Natural Health Products: New Labelling Requirements

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Agenda

1. Existing Licensing and Labelling Requirements
2. Recent Changes to the Labelling Requirements
3. Impacts of Non-Compliance on Competition Bureau Opinions

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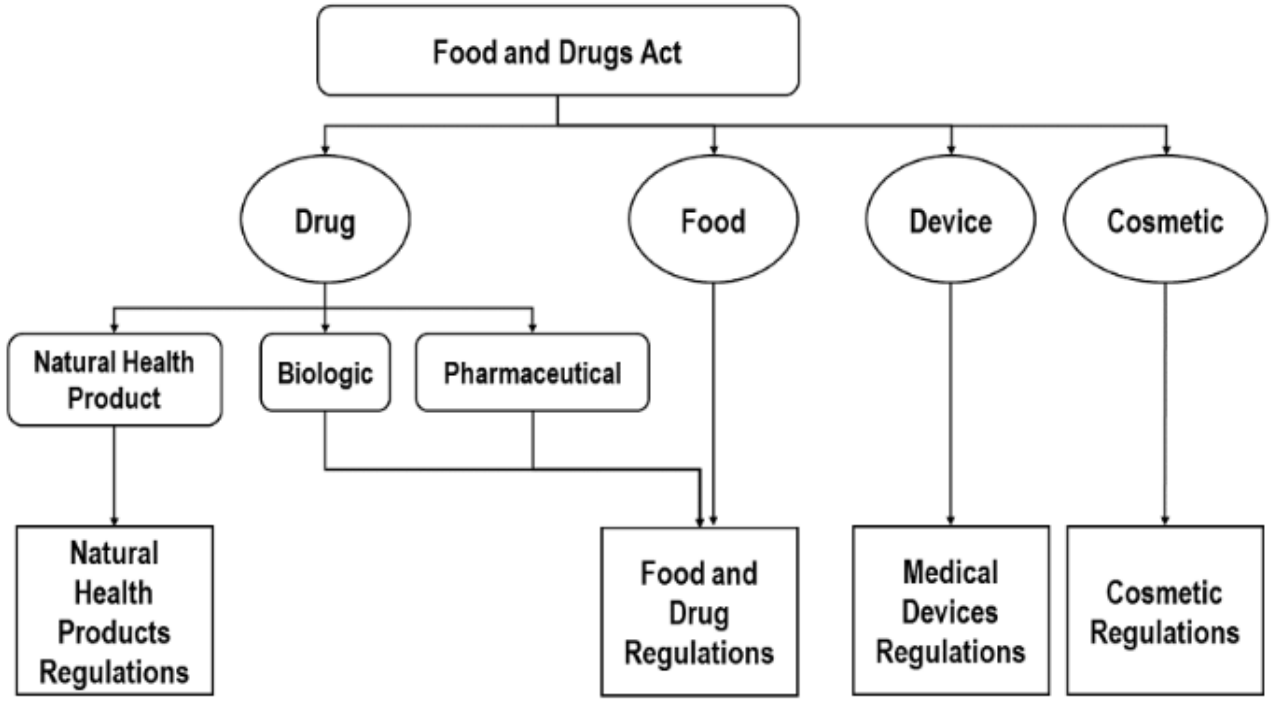
Existing Licensing and Labelling Requirements

What is a Natural Health Product?

Substances included in Schedule 1 of the NHPR
A plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material
An extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation
Any of the following vitamins: biotin, folate, niacin, pantothenic acid, riboflavin, thiamine, vitamin A, vitamin B6, vitamin B12, vitamin C, vitamin D, vitamin E, vitamin K1, vitamin K2
An amino acid
An essential fatty acid
A synthetic duplicate of a substance described in any of items 2 to 5
A mineral
A probiotic

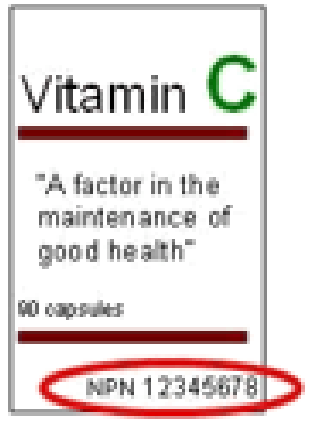


NHP Licencing

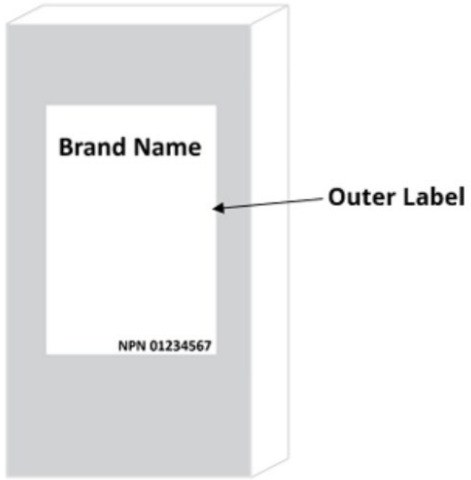
NHPs must be licenced by Health Canada before they can be sold on the Canadian market.

