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Abbreviated Labelling Standards for Natural Health Products

Discussion Paper

Natural Health Products Directorate
Health Products and Food Branch

Canada 

"Health Canada is the Federal department responsible for helping Canadians maintain and improve their health, while respecting individual choices and circumstances."

Health Canada

"Our role is to ensure that Canadians have ready access to natural health products that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity."

Natural Health Products Directorate

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Introduction

The Natural Health Products Directorate (NHPD)¹ is the regulating authority of **natural health products** (NHPs)² for sale in Canada. Its role is to facilitate ready access for consumers to NHPs that are safe, effective and of high quality while respecting freedom of choice and philosophical as well as cultural diversity.

Generalized claim
(NHPD working
definition)

A health claim
statement that
describes a
generalized or qualified
use or benefit of an
NHP, used to make a
claim more applicable
to the evidence.

The NHPD is exploring the use of abbreviated labelling standards for generalized claims as part of its new risk-based approach. A key element of this approach is the development of tools for NHP licence applicants and Health Canada assessment that support regulation proportional to risk, in keeping with the known risks, uses and benefits of these health products.

As part of this initiative, on January 21, 2009, the NHPD held a workshop with NHP stakeholders, including consumers, health care practitioners and industry, to obtain feedback on proposed abbreviated labelling standards and generalized claims. Appendix A provides information on the workshop discussion topics and questions as well as the list of workshop participants.

A draft of this discussion paper was provided to workshop participants as background to help guide the day's discussions. Comments received from participants during the workshop have been incorporated into this revised discussion paper.

A Regulatory Framework for Natural Health Products

1998 - Government
initiates SCOH review,
in response to
concerns raised by
consumers regarding
increasing numbers of
unregulated NHPs on
the market and
increasing use of
NHPs by Canadians.

Natural health products are an emerging, evolving group of health products in Canadian and international markets. A 2005 Health Canada consumer survey³ showed that 71% of Canadians regularly used NHPs. The regulatory framework for these products in Canada was initiated in 1997 when the House of Commons Standing Committee on Health (SCOH) tabled a report⁴ with 53 recommendations pointing to the development of a new framework for NHPs. The report included recommendations on allowing for a range of evidence (e.g., traditional use as medicine, published data, clinical trials), regulation proportional to risk and consumer information (informed choice).

The *Natural Health Products Regulations* came into effect on January 1, 2004.

Consumers want to
know that what is on
the label is what is "in
the bottle" and that the
NHP does what the
label says it does.

Consistent with the SCOH's recommendations, the NHP Regulations offer a regulatory framework that sets out the requirements for sale of NHPs in Canada, focused on product quality, safety and efficacy. The Regulations include provisions for product and site licensing, good manufacturing practices, NHP clinical trial authorization, adverse reaction reporting, and labelling.

The NHPD applies four principles to ensure the appropriate licensing of NHPs:

- product assessment tools should support timely, appropriate and consistent licence application submission and review;
- evidence should support product safety and efficacy;
- the totality of evidence should be evaluated, including emerging information;
- consumers have access to NHPs that are of high quality, are safe and bear health claims supported by data.

NHP Regulations, section 5(g)

A product licence applications must contain “information that supports the safety and efficacy of the NHP when used in accordance with the recommended conditions of use.”

Over 34,000 NHP licence applications have been received by Health Canada between January 2004 and January 2009. While there are currently some 120 NHP monographs available, these only cover a limited number of the ingredient combinations found in licence applications. Through experience and knowledge gained, the NHPD identified that some of the review challenges related to these and other NHP licence applications could be addressed through the development of pre-cleared information, in the form of labeling standards.

The New Risk-Based Approach for Natural Health Products

The development of pre-cleared information is an initiative under the new risk-based approach for NHPs. This approach envisions two classes of product licences. Determining the class of a product is dependant on the degree of certainty (that is, known and credible evidence) associated with a product’s safety, quality and health claim:

- Class I – products and/or claims for which there are readily available existing high quality sources of evidence; submission evaluation is focussed on specific pre-cleared parameters (pre-cleared information) related to efficacy, safety and quality.
- Class II – higher risk due to a new or emerging nature of some evidence (e.g., a new and novel product); require individual evaluation of each submission.

Generalized claims fall within the “Class I” category of licences. Use of abbreviated labelling standards for generalized claims would enable Health Canada to focus on the evaluation of Class II product licence applications.

The New Risk-Based Approach for NHPs aligns with the aim of the Health Products and Food Branch *Blueprint for Renewal*⁵ by:

- supporting a dynamic and flexible approach. Use of a generalized claim may be appropriate for a particular NHP and be kept by a licence holder over the long term. However, a licence holder may also choose to submit an amended application at a later date, as per s.11.1(d) of the Regulations, to change to a specific claim as evidence becomes available;
- supporting the life-cycle approach to health product regulation; managing product safety through re-evaluation of a product’s risk-benefit profile as knowledge about the product grows; and,
- providing a response to NHP stakeholder concern regarding the need to better include the concepts of health promotion and disease prevention as part of the regulation of NHPs, according to the known, risks, uses and benefits of NHPs⁶.

