

Canada: Regulatory Overview, Advantages, and Pitfalls

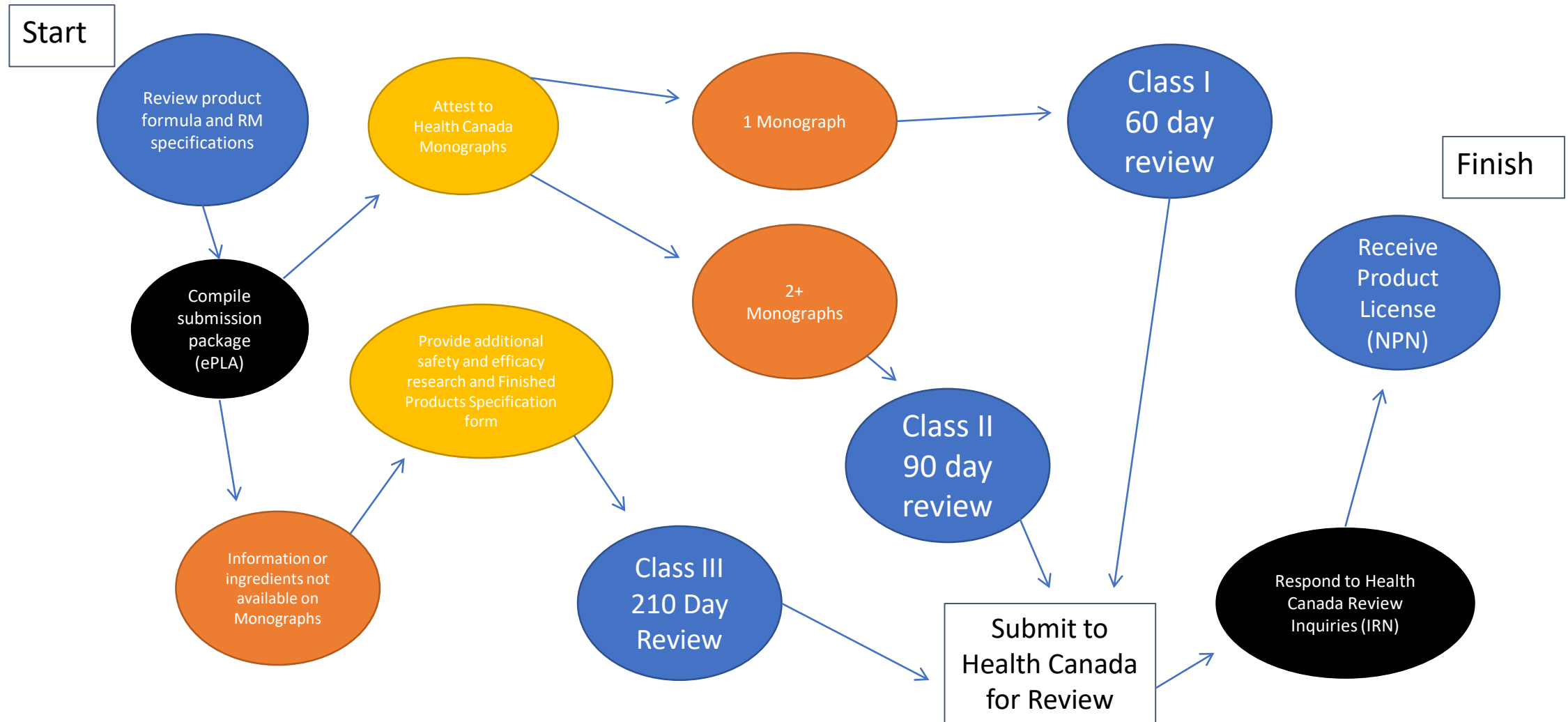
CRN ITMDC Presentation

May 11, 2021

Canada: Regulatory Overview

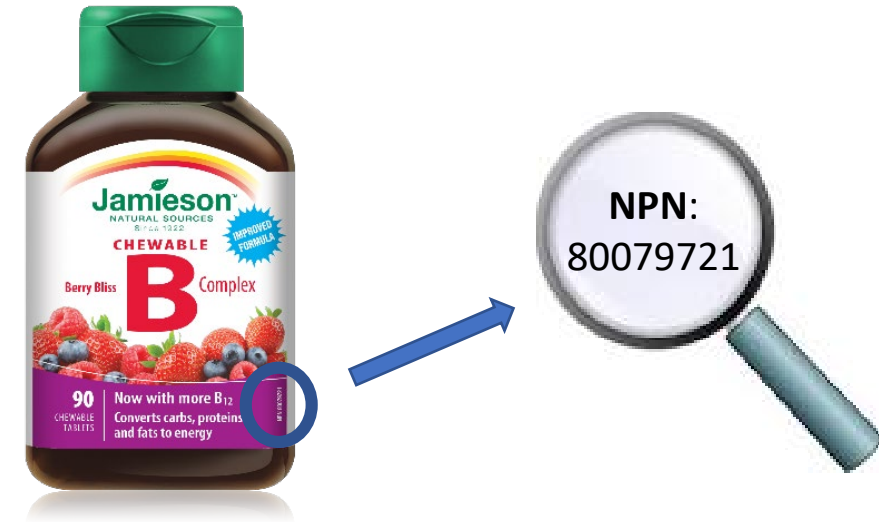
- Dietary Supplements = Natural Health Products (NHPs) in Canada
 - naturally occurring substances that are used to restore or maintain good health
- NHPs fall under the drug framework
 - Government oversight into formulation, claims and manufacturing
- **To manufacture an NHP**, must have an approved site license (SL) from Health Canada (HC)
- **To sell an NHP**, must submit product license application that includes sufficient data to allow HC to evaluate the safety, quality and efficacy of the NHP when used according to the recommended conditions of use