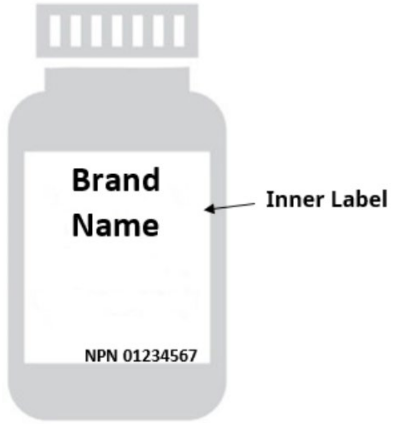
A Product Licence and terms of market authorization will be issued for applications satisfying regulatory requirements as outlined in the Natural Health Product Regulations.

The Product License will include the Natural Product Number (NPN) or Drug Identification Number-Homeopathic Medicine (DIN-HM) assigned to the product .



Different Types of Labels





Alternative Labels:

Innovative Labels

- A label that acts as an extension to a products label
- Examples: accordion labels, peel-backs, fold-out labels etc.

Leaflet

- A label attached to the outermost container which can easily be removed and contains information that does not fit on the label

Package Insert

- A document inserted in a sleeve on the product's outer package that allows for information to be removed from the label

Required Contents of the Labels

Information on Principal Display Panel (both Inner and Outer Label)

- Brand Name
- Product Number – NPN or DIN-HM
- “Sterile” – if applicable
- Dosage Form – “Tablets”, “Gel” etc.
- Net amount in the immediate container

Information required on the Outer Label

- Product Facts Table
- Name of the licence holder or importer
- Recommended route of administration
- Lot Number
- Expiry Date

Information required on the Inner Label

- Contact information of product licence holder
- Medicinal ingredients, quantity of each ingredient per dosage unit, and potency of each ingredient
- At least one use or purpose
- Dose
- Duration of use
- Source of food allergens, gluten and source of gluten, and added sulphites, if applicable
- Contains aspartame disclosure, if applicable
- Risk information
- Other information (for example, recommended storage conditions)

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Changes to the Labelling Requirements:

Regulations Amending the Natural Health Products Regulations

The Four Main Changes

Content Requirements

1. Labelling of allergens, gluten, added sulphites, and aspartame

2. Modernized contact information

Formatting Specifications

3. Product Facts Table

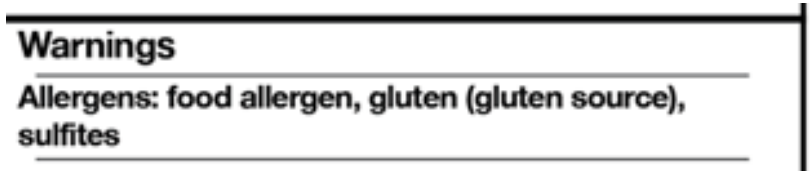
4. Clear and prominently displayed label text

1. Labelling of allergens, gluten, added sulphites, and aspartame

If a product contains:

- Food allergen (i.e. one likely to cause anaphylaxis)
- Gluten
- Added sulphites over 10 p.p.m.

then a statement is required on the label highlighting the allergen source, gluten source or added sulphite.



If aspartame is included in the product, this must be disclosed as well.

Allergens

- almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios or walnuts;
- peanuts;
- sesame seeds;
- wheat or triticale;
- eggs;
- milk;
- soybeans;
- crustaceans, mollusks, fish; or
- mustard seeds.

Gluten

- Any gluten protein from the grain of any of the following cereals
  - Barley, Oats, Rye, Triticale, Wheat; or
- Any modified gluten protein

2. Modernized contact information

Under the heading “Questions?” of the Product Facts Table the new regulations require contact information for more modern forms of communication

Postal Address → E-mail address, Telephone Number or Website Address

Questions? Call 1-8XX-XXX-XXXX

3. Product Facts Table (PFT)

Requirements for a PFT:

- Displayed on the outermost label of the packaging
- Must be either:
  - Bilingual
  - Shown in both in English AND French
- Reflect the terms of market authorization
- May not include marketing terms or promotional wording

Product Facts

Medicinal ingredients In each xx mL
Ingredient A (Ingredient A source material) X mL
Ingredient B (Ingredient B source material) X mL

Uses
For the relief of •xxxxxxx •xxxxxxxxxxxxx •xxxxxxxxxx

Warnings

Allergens: food allergen, gluten (gluten source), sulfites

Do not use if •xxxxxxx •xxxxxxxxxxxxx.

Ask a health care practitioner before use if •xxxxxxxxx •xxxxxxxxxxxx •xxxxx • if you are pregnant or breastfeeding.

When using this product consult a health care practitioner if •xxxxxxxxxxxxxxxx •xxxxxxxxxxxxxxxxx.

Stop use and ask a health care practitioner if •xxxxx •xxxxxxxxxxxx •xxxxxxxx.

Keep out of reach of children.

Directions
Children (6 to 11 years of age): Take xx mL once per day.