Developing Generalized Claims for Natural Health Products

Natural health products include vitamins, minerals, herbal products and homeopathic remedies.

A health claim can be described as “a statement that indicates the intended beneficial effect of a product when used in accordance with the recommended dose, duration of use, and route of administration.”⁷

Health claims for NHPs (as defined in the Regulations), must have evidence demonstrating they are truthful and can be relied upon by consumers. Health claims:

- should not mislead, exaggerate or deceive either directly or by implication; they should not suggest or imply health benefits beyond the scope of the evidence;
- should not lead to unsafe or inappropriate use of the product;
- supporting evidence should show that the claim outweighs any opposing evidence or opinion; and,
- should consider risk; risk is relative to the claim.

A generalized claim is a health claim statement that describes a generalization or qualified use or benefit of an NHP, and is used to make a claim more applicable to the evidence (working definition). A generalized claim should be clear, meaningful and helpful to consumers in making informed choices.

Evidence for Natural Health Products

Use of a generalized claim does not replace requirements for applicants to provide assurances of quality of a product.

As with all NHPs, the required risk information (cautions, warnings, contra-indications) is identified according to the risk profile of the particular product. It may be possible to apply standard risk information to generalized claims (for example, “if symptoms persist or worsen, consult your healthcare practitioner” for claims for symptomatic relief). As the *Evidence for Safety and Quality of Finished Natural Health Products* guidance document⁸ indicates, where safety issues are identified, evidence that the strategies are viable is required. This may be provided through the following sources.

Traditional	references to traditional uses (at least 50 consecutive years of use) e.g. pharmacopeias
Clinical Trials	well-designed systematic reviews and meta-analyses of randomized controlled trials (RCTs) or other clinical trials, or at least one well-designed RCT (preferably multi-centred).
Studies	well-designed descriptive and observational studies, such as correlational, cohort studies, case-control studies.
Publications	peer-reviewed published articles, pharmacopeias, conclusions of other reputable regulatory agencies, previous marketing experience and expert opinion reports.

See Appendix B
Glossary of Terms

Conditions for claims exist within each of the health product categories. For example, public advertising of health claims is prohibited under the *Food and Drugs Act* for prescription medications. For NHPs, claims can be traditional, referring to practices based on indigenous or cultural experience with evidence of at least 50 consecutive years of use. They can also be non-traditional, that is supported by scientific evidence acquired from sources including clinical studies, pharmacopoeias, textbooks and expert opinion reports.

Whether traditional or non-traditional, NHP claims may relate to:

- treatment—diagnosis, treatment, mitigation or prevention of a human disease or health condition,
- risk reduction—relationship between an ingredient and reduction in risk of developing a certain disease or health condition, or
- structure-function—effect or support of an ingredient on a human structure or anatomical, physiological, or mental function; claims may include broad statements related to the promotion of overall health.

As with any NHP claim, a generalized claim is based on all available evidence that adequately supports the claim. The type and level of evidence required to support the claim is related to level of risk and benefit, which in turn relates to the specificity of the proposed claim. As with all NHPs, efficacy for generalized claims can be substantiated using a range of evidence.

Supplemental evidence:

Evidence provided to support the safety or efficacy evidence provided through other reference sources and evidence levels.

Currently, evidence derived from in vivo or in vitro studies and non-clinical studies, such as nutritional and microbiological studies, may only be used as supplemental evidence. The NHPD included, as part of the January 2009 workshop, a discussion on use of animal studies as support for safety or efficacy of an NHP. Comments received from workshop participants are presented in section 3.2.

Specific versus Generalized Claim

As stated in the *Evidence for Safety and Efficacy of Finished Natural Health Products* guidance document⁹, NHP claims may be specific or non-specific. While the guidance document states that Health Canada prefers the use of specific claims, non-specific claims are also considered in cases where there is adequate evidence to demonstrate safety. Examples of non-specific claims provided in the guidance document include terms such as "tonic" in the context of a traditional Chinese medicine claim and "adaptogen" in the context of a naturopathic claim. Some of the claims explored as part of the development of abbreviated labelling standards can be described as "non-specific" (for example, claims related to relaxation and vitality). Comments received from workshop participants regarding non-specific claims are presented in section 3.3.

In some instances, the NHPD *Compendium of Monographs*¹⁰ includes both general and specific claims. For example, the monograph for Iron provides the following under "use or purpose":

- General: A factor in the maintenance of good health (IOM 2006; IOM 2001).

- Specific: Helps to form red blood cells and helps in their proper function (IOM 2006; Shils et al. 2006; IOM 2001; Groff and Gropper 2000); Helps to prevent iron deficiency, or Helps to prevent iron deficiency anemia (IOM 2006; Shils et al. 2006; IOM 2001; Groff and Gropper 2000).

