
| **Testing Building (N/A if same as fabrication building)** |
| Country name: |
| Company name: |
| Building address: |

## Part IV: Quantities and Timelines for Importation

Please provide details on quantities and estimated timelines for availabilities to the Canadian market.

## Part V: Verification

| | | |
|---|---|---|
| Name of Signatory: | | |
| Company Name: (If different from Importer in Part I above) | | |
| Signature: | Company Position or Title: | Date: |
| ☐ I hereby authorize Health Canada to communicate with the Importer for the purposes of this Proposal. | | |
| and/or ☐ I hereby authorize Health Canada to communicate with my consultant: | | |
| Name: | Title: | |
| Phone Number: | | |
| Email address: | | |
| or ☐ Not Applicable | | |

Please provide additional information that does not fit in the previous sections in a separate dated and signed document. (example, .doc, .docx, etc.).

**Privacy Notice**

The personal information you provide to Health Canada will be used by the Drug Shortages Unit within the Health Product Compliance Directorate (HPCD)'s in the Regulatory Operations and Enforcement Branch (ROEB) under the *Food and Drugs Act* and handled in accordance with the Privacy Act.

**Why are we collecting your personal information?** The personal information collected in this form, such as your name, telephone number, business address, email, and company position or title will be used for the purposes of contacting you regarding your application.

**Will we use or share your personal information for any other reason?**

The personal information may be shared with the Canada Border Services Agency (CBSA) and internally with Health Canada's Health Product Border Compliance Program, Health Canada's Regulatory Operations and Enforcement Branch and Health Products and Food Branch.

In accordance with section 8(2)(a) of the Privacy Act, the personal information collected will be shared for the purpose for which it was obtained or for a use consistent with that purpose.

**What happens if you don't want to provide your personal information?** If you chose to not provide the requested information, we will be unable to process your application and you will not be considered for the sale/importation of your product.

**What are your rights?** You have the right to access and request a correction and/or notation to your personal information. You also have a right to complain to the Privacy Commissioner of Canada if you feel your personal information has been handled improperly. For more information about these rights, or about how we handle your personal information, please contact the Drug Shortages Division at drugshortages.prop.notif-penuriesmedicaments@hc-sc.gc.ca

**For more information:** The collection of your personal information is described in Info Source at infosource.gc.ca. Refer to the personal information bank HC PPU 407 – Compliance and Enforcement – Pharmaceutical Drugs.

**Annex A: Tabular Comparison**

| | Drug substance (Active Pharmaceutical Ingredient) | | | | Drug product | | | | | Marketing Authorization Holder (MAH) and marketing status of the drug product |
|---|---|---|---|---|---|---|---|---|---|---|
| | Notable general properties of the API (for example., solubility) | Copies of the company's API specifications in Canada and in the foreign jurisdiction and a summary of any differences | Re-test period for the API and a summary of relevant stability data | Brief description of the synthetic sequence (for example., flow chart including all reagents, solvents) | Description of the drug product (for example., immediate-release/extended-release tablet) | Drug product formulation in Canada and in the foreign jurisdiction and a summary of any differences | Brief description of the manufacturing process and critical controls (for example., flow chart, brief narrative description) | Copies of the company's drug product specification in Canada and in the foreign jurisdiction and a summary of any differences | Shelf-life for the drug product | |
| *Insert Drug Product Name* | | | | | | | | | | |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| *Insert Drug Product Name* | | | | | | | | | | |
| *Insert Drug Product Name* | | | | | | | | | | |

Where appropriate this information may be submitted separately in PDF format if not readily transferred to a tabular comparison.