Other information
Store between 15-25°C. •After opening, Product XXX can be stored for xxxxxxxxx. •Do not use if xxxxxxx.

Non-medicinal ingredients
Gluten source (gluten) List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs

Questions? Call 1-8XX-XXX-XXXX

Product Facts

Medicinal ingredients Each tablet contains
Ingredient A (Ingredient A source material) X mg
Ingredient B (Ingredient B source material) X mg

Uses
For the relief of •xxxxxxx •xxxxxxxxxxxxx •xxxxxxxxxx

Warnings

Allergen: food allergen, gluten (gluten source), sulfites

Do not use if •xxxxxxx •xxxxxxxxxxxxx.

Ask a health care practitioner before use if •xxxxxxxxx •xxxxxxxxxxxx •xxxxx •if you are pregnant or breastfeeding.

When using this product consult a health care practitioner if •xxxxxxxxxxxxxxxx •xxxxxxxxxxxxxxxxx.

Stop use and ask a health care practitioner if •xxxxx •xxxxxxxxxxxx •xxxxxxxx.

Keep out of reach of children.

Product Facts (continued)

Directions
Do not chew tablets.
Children (6 to 11 years of age): Take x tablet once per day.

Other information
Store between 15-25°C. •After opening, Product XXX can be stored for xxxxxxxxx •Do not use if xxxxxxx.

Non-medicinal ingredients
Gluten source (gluten) List of NMIs List of NMIs List of NMIs List of NMIs List of NMIs

Questions? Call 1-8XX-XXX-XXXX

4. Clear and prominently displayed label text

Label information must be clearly displayed and accessible to customers when they **buy it** and when they **use it.**

Example of Font

Calibri	9 point
Arial	9 point
Arial Black	**9 point**
Univers	9 point
Verdana	9 point

New Specifications:

1. **The type of font** – sans serif
2. **The spacing of the words and increased white space**
3. **The contrast between font and background** – font must be dark and the background must be light with minimal transparency
4. **The size of the font** - no smaller than between 5.5 and 6 points

Flexibilities

- When a product's package is too small to include the standard PFT on the label
- Flexibilities include, among other things, displaying a partial PFT on the label
- This does not change the order of the information in the PFT
- When moving information outside the PFT, a statement directing the consumer to the location of the displaced information must appear immediately below the Product Facts title

Products Facts/Info-produit
For information on medicinal ingredient source, potency, and non-medicinal ingredients see : www.websitename.ca./Pour des informations sur la matière d'origine et la puissance des ingrédients médicinaux et les ingrédients non médicinaux, voir : www.nomdusiteweb.ca.
Medicinal ingredients/Ingrédients médicinaux In each xx mL contains (xx drops correspond to x mL) •Ingredient A x µL •Ingredient B x µL. Dans chaque xx mL •Ingrédient A X mL •Ingrédient B X µL.
Warnings/Mises en garde Allergens: food allergen, gluten (gluten source), sulfites /Allergènes : allergène alimentaire, gluten (source de gluten), sulfites.
When using this product consult a health care practitioner if •xxxxxxxxxxxxxxx •xxxxxxxxxxxxxxxx./ **Lorsque vous utilisez ce produit, consultez un praticien de soins de santé si** •xxxxxxx •xxxxxxxxxx. **Ask a health care practitioner before use if** •xxxxxxxx •xxxxxxxxxxxx •xxxxx •if you are pregnant or breastfeeding./ **Consulter un praticien de soins de santé avant l'utilisation si** •xxxxxxxx •xxxxxxxxxxxx •xxxxx •si vous êtes enceinte ou vous allaitez **Stop use and ask a health care practitioner if** •xxxxx •xxxxxxxxxxx •xxxxxxxx./**Cessez d'utiliser ce produit et consultez un praticien de soins de santé si** •xxxxx •xxxxxxxxxxxx •xxxxxxxxx.
Keep out of reach of children./Garder hors de la portée des enfants.
Directions/Mode d'emploi Children (6 to 11 years of age): Take xx mL once per day./Enfants (6 à 11 ans) : Prendre xx mL une fois par jour.
Questions? Call/Appelez 1-8XX-XXX-XXXX

Exemptions from PFT and Labelling Requirements

1. Products in Very Small Packages

2. Products that contain doses for one day's use or less

3. Products containing no more than three recommended doses

4. Lowest-risk products

Exemptions

Transition Periods for Existing and New Products

New products that have not yet received a product license:

June 21, 2022
Registration Date of the Amending Regulations

→ 3 Years →

Comply by: **June 21, 2025**

Existing products that have already received a product license:

June 21, 2022
Registration Date of the Amending Regulations

→ 3 Years →

Compliance deadline for new products

→ 3 Years →

Comply by: **June 21, 2028**

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Impacts of Non-Compliance on Competition Bureau Opinions

Non-Compliance and Competition Bureau Opinions

Context: multi-level marketing businesses seeking written opinion from the Competition Bureau under the *Competition Act.*

The Competition Bureau may take note of the business' non-compliance with the *Food and Drugs Act* and related regulations, including those regulations discussed here, which can significantly complicate the written opinion process.

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Questions?

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