



Exporting Dietary Supplements from the U.S. to Canada: A Canadian Perspective

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Manufacturers and distributors intending to market their U.S. dietary supplements in Canada will want to understand the key differences between the regulation of dietary supplements in the U.S. compared to their regulation in Canada.

Introduction

Dietary supplements, which are classified as foods in the U.S., are typically classified as drugs in Canada, and are therefore subject to greater regulatory attention.



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Under the *Dietary Supplements Health and Education Act*, dietary supplements are defined by reference to their ingredients: specifically, whether the product contains a “dietary ingredient” that is intended to supplement the diet, including vitamins, minerals, herbs or other botanicals, amino acids, enzymes, organ tissues and metabolites.¹ Dietary supplements may be formulated as tablets, capsules or powders, but may also take more “food-like” forms such as drink and energy bars. Since these products are regulated as foods, manufacturers are not required to submit evidence of safety or efficacy to the FDA before products go to market.

Conversely, with the exception of a few specific products,² most products classified as dietary supplements in the U.S. would be classified as natural health products (NHPs) in Canada.³ NHPs are regulated as drugs in Canada, although under a different regime than classic prescription drugs. The *Natural Health Product Regulations* apply to NHPs, whereas the *Food and Drug Regulations* apply to prescription drugs. NHPs are defined as products containing specified natural ingredients, such as vitamins, minerals, amino acids, or plant, algal, bacterial, fungal, or non-human animal materials or extracts, which are intended for use in: (a) diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state; (b) restoring or correcting organic function; or (c) modifying organic functions.⁴

The database of licensed NHPs demonstrates the variety of different products approved as NHPs in Canada. In addition to products such as vitamin tablets that would be classified

as dietary supplements in the U.S., additional products are regulated as NHPs in Canada, including certain anti-dandruff shampoos, toothpastes, mouthwashes, antiperspirants, and antiseptic ointments and lotions, depending on both the ingredients of the products and the marketing claims made about those products.

Since NHPs are regulated as drugs, the marketing and sale of these products in Canada requires site license approval for a manufacturer and/or importer, as well as license approval of the product itself. Submission of evidence satisfying product safety, efficacy, and quality is generally required. Further, after licensing, NHP manufacturers and importers are subject to continuing regulatory obligations relating, for example, to labelling and marketing, record keeping and reporting of adverse events.

As a result of this more rigorous regulation, however, dietary supplements sold in Canada may be allowed to make more drug-like marketing claims, such as claims to the treatment or prevention of particular diseases or conditions (provided these claims are within the scope of the product’s Canadian NHP license).

NHP Licensing

In practice, product safety and efficacy are handled differently by the U.S. and Canadian regulatory systems for dietary supplements. In the U.S., there is no pre-approval requirement, and the FDA must demonstrate that a product is unsafe before it may take action to remove the product from the market. Conversely, in Canada, the manufacturer or importer must demonstrate to Health Canada that the product is safe, effective, and of sufficient quality before a license will

be issued and the product can be marketed for sale.

As mentioned above, a site license is required to manufacture, package, label or import an NHP for sale in Canada⁵. A site license may be required, for example, even if an importer immediately ships the product to retailers after entry into Canada without first storing the product.⁶ To obtain a valid site license for a particular NHP, an entity must submit Quality Assurance Reports for both the import site and for any foreign manufacturing sites to demonstrate compliance with Good Manufacturing Practices (GMP). Site licenses will only be granted for domestic Canadian sites; therefore, the NHP license holder is responsible for ensuring GMP compliance of a foreign manufacturer.

In addition to site licensing, Health Canada also requires NHPs to be licensed before marketing and sale in Canada.⁷ In order to streamline the licensing process, Health Canada has published monographs for ingredients that are commonly found in NHPs. These monographs list previously approved doses, administration methods, indications and claims that can be made with respect to a particular ingredient. Applications for NHPs that conform to the specifications of existing monographs can generally receive approval without further safety and efficacy data. Currently, Health Canada has established three target timelines for responding to NHP licensing applications, depending on the complexity and novelty of the application. Applications indexed against a single ingredient monograph will be reviewed and licensed within 10 days. Applications indexed against multiple monographs are targeted for review within 30 days.