This example illustrates how the type and level of evidence required for the specific claim is greater than that required for the general claim. The requirements differ, based on the product’s risk profile (including the strength of the claim), as outlined in the *Evidence for Safety and Quality of Finished Natural Health Products* guidance document.¹¹

The generalization of a claim is about making a claim more applicable to the evidence, as well as describing that the claim draws from specific cases for more general ones. These claims can be appropriate for structure-function, risk reduction and prevention claims, where such claims do not declare a curative effect.

Examples of Specific and Generalized Claims		
Relate to	Specific	Generalized
Treatment		
Diagnosis, treatment, mitigation or prevention of a disease or disorder	For the treatment of osteoarthritis	Helps to maintain healthy joints (preventive)
Risk reduction		
Relationship between an ingredient and reduction of risk of developing a disease	Use of this product is associated with a decreased risk of developing arthritis	Use of this product may help to reduce the risk of developing arthritis.
Structure-function		
Effect or support of an ingredient on structure or anatomical, physiological and mental functions	For temporary relief from arthritis and painful neuralgia.	Supports joint health

Use of generalized claims includes the identification of the rules or principles to apply in determining whether a basic generalization can be accepted as true for a particular NHP and can be used as the basis for supporting efficacy for a product claim.

Defining Abbreviated Labelling Standards for Generalized Claims

Attestation:

To certify by signature or oath or to certify in an official capacity.² Where NHP licence applicants point (attest) to pre-approved information, a monograph for example, to support the safety and

Abbreviated labelling standards, as they relate to generalized claims, include the following product label information to allow consumers to make informed choices:

- allowable generalized claim wording;
- information on dose, route of administration and risk (including warnings, cautions and contra-indications such as “Do not use if pregnant”).

The labelling standards include pre-cleared reference sources, including safety and efficacy evidence, to which an NHP licence applicants can attest. This is similar to a monograph, where an applicant attests to the labelling standard, there is no need for the applicant to submit additional evidence to support product safety and efficacy.

efficacy of their product, there is no need for the applicant to submit additional safety and efficacy evidence.

The following is an example of an abbreviated labelling standard.

Abbreviated Labelling Standard	
Ingredient	X
Route of administration	Oral
Claim	Helps to maintain XXX...
Duration of use	Ongoing
Risk information	Do not use if you are pregnant or breastfeeding
Dose	6 mg/day
Evidence Source	Human in-vivo studies, prospective cohort trials (observational)

Discussion on Generalized Claims for NHPs

As part of the January 2009 Workshop on Abbreviated Labelling Standards for NHPs, the NHPD presented a number of claim examples to participants to obtain feedback on the meaningfulness of the information, clarity and truthfulness. Comments received from participants have been summarized below under the heading “Comments from the January 2009 Workshop.”

The workshop consisted of a morning session, held with consumer, health care practitioner and industry representatives was aimed at gaining general feedback on the proposed labelling standards and generalized claims. The afternoon session included consumers and health care practitioners and focused on gaining consumer feedback on generalized claim discussion examples, specifically related to understanding of NHP health claims.

Based on the information provided in the draft version of this discussion paper, and the accompanying workshop presentation, participants discussed a series of topics and responded to a series of specific questions pertaining to each topic.

The first two topics presented in this section, “Generalized Claims Overview” and “Animal studies suggest...,” correspond to the discussions held in the morning portion of the workshop. The remaining topics were discussed in the afternoon session.

Generalized Claims Overview

Comments from the January 21, 2009, Workshop:

Workshop participants commented that the objective of abbreviated labelling standards was clear enough, noting for example that it is important to have a consistent and expedient process, that balance is critical, and that the concept is about Health Canada “wanting to capture how to fit information on labels that the consumer can easily understand.”

The purpose or reason for developing abbreviated labelling standards was not considered clear however, with participants noting that tools are already in place at Health Canada to do this (review) on a case-by-case basis or through the development of new monographs. They noted, for example:

- a lack of clarity on how the proposed generalized claims would affect products already on the market;
- a concern that the life-cycle approach could result in a “yo-yo” “on-off the market approach” and the need to clarify how products would be removed from the market; and
- a concern that generalized claims could be used to “lower the bar” on evidence or as a way to facilitate authorization of products using different (lower) standards than those currently in use.

Participants commented that the term “generalized claim” was vague and that there was different (broad) scope between the discussion examples. They noted that the some of the discussion examples “put the risk back on to the consumer to analyze the claim wording and decide [about] the strength of support for the claim.”

- Consumers need to be assured that a licensed product is safe and of high quality, and need labelling that is unambiguous and clear: terms must be defined and labels must stand alone.
- “Labels should have sufficient evidence to stand on their own, with further information supplied freely for consumers.”
- Labels should clearly state the health impact and benefit. Participants suggested that labels be tested by consumer panels or focus groups for consumer-friendliness and that consumer-friendly information be developed on NHPs, including the regulatory framework, efficacy classification, and definitions that help consumers interpret statements they see on the labels (glossary of terms).

