

Health Canada Form for Submitting a Proposal for Inclusion of a Non-Compliant Drug *under the Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19 on the List of Drugs for Exceptional Importation and Sale*

Due to the unprecedented demand and urgent need for access to drugs during the COVID-19 pandemic, an Interim Order has been implemented to expedite access to certain drugs that may not fully meet regulatory requirements under the *Food and Drugs Act*. At this time, Health Canada will only consider drugs that are confirmed to be a Tier 3 Shortage under the [Multi-Stakeholder Steering Committee Protocol on Notification of Drug Shortages](#) to be eligible for exceptional importation and inclusion on the *List of Drugs for Exceptional Importation and Sale*. For drugs confirmed to be a Tier 3 Shortage, a proposal can be submitted to include a drug on the *List of Drugs for Exceptional Importation and Sale* by completing the form below and submitting electronically to hc.ds-iopropau-pm.sc@canada.ca.

Part I: Importing Company Identifier	
Importing Company Name	
Importing Company Address	
Drug Establishment License (DEL) Number	
Are you licenced for this activity, category of drugs and dosage from?	
Storage location in Canada	
Key Contact Details	<i>Name</i> <i>Phone Number</i> <i>Email address</i>
Part II: Product Identifiers	
Name of Product To be Imported Brand name: Medicinal ingredient(s): Dosage form: Strength: Route of administration: Identifying code in authorizing country: Batch Number (if available):	Name of Canadian Reference Product (if available) Brand name: Medicinal ingredient: Dosage form: Strength: Route of administration: Identifying code:
Country and building where product is being exported to Canada from <i>Country name, Company name, Building address</i>	
*How are these products non-compliant with Canadian requirements?	

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*Please provide a detailed description of the conditions of use of the drug.		
*Please provide a description of the actions being taken to ensure safe use of the product, and indicate in what form the information is being made available.		
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
Signature:	Company Position or Title:	Date:

All information collected on this form will be protected according to Government of Canada security standards. All government departments are required to comply with the Access to Information and Privacy (ATIP) regulations.