Finally, applications with higher uncertainty, such as those with previously unlicensed claims for serious conditions, never-before reviewed ingredients or combinations, or products with safety concerns are targeted for review within 180 days.⁸

Health Canada takes a risk-based approach to evaluating safety and efficacy.⁹ The level of risk associated with an application will depend on the medicinal and non-medicinal ingredients, as well as the recommended use and proposed health claims. Products that bear claims to treat, cure, or prevent serious diseases will attract a higher risk classification, while products directed at general health maintenance or which are directed at minor symptoms or diseases will attract a low-risk classification.

The minimum standard of safety and efficacy evidence depends on the risk categorization of an application. For low-risk products, references to human *in vivo* data in reputable textbooks regarding medicinal and non-medicinal ingredients may suffice. For high-risk products, Health Canada may require clinical trials.¹⁰ Health Canada will also consider positive decisions regarding health and efficacy from other regulatory agencies; however, this may be of limited assistance to exporters of U.S. dietary supplements as licensing approval for these products is not required to enter the U.S. market.¹¹

Labelling

Health Canada requires NHPs to carry specific information on inner and outer labels, reflecting their status as drugs.¹² The labels must include medicinal and non-medicinal ingredients, lot numbers, expiry dates, and recommendations for use, including dosage, frequency, and route of

administration. A description of the source of each medicinal ingredient must also be provided. Information on labels must be consistent with the information provided in the NHP licensing application, and labels cannot include claims beyond the scope of the license granted by Health Canada.

Certain text on labels must be provided in both English and French, including recommendations for administration, dosage and duration of use, risk information and known adverse reactions, medicinal and non-medicinal ingredients, and appropriate storage conditions.¹³ This text must be bilingual regardless of whether or not the product is sold in Quebec. If the product is sold in Quebec, additional French language requirements apply, including fully bilingual text and equal prominence of French and English text.¹⁴

Post-Licensing Product Changes

Health Canada must be notified if changes are made to the product after licensing. For minor changes with no significant impact on safety, efficacy or quality, Health Canada must be notified within 60 days of the change. Where changes may impact safety, efficacy or quality, Health Canada must approve the change through an amendment to the product license before it is implemented. In cases of fundamental changes to the product, Health Canada may require that a new license be issued, based on fresh supporting evidence of safety, efficacy and quality. Also, if Health Canada changes an ingredient monograph that is related to an NHP, the manufacturer or importer must submit either a notice of change or proposed amendment, depending on the impact of the change to the monograph.¹⁵

Adverse Event Reporting

As with prescription drugs, NHP licensees must report adverse events to Health Canada. Under the NHP Regulations, individual case reports must be sent to Health Canada within 15 days for each serious adverse reaction that occurs in Canada, and for each serious and unexpected adverse reaction domestically or internationally. Further, Health Canada requires annual reports to be prepared compiling all adverse reactions inside Canada and individual case reports as required above.¹⁶

Advertising of NHPs in Canada

Advertising for drugs in Canada, including NHPs, may be reviewed by Advertising Standards Canada (ASC), a self-regulatory body of the Canadian advertising industry. Although there is no legal requirement to submit proposed advertisements to ASC for review, as a practical matter, the majority of print and broadcast media outlets will not run advertisements without ASC approval. Although ASC is independent from Health Canada, it will review advertisements for compliance with Health Canada regulations.¹⁷ ASC will generally provide a review within four business days for a nominal fee, and will grant an ASC approval number that can then be provided to media outlets.

For television advertising, manufacturers and importers should also seek approval from the Television Bureau of Canada (TVB), a non-profit association that operates on behalf of the major Canadian television broadcasters, meaning that without TVB approval, the avenues for television advertising may be limited. Costs for review and approval of advertising by

TVB are paid by member television broadcasters, with reviews generally provided within one to three business days, and same-day review available for a nominal fee. Each version of a television advertisement should receive its own review and approval from TVB.