Participants suggested the creation of a consumer section on the Health Canada website, Public Service Announcements, (e.g., what does Health Canada approval mean), provincial partnerships and partnerships with consumer and practitioner organizations as a mechanism to get the message out. “Consumers are not seeing licensed products on the shelves (i.e., with NPN-natural health product license number).” Consumers will reject products if they are not correctly informed about the regulations and licensing process. They need the most recent information. Consumers require fast, accessible information.

It was noted that communicating claims to consumers may not be straightforward and suggested “evidence level charts” and posters at point of sale in pharmacies and elsewhere “to get more information on what a claim actually means.” There was also a remark made regarding the need to consider product name which “can also be a claim.”

“Animal studies suggest...”

As mentioned in Section 2, use of “animal studies suggests...” in an NHP claim was presented as a topic for discussion and comment in the morning portion of the workshop.

Comments from the January 2009 Workshop

Participants commented that, in their view, the inclusion of “animal evidence suggests...” on an NHP label did not provide useful information for consumers. They remarked that the claim put the onus on the consumer to discern the strength or weakness of the claim and that consumers may not understand the difference between animal and human evidence. They commented that the statement made the claim appear less credible, which could impact on product marketability and perhaps lead consumers to conclude that there was no scrutiny by Health Canada. “If [consumers] see an NPN, they expect appropriate scrutiny for safety, quality and efficacy.” Participants reiterated the need for consumer education on NHPs, including information that NHPs are now regulated.

Participants did not consider animal-derived evidence to be sufficient for supporting NHP safety or efficacy in humans. They noted that animal systems are different from humans and that human evidence was required to support use in humans. The statement may be appropriate for animal/pet products or for some topical products (such as cosmetics), some suggested, but not for products ingested by humans.

In discussing the link to clinical trials, they noted that there was risk associated with clinical trials for pharmaceuticals and NHPs. Therefore, the life cycle approach should be applied to both. Some participants noted that animal evidence might be considered, in some cases, where a medicine may still need to be made available, in which case “the label should be clear and the product labelled as such.” However, participants noted that risks and ethical issues (e.g., around animal testing, media interest in NHPs/evidence) would be great in allowing this type of claim. They remarked that NHPs should be labelled in similar fashion to other [therapeutic] over-the-counter products and that requirements should be consistent for all OTCs and not just NHPs.

Natural Health Products using “Vitality, “Immune System Stimulating and Well-Being”

Consumer literacy information discourages the purchase of products with claims that appear “too good to be true” and that use “pseudomedical jargon” such as “purify, detoxify and energize.” These are said to be used to “cover up lack of scientific proof.”¹²

Defining “non-specific” claim terms such as “vitality,” “immune system stimulant” and “well-being” is required as a first step in determining their use and meaningfulness for consumers in making informed choice.

Comments from the January 2009 Workshop

Workshop participants described the terms “vitality,” “immune-system stimulant” and “well-being” as ambiguous, subjective and not clearly communicating the role of an NHP to consumers.

Participants commented that the discussion examples lacked the specific information on health outcome needed to make informed choice, and that they were therefore not appropriate for NHP labelling unless accompanied by more specific health benefit information. It was noted that there would be less concern if the terms were included as a secondary claim, for example, immune system stimulant for common colds.

Participants further stated that, in their view, the claim examples were marketing or advertising tools. They commented that labels are used as sources of information by consumers to make informed choice and this is different from marketing and advertising. “Advertising versus labelling is push-pull... Push is marketing. Labelling is not about the push.”

Some participants remarked that the terms might be difficult to measure and define and that the “SMART” principles should be used (i.e., specific, measurable, achievable, realistic and timely). Concerns were expressed regarding safe use of products without greater definition and specificity. The suggestion was made that claims using these terms should carry the qualifier “may” to soften the statement and introduce an element of doubt. There is “a lack of general public understanding” respecting these terms which could result in the claims “being misleading and potentially prevent a consumer from using evidence-based medicine or from consulting a health care practitioner.” Consumers need more guidance on use and benefit of such claims.

It was also, however, noted that the terms “vitality” and ‘well-being’ were accepted phrasing within certain healing paradigms, referring to life forces in traditional Chinese medicine for example and perhaps applicable to some Aromatherapy claims (relaxes therefore increases well-being). In their proper place, the terms can be appropriate.

“Increased Vitality”

Participants commented that the discussion example brought to mind advertising terms – vitality, energy, with participants remarking that energy may be a more appropriate term, depending on method of action, and suggested for example “can/may provide sustained energy/increase in energy.” Participants commented that the term vitality needed to be better defined, that it meant “something different for everyone.” It could be interpreted as quality of life, implying abundant health in all systems and could also be interpreted as a burst of energy or mental alertness. Consumers need to know how the product is going to increase vitality.

