LABELLING REQUIREMENTS CHECKLIST

April 2011

Product licence applicants are responsible for ensuring that the label complies with the labelling and packaging requirements set out in Part 5 of the *Natural Health Products Regulations*, specifically Sections 93, 94, 95, and 97, if applicable. As per section 86(1) no person shall sell a natural health product (NHPs) unless it is packaged and labelled in accordance with these Regulations.

The following checklist is a resource tool to be used for label generation by applicants intending to submit a Product Licence Application (PLA) for a natural health product.

Applicants are encouraged to carefully review their label prior to submission to ensure that all necessary information has been provided.

Please refer to the *Labelling Guidance Document* for further interpretation of the labelling and packaging requirements for NHPs: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/labelling-etiquetage-eng.php

KEY POINT: WHEN PREPARING A LABEL FOR A PRODUCT LICENCE APPLICATION

*** The information provided on the label must be consistent with the information on the Product Licence Application form.**

*** If any advertising is to appear on the label, it must not contravene Section 9 of the *Food and Drugs Act.***
The NHPD no longer reviews advertising claims on labels. Applicants are responsible for ensuring that any advertising claims on the labels of their products do not contravene Section 9 of the *Food and Drugs Act*. Advertising claims must be consistent with the Consumer Advertising Guidelines for Marketed Health Products and the Guidelines for Cosmetic Advertising and Labelling.

Additional resources for product licence applicants:

- Product Licensing Guidance Document
- *Natural Health Products Regulations*
- *Food and Drugs Act*
- *Food and Drug Regulations*
- Consumer Advertising Guidelines for Marketed Health Products
- Guidelines for Cosmetic Advertising and Labelling Claims

Links to these documents can be found on page 4 of this document.

-THE CHECKLIST IS AVAILABLE ON THE NEXT PAGE-

LABELLING REQUIREMENTS CHECKLIST

Labelling Requirement	**Outer Label** (Section 93) **or Leaflet** (Section 94(2))	**Inner Label** (Section 93)	**Inner Label Small Packaging**[1] (Section 94)
1.0 Principle Display Panel			**On Any Panel**
1.1 Primary Brand Name			
1.2 Product Number (NPN or DIN-HM prefix)			
1.3 Dosage Form			N/A
1.4 if the product is sterile, the words “sterile” or “stérile”			
1.5 Net amount in the immediate container in terms of weight, measure or number			
2.0 On Any Panel			**On Any Panel**
2.1 Name and address of the product licence holder			N/A
2.2 Name and address of the importer (if applicable)			N/A
2.3 Common name of each medicinal ingredient			List by common name only if the proper name is the chemical name, in descending order of quantity per dosage unit.
2.4 Proper name of each medicinal ingredient, if the proper name is not the chemical name			
2.5 Quantity of each medicinal ingredient per dosage unit (including potency, extract ratio and Quantity Crude Equivalent, if applicable) associated with proper name			N/A
2.6 Description of the source material of each medicinal ingredient			N/A
2.7 Recommended use or purpose			
2.8 Recommended route of administration (if not self-evident)			N/A
2.9 Recommended dose (including subpopulation, amount, frequency, and directions of use, if any)			
2.10 Recommended duration of use, if any			
2.11 Risk information			N/A
2.12 List by common name, preceded by the heading “non-medicinal ingredients”, of all non-medicinal ingredients		N/A	N/A
2.13 Recommended storage conditions, if any			N/A
2.14 Lot number prefix			
2.15 Expiry date prefix			
2.16 Security feature Unless the security feature is self evident and is an integral part of the immediate container, a statement or illustration that draws attention to the security feature of the security package must be shown on the inner label; and if the security feature is part of the outer package, on the outer label. If the security feature is self-evident, it must be indicated in a cover letter on in a statement on the label.			
2.17 If the product contains mercury or its salts or derivatives as a non-medicinal ingredient, the quantity of mercury in the product		N/A	N/A
2.18 Storage conditions (if outside normal storage conditions)		N/A	N/A
3.0 Other			**On Any Panel**
3.1. When the package does not have an outer label, a statement that refers the purchaser or consumer to a leaflet (as per Section 94 (2))	N/A		
3.2 Cautionary Statements and Child Resistant Packages (Section 97)			
3.3 Statements, information and declarations are clearly and predominantly displayed and readily discernible to the purchaser or consumers of the NHP under the customary conditions of purchase and use (Section 88(a))			

[1] *If the label is for a small package, please indicate so in a cover letter or in a statement on the label text submitted.*

Extremely Small Package Labelling Requirements:

The following guidelines for extremely small package labelling were developed for those packages that cannot meet the reduced small packaging requirements under Section 94 of the Regulations due to their size. Please indicate in a cover letter or in a statement on the label text submitted that the label is an extremely small package.

What is an extremely small package?

The labelling guidelines for extremely small packages apply to:

- multiple-dose packs, such as blisters, strips, push-through cards, ampoules or vials attached by a plastic strip, etc., and
- single-dose packs, such as sachets, pouch-type packs, individual dose vials of liquid, etc.

Minimum requirements for multiple-dose and single-dose extremely small packages

a) The label on the immediate container must contain the following information:

- the brand name (the manufacturer's name and proper or common name of the medicinal ingredient is considered a brand name for the purposes of the *Natural Health Products Regulations*);
- the quantity and potency, if applicable, of each medicinal ingredient in the product except where,
    - *i.* in the case of a product with more than one medicinal ingredient, the brand name used for that product is unique for that particular combination of medicinal ingredients and their quantity/potency (this unique brand name is sufficient), or
    - *ii.* there is insufficient space for this complete listing, in which case the quantity and potency is to be replaced by the 8-digit NPN or DIN-HM;
- the lot number; and
- if space permits, the expiry dates.

b) Information affixed to the immediate container must meet the requirements of Section 94 of the Regulations (including the information that appears on the label in a)).

c) If there is an outer label, it must meet the requirements of Section 93 of the Regulations (outer labelling).

d) If there is no outer label, the information affixed to the immediate container must meet the requirements of Section 93 (outer labelling) – i.e., affixed information meets the requirements of Sections 93 and 94 of the Regulations.

Note: For multiple-dose packs, the information should be presented in a manner that ensures that the package can be identified after units have been removed. This can be done by printing in a repetitive manner or by embossing on the edge of each card (e.g., blister packages should be printed so that the information can be read for individual units after destruction of part of the package).

Links to additional resources for product licence applicants:

Product Licensing Guidance Document
http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/license-licence_guide_tc-tm-eng.php

Natural Health Products Regulations
http://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/

F*ood and Drugs Act*
http://laws-lois.justice.gc.ca/eng/acts/F-27/

Food and Drug Regulations
http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html

Consumer Advertising Guidelines for Marketed Health Products
http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/guide-ldir_consom_consum-eng.php

Guidelines for Cosmetic Advertising and Labelling Claims
http://www.hc-sc.gc.ca/cps-spc/pubs/indust/cosmet/index-eng.php