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Communiqué

for Health Industry Clients
on the Legal Retainer Program

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Canada's New Natural Health Products Regulations

On December 22, 2001, the long awaited and eagerly anticipated draft Natural Health Products Regulations were published in Canada Gazette Part I. [http://www.hc-sc.gc .ca/english/media/releases/2001/2001 136e.htm].

In announcing the new Regulations Health Canada acknowledged the large scope of this industry, indicating that Canadian sales are estimated to exceed $1.5 billion and noted that recent surveys have shown that more than half of Canadians regularly consume natural health products ("NHPs").

Once the new regulations are enacted, Canada's Federal Department of Health will transfer responsibility for an estimated 25,000 – 30,000 products to the regulatory authority of the Natural Health Products Directorate ("NHPD") of Health Canada. This will include products that are currently regulated as drugs (such as vitamins and mineral supplements) as well as many products that are currently unregistered.

Historically, in Canada, NHPs have been regulated as either food or drugs. This has led to significant confusion in the market place as consumers have been offered products labeled as foods (without health claims) along side of almost identical products labeled as drugs (with health claims and directions for use). This situation led Canadian consumers to demand regulation of these products in order to obtain assurances of both the safety and quality of NHPs.

The proposed Regulations contain requirements governing the manufacture, packaging, labeling, storage, importation, distribution and sale of NHPs. Under the new Regulations, NHPs will be considered a sub-set of drugs under the *Food and Drugs Act*.

Proposed Definition of A Natural Health Product

The proposed definition of a natural health product [1] has two components, a function and a substance component. The function component relates to NHPs which are manufactured, sold or represented for use in:

i. the diagnosis, treatment, mitigation or prevention of a disease, disorder, or abnormal physical state or its symptoms in humans;
ii. restoring or correcting organic functions in humans; or
iii. maintaining or promoting health or otherwise modifying organic functions in humans.

You will note that the proposed NHP definition allows for a full range of health claims including structure-function, risk-reduction and therapeutic or treatment claims. The substance component of the NHP definition is ingredient driven. This is an inclusion list outlining the medicinal ingredients that can be contained within an NHP and an exclusion list which lists substances that are not permitted in NHPs.

Inclusion List (Schedule I)

Permissible medicinal ingredients of NHPs include:

(a) a plant or plant material, alga, fungus or non-human animal material,
(b) an extract or isolate of (a), the primary molecular structure of which is the same as that which it had prior to its extraction or isolation,
(c) a vitamin (a term which is defined in the Regulations) or any of its salts or derivatives,
(d) an amino acid or any its salts,
(e) an essential fatty acid,
(f) a synthetic duplicate of (b) to (e),
(g) a mineral, and
(h) a probiotic (a term which is defined in the Regulations and is intended to capture such things as acidophilus).

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[1] "Natural health product" means a substance set out in Schedule I or combination of substances in which all the medicinal ingredients are substances set out in Schedule I, homeopathic preparation or a traditional medicine, that is manufactured, sold or represented for use in … However, a natural health product does not include a substance set out in Schedule II or any combination of substances that include a substance set out in Schedule II.

Certain herbs given their known physiologic or pharmacological properties will be considered NHPs and an administrative list of these herbs is being prepared by Health Canada.

Exclusion List (Schedule II)

An antibiotic, a substance intended for injection, a substance regulated under the *Tobacco Act*, or a substance described in Schedule C (radiopharmaceuticals) or D (biologics) to the *Food and Drugs Act*.

The NHP definition does not include conventional foods, nor was it drafted with the intention of capturing traditional foods which are consumed primarily for nourishment or hydration.

The Proposed Regulatory Framework

The proposed regulatory framework for NHPs includes product licensing, adverse reaction reporting requirements, site licensing, good manufacturing practices, clinical trials and labeling/packaging.

Product Licensing

NHPs will be required to obtain a product license prior to sale in Canada. The applicant must provide information on the medicinal ingredient(s), recommended conditions of use, information that supports the safety and efficacy of the NHP, a copy of the specifications to which the NHP complies and an attestation that the NHP was manufactured, packaged, labeled, imported, distributed and stored in compliance with the NHP Good Manufacturing Practices ("GMPs") Regulations. For domestic products, GMP compliance information will be derived from the site license number and in the case of imported products, the applicant will be required to submit other evidence of GMP compliance. This evidence may include a report from a Health Canada Inspector or a compliance audit conducted by a person having the requisite technical expertise.