Unintentional Export

If a dietary supplement is not marketed or sold in Canada, and there is no intent to export the product to the Canadian market, U.S. manufacturers and distributors should still understand the implications of cross-border “spillover” of the product. Generally speaking, Health Canada has taken the position that where there is no intent to export and no marketing or sales operations are active in Canada,

domestic Canadian drug regulations would not apply.¹⁸ Further, individuals are permitted to cross the border with a three-month personal supply of a dietary supplement that has not been approved for sale in Canada, since this amount is regarded as insufficient for commercial sales.¹⁹ However, Health Canada has issued blanket prohibitions on the import of particular products and ingredients into Canada. Health Canada regularly issues recalls and press releases regarding particular NHPs that contain prohibited or toxic ingredients. A current list of product recalls, alerts, and advisories may be found on the Health Canada website.²⁰

Conclusion

Because of the differences in classification of dietary supplements as

foods in the U.S. and NHPs (a class of drug) in Canada, any manufacturer who seeks to export a dietary supplement to Canada will want to be aware of applicable Canadian regulations.

1. 108 Stat. 4325.
2. In some circumstances, if the dietary supplement is in a particularly food-like form, is packaged and represented as a food product, and is perceived by the public as a food product, Health Canada is may classify a dietary supplement a food. Health Canada’s policy, for example, is to classify energy drinks as foods: <http://www.hc-sc.gc.ca/fn-an/legislation/pol/energy-drinks-boissons-energisantes-eng.php>.
3. Natural Health Products Directorate, Food Directorate, *Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats* (June, 2010); Health Canada,

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- Food Safety & Culinary Innovation
- Raw to RTE
- Food Service to Retail



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- Foods Marketed as Natural Health Products*, online <<http://www.hc-sc.gc.ca/fn-an/prodnatur/index-eng.php>>.
4. *Natural Health Products Regulations*, S.O.R./2003-196, s. 1 [*NHP Regulations*].
 5. *NHP Regulations*, *supra* note 4 s. 27.
 6. *NHP Regulations*, *ibid*; see Natural Health Products Directorate, *Site Licensing Guidance Document*, (September 2007), online <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodnatur/slgd-drle-eng.pdf>.
 7. *NHP Regulations*, *supra* note 4 s. 4; see Natural Health Products Directorate, *Pathway for Licensing Natural Health Products Making Modern Health Claims*, (December 2012), online <<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/modern-eng.php>> [*Licensing Pathway*]; see also Natural Health Products Directorate, *Pathway for Licensing Natural Health Products used as Traditional Medicines*, (December 2012), online <<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/tradit-eng.php>>.
 8. Health Canada, *The approach to natural health products*, online <<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/nhp-new-nouvelle-psn-eng.php>>.
 9. *Licensing Pathway*, *supra* note 7.
 10. *Ibid*.
 11. *Ibid*.
 12. *NHP Regulations*, *supra* note 4 s. 86; see Natural Health Products Directorate, *Labelling Guidance Document*, (August 2006), online <<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/labelling-etiquetage-eng.php>> [*Labelling Guidance*]; see also Health Canada, *Labelling Requirements Checklist*, (April 2011), online <<http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/label-list-etiquet-eng.php>>.
 13. *NHP Regulations*, *supra* note 4 s. 87; *Labelling Guidance*, *supra* note 12.
 14. *Charter of the French Language*, C.Q.L.R. c. C-11, s. 51.
 15. *NHP Regulations*, *supra* note 4 ss. 11-13; see Natural Health Products Directorate, *Post Licensing Guidance Document*, (December 2007), online <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/plgd_ps-ddlr-eng.php>.
 16. *NHP Regulations*, *supra* note 4 s. 24; see Health Canada, *Guidance Document for Industry – Reporting Adverse Reactions to Marketed Health Products*, (2 March 2011), online <http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2011-guidance-directrice_reporting-notification/index-eng.php>.
 17. see e.g. Health Canada, *Guidance Document: Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)*, (18 October 2006), online <http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/guide-ldir_consum_consum-eng.php>.
 18. see Health Products and Food Branch Inspectorate, *Import and Export Policy for Health Products Under the Food and Drugs Act and its Regulations*, POL-0060, (1 June 2010), online <http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/pol-0060_biu-uif-eng.php>.
 19. *Ibid*.
 20. Online <<http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/index-eng.php?cat=5>>.