



Health Products and Food Branch Regulatory Enrolment Process

[Français](#)

Select the product line you want to create or modify an enrolment

- ☒ Pharmaceutical or Biologic Product
- ☐ Medical Device
- ☐ Drug Master File

Enrolment Types[Company Information Enrolment](#)[Dossier Information Enrolment](#)[Regulatory Activity Information Enrolment](#)[Regulatory Transaction Enrolment](#)

Note: To complete a Regulatory Transaction, you need to have
HPFB approved Dossier, Company, and Regulatory Activity XML Files



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Health Products and Food Branch Regulatory Enrolment Process. Intiate Pharmaceuatical Dossier

Load a Draft or Completed file

Browse

Enrolment Type

New Enrolment



Enrolment Version

1.0

Amend Enroilment

Save Draft

Proceed to step 2 of 2

HPFB Dossier

http://www.hpfb.ca/en/EnrolDossier.html

Home

>

Product Line

>

Dossier

Health Products and Food Branch Regulatory Enrolment Process. Pharmaceutical Dossier Enrolment

Step 2a Dossier Information

Dossier Information

Ingredients

Formulations

Formulation Details

Container

Country and Route of Administration

Brand or Proprietary or Product Name

Proper, Common or Non-Proprietary Name

Related Dosssier ID [if applicable]

Therapeutic Classifications

Classification

Therapeutic Classification 1

Therapeutic Classification 2

Therapeutic Classification 3

Therapeutic Classification

Therapeutic Classification 2

Add

Delete

Canadian Reference Products

Brand Name

My Drug 1

My Drug 2

Medicinal Ingredient

Medicinal Ingredient 1

Medicinal Ingredient2

Canadian Reference Product Details

Brand Name

My Drug 2

Medicinal Ingredient

Medicinal Ingredient 2

Strengths

Company Name

Drug Use. Select at least one

☐ Human

☐ Veterinary

☐ Radiopharmaceutical

☐ Disinfectant

Dosage Form

Is this a non prescription drug to which one or more Schedule A claims apply?

Yes

Drug Identification Number (DIN)

Please select the diseases or disorders that apply to the claims made. Select at least one.

☐ Acute alcoholism

☐ Acute infectious respiratory syndromes

☐ Acute psychotic conditions

☐ Atherosclerosis

☐ Asthma

☐ Congestive heart failure

☐ Dementia

☐ Diabetes

☐ Glaucoma

☐ Hepatitis

☐ Nausea and vomiting of pregnancy

☐ Rheumatic fever

☐ Sexually transmitted diseases

☐ Thrombotic and Embolic disorder

☐ Ulcer of the gastro-intestinal tract

☐ Acute anxiety state

☐ Acute inflammatory and debilitating arthritis

☐ Addiction (except nicotine addiction)

☐ Appendicitis

☐ Cancer

☐ Convulsions

☐ Depression

☐ Gangrene

☐ Haematologic bleeding disorders

☐ Hypertension

☐ Obesity

☐ Septicemia

☐ Strangulated hernia

☐ Thyroid disease

Please list the schedule A Claims / Indications associated with this product

Step 2b: Main Contact Information. Add one to three contacts

Contact Type

Surname

Given Name

Phone

Primary

Guilizzoni

Giacomo

613-304-1434

Secondary

Marco Botton

Tertiary

Valerie Liberty

Delete Selected Contact

Add Contact

Contact Details

Salutation

Given Name

Dr.

Guilizzoni

Surname

Language of Correspondence

Giacomo

English

Telephone Number

Telephone Extension

Fax Number

613-304-1434

613-304-1434

Email

Return to Step 1 of 2

Save Draft

Generate XML

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Health Products and Food Branch Regulatory Enrolment Process. Pharmaceutical Dossier Enrolment

Drug
Product

Ingredients

Formulations

Formulation Details

Container

Country of
Manufacture

Ingredient Name ▲	Role ▲	CAS	Human or Animal Sourced?
Water	Non-Medicinal	7732-18-5	No
Ingred 2	Active		Yes

Delete Selected Ingredient

Add Ingredient

Ingredient Name

Ingred 2

Ingredient Role

Active ▼

Non-Medicinal Ingredient

Material used in Manufacture

Chemical Services Abstract Number

Standard

Is a NanoMaterial?

Not a Nanomaterial ▼

Animal or Human Sourced?

Yes ▼

Animal and / or Human sourced Ingredients

Sourced From: ☒ Human ☐ Animal

Tissues or Fluids of Origin

☒ Nervous System☒ brain☒ brain stem☐ cerebellum☐ cerebrospinal fluid☐ dorsal root ganglia☐ dura mater☒ hypothalamus☐ retina / optic nerve☐ spinal cord☐ trigeminal ganglia☐ other☐ Reproductive and Urinary Systems☐ Cardio-Respiratory Systems☐ Immune System☐ Skin and Glandular Systems☐ Musculo-Skeletal System☐ Other Tissues or Fluids

Save Draft

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Health Products and Food Branch Regulatory Enrolment Process. Pharmaceutical Dossier Enrolment

Drug Product

Ingredients

Formulation

Formulation Details

Container

Country and

Route of Administration

Formulation ▲	Formulation Name ▲
1	Main Formulation
2	Alternate 1

Delete Selected Formulation

Add Formulation

Formulation Name

Main Formulation

Save Draft

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Health Products and Food Branch Regulatory Enrolment Process. Pharmaceutical Dossier Enrolment

Drug Product

Ingredients

Formulations

Formulation Details

Container

Country and
Route of Administration

Main Formulation

Type^	Ingredient Name ▲	CAS	Variant
Non-Medicinal	Water	732-18-5	Var1
Non-Medicinal	20% Ethanol	64-17-5	Var1
Active	levothyroxine sodium	25416-65-3	
Material	Chitosan	9012-76-4	

Add Nonmedicinal Ingredient

Add Active Ingredient

Add Material

Delete Selected Ingredient

Selected Ingredient Details

Variant Name

Var1

All ingredients in one tab

Details view- based on type of ingredient - shows relevant fields on selection of an ingredient

Non Medicinal Ingredient Name

20% ethanol ▼

CAS

7732-18-5

Type

Standard

Strength

Units

Per

Calculated as Base?

Animal or Human Sourced?

NanoMaterial?

No ▼

No ▼

Not a nanoMaterial ▼

Save Draft

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Health Products and Food Branch Regulatory Enrolment Process. Pharmaceutical Dossier Enrolment

Drug Product

Ingredients

Formulations

Formulation Details

Container

Country and
Route of Administration

Main Formulation

Proposed Shelf Life, Container Type, and Package Size

Container Type	Package Size	Shelf Life

Add Container

Delete Selected Container

Container Type

Package Size

Shelf Life Years

Shelf Life Months

Minimum Temperature (Celcius)

Maximum Temperature (Celcius)

Save Draft

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Health Products and Food Branch Regulatory Enrolment Process. Pharmaceutical Dossier Enrolment

Drug Product

Ingredients

Formulations

Formulation Details

Container

Country and
Route of Administration

Main Formulation

Country of Manufacture

Canada

Add a Country

Remove Country

Country of Manufacture

Canada

Route of Administration

Transdermal

Add

Delete

Route of Administration

Transdermal

Save Draft