

## Natural Health Products Directorate (NHPD) since 2004

Information summarized from Rishma Walji Bsc ND PhD Dietitians of Canada seminar on *Healing Herbs Part 1 Safe and Effective Botanicals for Cardiovascular Disease and Mental Health (June, 2013)*

Update: \* Health Canada > Drugs & Health Products > Natural Health Products

(NHPD) has changed its name to the **Natural and Non-prescription Health Products Directorate (NNHPD)** subsequent to its recently expanded mandate to include the oversight of non-prescription and disinfectant drugs in addition to natural health products (NHPs). Please note that we are currently modifying documents to reflect this change.

Natural Health Products (NHP): Regulated as a subset to drugs

Components to regulation:

- Definition
- Site licensing
- Product licensing
- Labeling
- Clinical trials
- Adverse Drug Reporting

The Regulations were established since 2004 are there to help give Canadians access to a wide range of natural health products that are safe, effective and of high quality.

### Licensing

Product licensing: Needs an 8 digit Health Product Number (NHN) or Homeopathic Health Number (DIN-HM) on the label.

Site licensing: Need good manufacturing methods, keep good records, proper procedures throughout manufacturing to customer and for product recalls.

### Labeling

On label: Has brand name, latin name of product, dosage and strength of each ingredient, quantity, recommended condition of use, route, dose duration, cautionary statements, contraindications and possible adverse reactions.

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\*<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/index-eng.php#a5> |



Treatment Claims: Need a weight of scientific evidence.

Risk reduction Claims: Describe the relationship of ingredient to risk of developing a disease. Have observational studies to support claim.

Structure and Function Claim: Describe effect of ingredient on structure or anatomical, physiological or mental function. This can include a claim for overall health.

Traditional Use: Can be labeled as traditional if ingredient has been in use for over 50 years and is supported by independent references.

Non-traditional Use: There are stringent requirements for scientific evidence. The strength of evidence should be graded (Grade A is the best Grade D low). The claims for serious health conditions need the strongest level of evidence.

### **Clinical Trials**

The health product is tested on humans: For verification or discovery of products effects, test for adverse reactions, study its absorption, distribution, metabolism and excretion and test its safety.

### **Adverse Drug Reporting**

All license holders must report any adverse effects to Health Canada and Canadian consumers should report any adverse side effects to their health provider and Health Canada.

See [Adverse Reaction Reporting](#) for more information.

### **Licensed Natural Health Products Database**

For licensed natural health products, search using Health Canada's [Licensed Natural Health Products Database](#).

### **Safety Issues**

Natural does not mean safe and adverse effects can be experienced.

Imported and internet purchases from international sources are not regulated to Canadian standards.

Beware of drug and natural health product interactions (this includes contraceptive medication).