“Improves Well-Being”

Participants commented that the discussion example “improves well-being” required clearer indication of health benefits. “Shoe polish may improve the well-being of a shoe. It does not mean the shoe fits you.” Participants reiterated that claims should be very clear about the end benefit. Suggestions included: “supporting good health” or “maintaining good health”. It was also noted that the discussion example “brings to mind the idea of taking [the product] for ever,” introducing safety concerns. “Many things can improve well-being. Exercise and a good meal can improve well-being.”

It was suggested that, if these terms were used, Health Canada develop a product monograph which would list their definitions and the applicable ingredients. It was further noted that the onus to educate consumers should also be on the NHP industry. Participants commented that efficacy of a product “will show itself. If a product works, then the consumers will buy it.”

“Immune System Stimulant”

Some participants commented that “immune system stimulant” was preferred over the discussion examples for vitality and well-being, but that the claim was nevertheless also problematic: there is a “need to drill down.” The example was considered to be a blanket statement that a consumer may not understand. There could be subjective interpretation and potential misuse (unsafe use) by consumers. For example, the claim may be interpreted to mean the product is intended for infections or for a serious condition. Some participants commented that the example, as is, would require consumers to consult a health care practitioner and that there was, therefore, a need for better consumer language to clarify the claim and make the information more meaningful. Participants noted that it would be necessary to specify which part of the immune system was involved more precisely, the mechanism of action and the circumstances for the immune system stimulation. More information on the function would be required.

Safety concerns were expressed regarding use of the term “immune-system,” including a negative impact in the case of auto-immune deficiencies. The term was described as appearing to be “a category as opposed to a claim.” Concern was also expressed regarding use of the term ‘stimulation’ with participants noting that some consumers may need modulation as opposed to stimulation and that, conversely, a modulator labelled as a stimulant may deter some consumers from purchasing a product potentially beneficial for them. The terms “modulator,” “regulates,” “boosts” and “supports” were all considered better descriptors than “stimulant.”

Natural Health Product “Helps to”

In exploring the issues described in this discussion paper, the NHPD conducted a literature review on health claims which included international reviews and decisions, and consumer literacy and opinion studies.

While studies of the impact of health claims on consumers draw primarily from experience with food and dietary supplements, their conclusions may potentially be applied to NHPs. They show, for example, that consumers consider claims about

familiar product components or health promoting effects to be the most credible. Those concerning well-known components, such as vitamins, are further considered to be more convincing than those for less familiar components.¹³ Likewise, there is preference for familiar dosage forms.

Claims related to health maintenance or enhancement linked to vitamins, minerals and other supplements, such as amino acids, have been recognized for many years as acceptable claims, including under the *Food and Drug Regulations* and by international regulatory agencies such as Australia's complementary medicine framework and the U.S. Food and Drug Administration. The health benefits of supplements are well publicized and, as such, health supplement claims ("Source of calcium, for the maintenance of good health") can be said to meet the label criteria of ensuring the active ingredient is identified for the consumer. Such claims further provide the context for the health impact, in this case general good health. NHPD monographs are available for many health supplement ingredients and many issued NHP licences carry health maintenance claims. As such, development of abbreviated labelling standards for "health maintenance" claims for the above noted ingredients is not considered to be required.

Consumer studies propose that structure-function claims should clearly describe a product's intended use and specific health maintenance area to allow the consumer to understand which structure or function of the body is affected. A challenge for regulators is to make scientific probability-based information short and simple and still maintain the truthfulness of a claim.¹⁴

Abbreviated labelling standards for generalized claims may assist with establishing consistency and predictability in the context of this varying evidence.

"Helps to" claims support a range of structure-function indications. This type of claim is carried by several licensed NHPs, is permissible under the U.S. FDA and the Australian complementary medicine framework. They are found in regulatory agency monographs, including those of the NHPD, the World Health Organization and the British Herbal Compendium.

It may be possible to adopt standard risk information for "helps to" claims. For example, "If symptoms persist or worsen, consult your health care practitioner" for symptomatic relief claims.

Health Canada explored "helps to" claim wording as part of the development of abbreviated labelling standards to identify how these terms relate to the strength claim, as applied to the available evidence, and the clarity and meaningfulness of these words as they apply to an NHP label or in advertising.

Comments from the January 2009 Workshop

Participants commented that the discussion example *"Helps support and/or maintain liver health"* was vague, stating that the term "supports" may give a false sense of security to consumers, especially those with liver disease, and that "supports" appeared to be a marketing term. Participants considered that "maintain" better described the method of action and preferred use of a statement such as "helps to maintain liver/healthy liver function." It was also noted that the claim should state what function of the liver the product addressed. "Supports" was described as meaning to "hold up," "to do the job by itself."

Some participants considered the discussion example *"Helps in the absorption and use of calcium and phosphorus (vitamin D)"* to be clear and meaningful while others considered it vague, and suggested that it would be clearer to use, for example, "benefits bone health by helping with the absorption of calcium" or to add phrasing such as "can aid bone health." The term "helps" was considered sufficient, if followed by specific information (including nouns) such as "absorption" and "use." Participants reiterated that health outcomes should be stated in NHP claims to make claims useful to consumers.

