



DIY NATURAL PRODUCT NUMBER SUBMISSION

This document addresses the process of applying for a Natural Product Number issued by Health Canada.

To be able to list the therapeutic value of your product on the label, Health Canada requires that you be licensed under the Natural and Non-Prescriptive Health Product Directorate (NNHPD). You can only make claims that are listed in the Health Canada database. The link to that database can be found below under 'product monograph'.

Once a product is licensed it will be assigned an NPN number (natural product number) that must be displayed on the label.

To start down this path:

A. Establish yourself as a Trading Partner with Health Canada. This allows you to communicate directly with Health Canada personnel.

1. Establish yourself with E-Post
<https://sso.epost.ca/sso/lfe/ui/login?templateId=&sourceUrl=&targetUrl=&authlvl=>
2. Fill out the required Health Canada forms to become a trading partner
<https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/natural-health-products/guidance-document-interact-natural-health-products-directorate-electronically-0-health-canada-2013.html>

Visit the NNHPD site and determine what 'stream' you fall under.

- Traditional
- General (non-traditional)
- Compendial (including compendial homeopathic)
- Homeopathic (non-compendial)

Explanations for these 'streams' can be found at the following link:

<https://nnhpd-pla-dlmm-dpsnso.hc-sc.gc.ca/pla-dlmm/en/guide>

If you decide to proceed:

You will need to develop a master document list that describes your Standard Operating Procedures (SOPs) and related forms. An SOP is a detailed description of the procedures you follow. Some of these SOPs and forms are required as part of your license submission.

While you do not currently need audited certification for your manufacturing practices, you will need some form of certification for your production practices if you are growing and distilling your own lavender.

Ontario Lavender Association

"To grow a prosperous and vibrant Ontario lavender industry, together"



You will need to be able to show that your product is free of contaminants such as heavy metals, harmful bacteria and moulds, pesticides and foreign material. And you will need a GC/MS (gas chromatography/mass spectroscopy) certificate of analysis.

Applying for a product license

Guidance documents are listed on the Health Canada website. These documents contain links to procedures and to the forms required to submit an application. Do not use any documents that are listed as “archived”. To the best of our knowledge, the links we have provided are current. The NNHPD frequently revises these documents.

All about natural Health Products and Health Canada

<https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription.html>

Use the Health Canada Guidance documents supplied by the Natural and Non-prescription Health Product Directorate.

1. Good Manufacturing Practices

<https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/good-manufacturing-practices.html>

This document was prepared in 2015 and may currently be under review. As of now, it is the most current document listed by Health Canada for Natural Health Products.

In an NPN submission the practices in this guidance document are referred to frequently and you will be expected to show proof that you follow the guidelines.

2. Product License Application

<https://nnhpd-pla-dlmm-dpsnso.hc-sc.gc.ca/pla-dlmm/en/landing?lang=eng&wbdisable=true>

Read this document thoroughly. It lists the forms you will need to fill out. This document will guide you through the various forms required.

There are many sections in the product License Form. You will be asked to supply supporting documents that show Standard Operating Procedures and associated forms. You will also be asked for information regarding quality control, safety procedures and more.

3. Product Specification Form

This form details all the information you must supply about your product. You will need to know the dosage associated with your application method and the wording you must use on your label.

4. Product Monograph

There is no official monograph for lavender in the Health Canada Database. The following link is in the ‘ingredients database’. You will need to enter ‘lavender’ in the search area. Scroll down to find the lavender data that is ‘pre-cleared’. Both lavenders and lavandins are pre-cleared. This means that the information in this section can be used to fill in some of the requirements for the product



1283 Blueline Road,
P.O. Box 587
Simcoe, Ontario. N3Y 4N5
ontariolavenderassociation@gmail.com

license. This will also include the accepted concentration of active ingredients. You must be within these guidelines for your product.

<http://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/ingredsReq.do?srchRchTxt=lavender&srchRchRole=-1&mthd=Search&lang=eng>

In the ingredients database you will also need to look up your carrier oil and any other ingredients in your product.

Health Canada guidance documents are generally very helpful. Once you submit an application you are assigned a reviewer with whom you will communicate until your product meets approval.

Ontario Lavender Association

"To grow a prosperous and vibrant Ontario lavender industry, together"