Upon successful completion of pre-market review, the NHP will be issued a product license which will include the product license number.

License applications for NHPs that comply with a monograph found in the Compendium of Monographs

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published by Health Canada will be subject to a 60-day disposition clause.

Adverse Reaction Reporting

Product License holders are responsible for providing Health Canada with a case report for each serious adverse reaction to their products within 15 days after becoming aware of the reaction.

Site Licensing

A site license will be required for importers, distributors, manufacturers, packagers and labelers of NHPs. A site refers to any building in which a NHP is imported, distributed, manufactured, packaged, labeled or stored prior to sale. The site license will specify which activities are permitted at the site for which it is issued.

Good Manufacturing Practices

Part 3 of the Regulations set out the proposed Good Manufacturing Practices Regulations for NHPs. These provisions set out the requirements for product specifications (identity, purity, potency), premises, equipment, personnel, sanitation program, operations, quality assurance, stability, records, sterility, lot or batch samples, and recall reporting.

Clinical Trials

The Regulations contain detailed information in connection with the sale or importation of NHPs for clinical trials.

Labeling and Packaging

NHP labels will be required to include product information such as the brand name, product license number, dosage form, net quantity, the license holders name and address, the strength or potency of each medicinal ingredient, a qualitative list of all non-medicinal ingredients, the recommended use, the recommended route of administration, warnings, contra-indications or known adverse reactions associated with the product's use. storage conditions, lot number, expiration date, and a description of the source material from which the medicinal ingredients are derived or obtained (for example, root of plant).

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There are also provisions dealing with small containers, security packaging, pressurized containers, cautionary statements and child resistant packaging.

Schedule A Claims

Industry stakeholders have voiced concern that NHPs will be unable to make certain label claims even if there is scientific evidence to justify them due to the restrictions of section 3 and Schedule A of the *Food and Drugs Act*. The NHPD is currently working with other Directorates within Health Canada to resolve this difficulty.

Standards of Evidence for Safety and Claims

A significant component of the new regulatory framework, namely, the standards of evidence for the evaluation of safety and claims for NHPs also remains undetermined at this time. A discussion document was tabled by the NHPD during a stakeholder consultation meeting in late October 2001, that sets out a proposal that is based on traditional and non-traditional use of NHPs.

Conclusion

In comparing the Canadian *Natural Health Products Regulations* to the American *Dietary Supplement Health and Education Act of 1994*, it has been noted that Canadian NHPs have the potential to legally make a wider array of claims than their US counterparts. The flip side of the coin, is the requirement for product and site licensure for NHPs sold in Canada.

Perhaps coincidentally, only days after the introduction of the draft NHPs Regulations came two Advisories from Health Canada in connection with two products traditionally regarded as natural health products, ephedra and kava. On January 8, 2002, Health Canada requested the recall of all ephedra products in the Canadian marketplace that did not carry a drug identification number ("DIN"). On January 16, 2002, Health Canada issued another advisory requesting that consumers not use kava products with or without a drug identification number.

Not surprisingly, members of the NHP industry in Canada have voiced concern over the potential cost of compliance with the new Regulations. Many stakeholders regard the

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new Regulations with mixed feelings. It is widely acknowledged that it is realistic to anticipate that there will be fees associated with the licensing of both products and sites in the foreseeable future.

With the publication of the draft Regulations on December 22, 2001, a 90-day comment period commenced during which industry stakeholders may offer comments on the proposed Regulations. The new Regulations will not become law until they are published in Part II of Canada Gazette. Following enactment of the Regulations, there will be a period of time for NHP manufacturers and importers to bring their products and sites into compliance with the new Regulations. In the meantime, most NHPs are treated by the Canadian regulatory authorities as "Products Subject to Special Measures" and accordingly, are subject to Health Canada's *Interim DIN Enforcement Directive.*

About the author:

Wendy G. Hulton is a Partner in our Health Industry Practice Group. She advises food, drug, cosmetic and natural health product companies on a variety of regulatory matters.

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