The discussion example *"Contributes to healthy liver function"* was considered clear but not meaningful. Participants commented that the difference between keeping a liver healthy and preventing disease may not be clear to consumers. Some participants remarked that the term "contributes to" could give a false sense of security to consumers (health versus contributes to health). Participants further described the term as "one piece of the puzzle," as "suggesting the addition of something" and as a term that "implies it is only one part of the picture."

Regarding the discussion example *"Promotes relaxation,"* participants commented that it would be necessary to define relaxation for the claim to be meaningful and useful: is the product a muscle relaxant, a sleep aid? It was also noted that the terms "helps," "promotes," "contributes to" and "supports" were used differently in English than they were in French. For example, the "contribute" is used in French to describe both "helps" and "contributes to." The term "promotes" was described by participants as "causing something to happen versus just helping it along the way" and was considered by some to be higher level than "helps" and "contributes" and that, therefore, use of "promotes" would lead consumers to think that the product worked better or that there is a higher level of supporting evidence. The term "promotes" was considered useful but vague by other participants, adding that the term may not mean the same to everyone.

The term "aid" was noted as being an appropriate term for an NHP claim, providing it was accompanied by a qualifier (clear health outcome). Some participants commented that there would be a dichotomy for consumers regarding the discussion example, *"Digestive aid: helps improve nutrient availability,"* with some consumers responding favourably and others unfavourably. "Digestive aid is important information but does the average consumer know what an enzyme is?" The claim could be interpreted as promoting regularity without additional information. "Helps improve digestion does not equal digestive aid." Without more information, the claim would need more qualifying to be meaningful, including for example the specific method of

action and information on the active ingredient. Participants remarked that claim wording should be aimed at the average consumer, at high school level. Some participants considered “nutrient” to be a good qualifier, clarifying the intent, while other participants did not consider the term consumer-friendly.

Participants also noted that consumers might better understand “absorb” over “availability” and that they would want to see “may” on the label claim where evidence pointed to this: for example “may help improve digestion,” “may help nutrient availability,” “may help breakdown of protein.”

Claims Including Evidence Basis for Efficacy

“Consumer enthusiasm for complementary and alternative medicine presents complex challenges for conventional Western biomedically dominated health care systems In particular, these trends force new ethical dilemmas related to how we create consensus about ... what constitutes evidence sufficient for public health policy.”¹⁵

Food and nutrition studies show that consumers have difficulty sorting out the strength of scientific evidence associated with different claim levels, regardless of claim type. “This may be indicative of a consumer desire for simpler language on food and health products, as seen in structure-function claims [and] dietary guidance statements.”¹⁶

Health Canada explored the use of this type of claim as part of the development of abbreviated labelling standards to determine the feasibility and usefulness of specifying the evidence basis of a claim on an NHP label or in advertising. This approach is in keeping with the Standing Committee on Health recommendation that “the label indicate clearly the type of evidence used to support the claim.”

Health Canada recognizes the importance of reliable and transparent labelling information to facilitate informed choice for consumers.

Comments from the January 2009 Workshop

Regarding the discussion example “*Observational studies show vitamin D supports colorectal health*,” participants commented that the term “observational” was “an outlier,” advertising-like and conveyed that the product may or may not do what was claimed. They remarked that consumers may not understand “observational study” or may assume the studies involved significant (enough) number of people. Concern was expressed that the term may lead to unsafe use by consumers. Participants stated that a claim should match the evidence and, based on the strength of the evidence (studies), a product will have strong or less strong claim.

Instead of the specific evidence source, participants proposed that Health Canada use the levels of evidence, as currently done, and put more information on the Internet. Evidence should be reflected, as per the Standing Committee on Health, but the information should be off the label. Some participants suggested that, if it were deemed appropriate to include this type of information on the label, the term “evidence shows” would be sufficient, noting that removal of the (evidence source) qualifier strengthened the claim. Some participants commented that “show” was a strong word

and also a broad one, and suggested that use of the terms “associated with” or “linked to” softened the claim and added specificity.

Regarding the discussion example “*Early studies suggest that use of Yeast Beta-glucan may reduce the risk of developing colds and flus,*” participants did not view the term “early study” as clear or meaningful, particularly with respect to a lack of clarity on what was being studied. They commented that use of “studies” only or of “studies show” elevated a claim compared to ‘early studies’, but that it was confusing either way. Using this type of terminology was noted as “one way to interpret, but not the best.

Participants further remarked that it was more important for Health Canada to set standards for what constituted enough evidence and allow claims based on this. “If a product meets the standards, then the claim is permitted. It is Health Canada’s responsibility to determine whether or not the evidence is sufficient” As expressed by some participants, scientific evidence should guide the level of claim allowed, but it was not necessary to include this information on the label. If evidence was available, then the consumer did not need to see this level of information on the label. Consumers need to understand, but increased information on the label may be confusing and make it more difficult for them. A consumer “needs too much science background to understand the evidence” and it should not be assumed that all consumers would want this level of information. There needs to be an appropriate place to access the full scientific information, for those who want it.

