

Guidelines for Advertising NHP's

**Jennifer McKenzie and Catherine Lovrics of Bereskin & Parr
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Bereskin & Parr
40 King Street West, 40th Floor,
Toronto, Ontario, Canada M5H 3Y2

Phone: 416-364-7311

Fax: 416-361-1398

www.bereskinparr.com

On April 10th 2006, Health Canada released the second consultation draft of the *Consumer Advertising Guidelines for Marketed Health Products (for nonprescription drugs including NHPs)* ["the Guidelines"]. The Guidelines are intended to be used by industry and Advertising Standards Canada (the preclearance agency for broadcast and mass print advertising to consumers) to ensure that direct-to-consumer advertising in Canadian media of nonprescription drugs, including NHPs, meets legal requirements.

The revised Guidelines are the product of two rounds of external stakeholder e-consultation in February 2005 and April 2006. There was overall support for the Guidelines with one exception: consensus was not reached on the requirements relating to "risk information communication" (Section 2.21). The Section states that consumers should always be advised to read the label, follow directions of use for the advertised product, and be provided with an easily accessible source of additional appropriate information. Section 2.21 also provides that when applicable, or where appropriate, consumers should be: warned of side effects and interactions of the product; informed that the product is not suitable for everyone; and advised to speak to a health professional for additional information and appropriate advice. The Section specifically states that television and radio ads should carry a verbal message stating that the labels should be consulted to obtain risk information. Visual disclosures (supers) in broadcast advertisements must be of a size and shade and appear on the screen for a duration sufficient for an average person to read and comprehend it. Disclosures in print advertisements must also be in a type size and location sufficiently noticeable for an average person to read and comprehend, and in a print that contrasts with the background against which it appears.

On June 28th 2006, Health Canada hosted an invitational roundtable of 20 participants, with a balanced representation of views. Section 2.21 will be discussed at the roundtable, and it is expected that the Section will be amended.

NHP PLA APPLICATIONS: NHPs

In March 2006, Health Canada revised the Compliance Policy for Natural Health Products that supplements the Natural Health Products Compliance Guide (NHPCG). The Policy replaces and supercedes the Interim DIN Enforcement Directive (1998) and the Therapeutic Products Compliance Guides as applicable to NHPs. It explains Health Canada's approach to regulating and approving NHPs that have not received market authorization.

Health Canada will undertake the following approach to compliance: priority will be determined on a risk-mitigation basis; product categorization priorities complement the risk-based approach.

Accordingly, priority is given to the following categories of NHPs in sequence: 1) NHPs listed as drugs (June 1, 2004), 2) isolates, amino acids, fatty acids, concentrated volatile (essential oils) for internal use, and extracts that are not prepared by traditional methods (January 1, 2005), 3) algal, bacterial probiotic, fungal and non-human animal materials (June 1, 2005), 4) plants, plant materials; extracts prepared by traditional methods, volatile (essential oils) not for internal use (June 1, 2007), 5) vitamins and minerals and 6) homeopathic medicines (June 1, 2008).

On April 25th 2006, the Natural Health Products Directorate (NHPD) issued an important notice related to the backlog of over 10,000 product license applications (PLAs) for NHPs. Nonetheless, the NHPD is aiming to acknowledge all PLAs within *three days of receipt*. To address the backlog, performance standards and backlog elimination measures will be put in place. For example, the NHPD will now only process complete PLAs; incomplete applications will be refused entry to the "level one" processing queue and removed from the "level two" processing queue, and returned to the applicant. To avoid seeing your application returned, consult the checklist below to help ensure your application is complete.

INFORMATION REQUIREMENTS	PRODUCT LICENCE APPLICATION TYPE						
	Traditional	Non-Traditional	Homeopathic		Compendial (NHPD Monograph)	TPD Labelling Standard / Category IV Monograph	Transitional
			Specific Claim	Non-specific Claim			
Product Licence Application Form	✓	✓	✓	✓	✓	✓	✓
Proposed Label Text	✓	✓	✓	✓	✓	✓	The most recent version of the approved text
Evidence Summary Report	✓	✓	NA	NA	NA	NA	NA
References	A	B	C,D	D	E	F	NA
Safety Summary Report	✓	✓	NA	NA	NA	NA	NA
Quality Summary Report	✓	✓	✓	✓	NA	✓	✓
<p>A. Minimum of two traditional references. Please photocopy the relevant pages, including the cover page.</p> <p>B. Minimum of two pieces of evidence to support the product. Abstracts are not accepted a key references; however, they may be included as part of evidence.</p> <p>C. Minimum of two homeopathic references per medicinal ingredient to support the health claim.</p> <p>D. One reference to an acceptable homeopathic pharmacopoeia per medicinal ingredient.</p> <p>E. Reference of a NHPD monograph from the <i>Compendium of Monographs</i>.</p> <p>F. Reference to a TPD Labelling Standard or Category IV monograph in a cover letter.</p>							