Canada: Regulatory Overview



Canada: Regulatory Advantages

- NHPs covers various dosage forms;
- Clear product indicator (NPN = NHP);
- Claims are approved by Health Canada;
- Need to provide adequate scientific evidence to support safety and efficacy;
- Clear and consistent guideline on quality standards (micro, heavy metal, etc.), advertising & label guidance for industry



Canada: Regulatory Advantages

- A lot of pre-cleared information (monographs) available to industry, making it easier at formulation stage
 - Database continues to evolve, and industry can influence with new/emerging science trends
- Ingredient database of what is allowed and not allowed in NHP
 - This database also continues to evolve, and industry can influence with new/emerging science trends

Ingredient Search

Search For:

Role:

Date Database Last Changed: 2021-01-15 13:38:48

Search Results

Your search found 13 Ingredients:

Result Page: 1

List of Returned Ingredients

Ingredient	Proper Name(s)	Common Name(s)
Eleutherococcus senticosus (Organism) Pre-cleared Information: • Eleuthero • Cognitive function products • Workout Supplements	Eleutherococcus senticosus	• Ci wu jia • Eleuthero • Siberian ginseng
Folium ginseng (Defined Organism Substance)	Panax ginseng	• Folium ginseng • Ren shen ye
Lepidium meyenii (Organism) Pre-cleared Information: • Maca - Lepidium meyenii • Antioxidants	Lepidium meyenii	• Maca • Peruvian-ginseng
Panacis Majoris Rhizoma (Defined Organism Substance)	Panax japonicus var. major	• Largeleaf Japanese ginseng rhizome • Panacis majoris rhizoma • Zhu zi shen
Panax ginseng (Organism) Pre-cleared Information: • Cognitive function products • Workout Supplements • Ginseng, Panax	Panax ginseng	• Asian ginseng • Chinese ginseng • Hong shen • Korean ginseng • Korean red ginseng • Oriental ginseng • Panax ginseng • Red ginseng • Ren shen

Canada: Regulatory Advantages

- License database for consumer to know what is approved and at what dosage

Search results

From [Health Canada](#)

Note - The product information found within this database originates from organizations not subject to the [Official Languages Act](#) and is available in the language in which it was written and submitted to Health Canada.

[New search](#)

Filter items Showing 841 to 842 of 842 entries | Show entries

List of searched natural product

NPN/DIN-HM ¹ ↑ ↓	Brand name(s) ↑ ↓	Licence holder ↑ ↓	Current status ↑ ↓
80109538	Probiotic 10 Billion; Probiotic Complex 10 Billion; Probiotic Complex 10 Billion Active Cells	Jamieson Laboratories Ltd./ Nutricorp International	Active
80109610	Probiotic 25 Billion; Probiotic Complex 25 Billion; Probiotic Complex 25 Billion Active Cells; Women's 25 Billion; Women's 25 Billion Active Cells	Jamieson Laboratories Ltd./ Nutricorp International	Active



Product information

From [Health Canada](#)

Note - The product information found within this database originates from organizations not subject to the [Official Languages Act](#) and is available in the language in which it was written and submitted to Health Canada.

[New search](#)

Natural Product Number (NPN):
80109610

Market status:

Current status:
Active

Brand name(s):
Probiotic 25 Billion;
Probiotic Complex 25 Billion;
Probiotic Complex 25 Billion Active Cells;
Women's 25 Billion;
Women's 25 Billion Active Cells

Licence holder:
Jamieson Laboratories Ltd./ Nutricorp International

Dosage Form:
Capsule

Recommended route of administration:
Oral

- More vigilance on the market
 - Retailer can check product for compliance via the NPN before selling on shelves

Canada: Regulatory Pitfalls

- Lack of flexibility with respect to wording
- Lengthy review timelines (no direct access to market)
- Inconsistent review by Health Canada
 - Evidence of standard can be subjective from one reviewer to another
 - Constantly evolving internal policies creates market inconsistency
- Constant delays (mainly due to no cost recovery)
- Excessive warnings and inconsistent use of consumer-friendly language
 - Warnings are not written in plain language
- Lack of standardized formatting (two products side-by-side will have different layouts making it hard for consumer to find critical info)

WARNING: Do not use this product if you are pregnant or breastfeeding. Avoid taking with alcohol or products that increase drowsiness. Consult a health care practitioner if sleeplessness persists for more than 1 month (chronic insomnia). Consult a health care practitioner prior to use if: you are taking steroids, blood thinners, or medications for seizures, blood pressure, to suppress the immune system, to affect mental state or increase sedation; you have cardiovascular, immune, liver or chronic kidney disease, hormonal or seizure disorders, asthma, depression, diabetes, low blood sugar or migraines. Stop use if allergic reaction occurs or if you experience headache, confusion or nausea.

Thank you!