Regarding the discussion example “*Pilot study suggests that Colostrum reduces risk of complications due to flu,*” participants did not view the term “pilot study” as helpful and noted that if consumers understood its definition, they would not buy the product. They commented that the term could be confusing and misleading, and could give more credit to a product than deserved. They also remarked that it would be necessary to specify which “complication,” as the statement did not let the consumer know if the claim referred to a serious complication or not. It was also noted that the statement made the evidence seem insufficient, “even in seeking to support accessibility of products... A proof of concept study should be reproducible.”

Participants suggested that, if the terms presented in the discussion examples were needed, the claims include “may” with supplemental information available off-label. The most meaningful way to convey information to consumers, it was suggested, would be through a coding system that indicated the strength of the evidence. This would remove the onus from consumers to evaluate the credibility of the evidence. Consumers should not have to make this decision. A coding system could be supported by an accessible, explanatory document (e.g., a glossary).

“The individual ingredients in this product have been shown to...”

Multi-ingredient products often consist of ingredients that are known to be safe and for which evidence is well-established, whether through traditional evidence or scientific data. However, while each ingredient in the product may have evidence supporting efficacy of the individual ingredients, interactions between ingredients may not be known.

Applying the claim prefix “individual ingredients in this product” can be said to support clarity for labelling (truthful, accurate).

Health Canada included this type of claim wording in its project on abbreviated labelling standards to explore the feasibility and usefulness of applying this wording to NHPs, for truthfulness and meaningfulness in labelling and advertising.

Comments from the January 2009 Workshop

Regarding the discussion example “*The individual ingredients in this product have been shown to relieve symptoms of congestion associated with colds. The combination of ingredients has not been assessed,*” some participants considered the second sentence to add value because multi-ingredient products may or may not be more beneficial than single ingredient products. It was further noted that “the” implies general while “this” implies specific. Participants also commented, however, that the example carried a negative connotation that may deter consumers from purchasing the product but that may also conversely encourage manufacturers to increase product testing and quality, and provide a way to continue to assess a product after licensing. Some participants considered the example to be unclear, implying potential safety and efficacy while at the same time implying that these had not been tested. Participants proposed that a label could list (identify) the ingredients that actually benefit/fit the claim and that by virtue of this, the label would convey to consumers that those ingredients not in the list “may or may not be beneficial for that health effect.”

Use of “may” in Natural Health Products Claims

Research on health claims reports that it can be difficult to communicate to consumers that scientific knowledge is based on best understanding and probabilities, but still contains limitations. The information provided in a claim must be balanced between being intelligible to the average consumer and presented in a way that is scientifically accurate.¹⁷

A 2008 consumer survey found that having the word “may” in a claim was enough of a qualifier to make it appear that the claim was not the subject of Significant Scientific Agreement (SSA).¹⁸ Other studies show consumer support for “may” claims, with consumers stating they “believed that the product would work for them.” These conflicting results make it unclear whether or not consumers support claims using “may.”

“May Reduce the Risk of”

Use of “may” for risk-reduction claims is consistent with risk-reduction claims allowed for foods in Canada (*Food & Drug Regulations*, section B.01.603), for food and dietary supplements in the U.S. and is included in the NHPD Compendium of Monographs (Calcium for example). The term “may” in a risk-reduction claim can be considered to improve scientific accuracy of a claim by conveying the message that the effect is possible while recognizing that health conditions and diseases may have many causes.

Health Canada included this type of claim wording in its project on abbreviated labelling standards to explore the feasibility and usefulness of applying this wording to NHP risk-reduction claims.

Comments from the January 2009 Workshop

In some participants’ view, use of “may” makes a risk-reduction claim more scientifically accurate and also more truthful: no product is guaranteed to work on every individual. They commented that, as long as safety was guaranteed, use of “may” in a risk-reduction claim supports truthful labelling that leaves the decision up to the consumer. It was noted that consumers would buy products that have this “element-of-doubt” qualifier, that the qualifier effectively managed consumer expectations and could encourage consumers to talk to a health care practitioner. Conversely, concern was expressed about putting the onus on consumers to decide what a “may” claim means. Information for consumers on the definition and use of “may” would be required.

Regarding the discussion example “*Calcium intake when combined with sufficient vitamin D, a healthy diet and regular exercise may reduce the risk of developing osteoporosis,*” participants reiterated that the qualifier “may” introduced a truthful element of doubt appropriate for risk-reduction claims and that use of “may” could provide consistency for this type of claim. It was also noted however that “may” should not be overused and should not be required where evidence is strong enough as “may” adds an element of doubt (may or may not work).

