Archived Content

- Fact Sheet –
Schedule A Health Claims for Natural Health Products
Updated - November 2010

The purpose of the following fact sheet is to provide clear and precise information to natural health product (NHP) stakeholders on Schedule A to the *Food and Drugs Act* (FDA) and how it pertains to NHPs. This fact sheet updates and replaces the fact sheet dated May 9, 2007.

The information found in this fact sheet has been categorized as follows:

- What is Schedule A?
- What is a Schedule A Health Claim?
- Prohibitions Regarding Schedule A Health Claims
- Amendment to the *Natural Health Products Regulations* Regarding Schedule A
- Guidance Document: Schedule A and Section 3 of the *Food and Drugs Act*
- Product Licences for NHPs
- NHPs Making Preventative Health Claims for Schedule A Diseases or Conditions
- Labelling and Advertising of Schedule A Health Claims

What is Schedule A?

Schedule A (http://laws.justice.gc.ca/PDF/Statute/F/F-27.pdf) to the FDA is a list of diseases, disorders, or abnormal physical states. These include such things as acute anxiety, asthma, cancer and diabetes.

What is a Schedule A Health Claim?

When the health claim (recommended use or purpose of the NHP) relates to a disease, disorder or abnormal physical state listed on Schedule A, the health claim is considered to be a “Schedule A health claim”.

Prohibitions Regarding Schedule A Health Claims

Section 3(1) of the FDA(http://laws.justice.gc.ca/en/showdoc/cs/F-27/bo-ga:l_I-gb:s_3/en#anchorbo-ga:l_I-gb:s_3) prohibits the advertising to the general public of drugs, including natural health products, for the treatment, prevention or cure of the diseases, disorders, or abnormal physical states listed on Schedule A.

Further to this, Section 3(2) of the FDA (http://laws.justice.gc.ca/en/showdoc/cs/F-27/bo-ga:l_I-gb:s_3/en#anchorbo-ga:l_I-gb:s_3) prohibits the sale of drugs, including natural health products, that are labelled, or that are advertised to the general public, for the

treatment, prevention or cure of the diseases, disorders, or abnormal physical states listed on Schedule A.

Amendment to the *Natural Health Products Regulations* Regarding Schedule A

On June 1, 2008, a regulatory amendment to the *Natural Health Products Regulations*[1] (NHPR) came into force to remove the prohibition on the labelling and advertising of Schedule A preventative health claims.

Guidance Document: Schedule A and Section 3 of the *Food and Drugs Act*

Detailed information on the interpretation of Section 3 and its applicability to NHPs and drugs can be found in the **guidance document on Schedule A and Section 3 of the *Food and Drugs Act* (**http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/scha_guide_ld-eng.php**)**.

Product Licences for NHPs

All NHPs must undergo a pre-market review before they may be sold in Canada. This process requires that evidence supporting the safety, efficacy and quality of the product be submitted to the Natural Health Products Directorate (NHPD) for assessment by means of a product licence application. Those products supported by sufficient evidence to support the safety, efficacy and quality of the product are issued a product licence and corresponding Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM), which must appear on the product label (e.g., NPN 12345678) as proof that Health Canada has authorized the sale of the product.

NHPs Making Preventative Health Claims for Schedule A Diseases or Conditions

The evidence required to support the safety and efficacy of an NHP making a preventative Schedule A health claim is outlined in Appendix C of the guidance document on Schedule A and Section 3 of the *Food and Drugs Act*.

Labelling and Advertising of Schedule A Health Claims

For approved Schedule A preventative health claims:

- The Schedule A health claim appears on the label.
- The Schedule A health claim appears in advertisements to the general public.

For any other Schedule A health claim:

- The Schedule A health claim must not appear on the label.

[1] A similar amendment was made to the *Food and Drug Regulations* with respect to drugs making Schedule A claims.

- The Schedule A health claim must not appear in any advertisement to the general public.

More information on advertising can be found in the **Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)** *(*http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/guide-ldir_consom_consum-eng.php)