Regarding the discussion example, “*May reduce the risk of developing age-related macular degeneration (Zeaxanthin),*” participants noted that, depending on how Health Canada would implement the use of “may,” the qualifier may encourage manufacturers to increase the quality of their product. It was suggested that the term “might” could be more useful than “may” as it conveys probable outcome rather than permission. It was also reiterated that information on claim categories and strength of evidence would be useful for consumers.

Some participants commented that they preferred the risk-reduction examples without the qualifier “may,” stating that if the evidence existed, then the qualifier was not required. Others stated that all claims should have “may” as there was no guarantee for all people.

Use of “may” in Non-Risk Reduction Claims

Use of “may” as a qualifier for non-risk reduction claims is consistent with claims used within Australia’s complementary medicine framework (for example, “May assist in the management of sore throats.”)

Use of “may” can be said to increase the generality of a claim, in that it references a specific health outcome but applies a qualifier on its proven effectiveness across populations. However, it may also suggest that there is a lack of existing convincing efficacy evidence.

Health Canada included this type of claim wording in its project on abbreviated labelling standards to explore the feasibility and usefulness of applying this type of claim qualifier to NHPs.

Comments from the January 2009 Workshop

Regarding the discussion example “*May improve symptoms of maldigestion; enzyme catalyzes breakdown of fibre,*” participants commented that it was truthful but not necessarily helpful. “If consumers need a guarantee, they might not get it.” They commented that the language of the claim was too high level, suggesting use of “helps” or “assists with” instead of “catalyzes” and to reverse the claim statement to provide more clarity: studies show that [the enzyme] helps breakdown fibre, and therefore, it may help with symptoms of maldigestion. The qualifier “may” was described by some participants as removing liability from the manufacturer and label but also reducing the strength of the claim, in that it implied the evidence was not good enough and reflected a lower-level of evidence.

Participants noted that consistency was key in identifying appropriate use of “may” with a number of suggestions noted:

- not for use with treatment claims, where stronger wording is needed;
- to be reserved for products where a guarantee is not required;
- not needed where evidence does not require it, for example not appropriate for well-known ingredients such as calcium but perhaps appropriate for Zeaxanthine;
- for use only when evidence or probability presents variability in product effectiveness;
- for use where there is a reasonable amount of evidence, but not where there is a lack of evidence.

The term “may” was described by participants as subtle and needing clarification to provide meaningful information for consumers. Participants suggested that there “not be too many different types of phrases... consumers become more familiar with certain phrases, “may contain peanuts,” for example.” There should be consistent use of language and glossaries. Health Canada was noted as a trusted provider of information, seen as independent and unbiased.

Natural Health Products with Qualifiers Specifying Use within a Particular Healing Modality

“Used in herbal medicine...”

Multi-ingredient natural health products may include both traditional ingredients (herb) and non-traditional ingredients (vitamin). In many cases, traditional evidence is provided by licence applicants to support some of the ingredients (e.g., herbal), resulting in applications that include both traditional and scientific evidence.

Concerns raised regarding the use of traditional evidence to support non-traditional products include the different preparation methods and the reliance on historical and cultural use as evidence rather than scientific data. It is not considered feasible to use homeopathic medicine (HM) references, for example, given the unique dosage forms and preparation methods used within this paradigm. Labelling standards for HMs were developed in spring 2008. While it may not be appropriate to support claims for non-traditional NHPs solely using traditional evidence, it may be possible to use this level of evidence to support evidence for some of the ingredients, supplemented by evidence provided through other references or evidence levels.

The claim phrasing “Used in Herbal medicine” supports the concept of complementary and alternative health systems as off-shoots of traditional medicine and recognizes the range of evidence and healing modalities applicable to NHPs. As presented in the article “Ethics in Herbal Medicine”, based on the WHO definition of Complementary and Alternative Medicine (CAM), “Broadly speaking, all systems defined under CAM come under Traditional Medicine. In other words, complementary and alternative systems are an off-shoot of traditional medicine. Alternative medicine includes replacement of one system with another. Complementary health practices include adding one system of medicine as adjunct to another.”¹⁹

Health Canada included this type of claim wording in its project on abbreviated labelling standards to explore the feasibility and usefulness of applying this wording to NHP labels to differentiate an NHP claim from a claim based strictly on traditional use in a specific culture as well as from a claim supported by higher level evidence (e.g., clinical trials).

“Used in Aromatherapy...”

A number of NHP licence applications have essential oils as medicinal ingredients. Efficacy evidence provided to support these licence applications are most often Aromatherapy references.

Health Canada intends to conduct a review of existing Aromatherapy textbooks to determine the most appropriate references (reliable, credible) and the allowable Aromatherapy claims. Consideration is being given through the abbreviated labelling standards project to allowing a limited set of Aromatherapy claims for topical use (e.g., massage) and inhalation (e.g., for relief of congestions from colds).

As with “Used in herbal medicine,” an Aromatherapy qualifier identifies the healing modality while differentiating use from other traditional uses within specific cultures

and from claims supported through higher level evidence (e.g., clinical trials). During NHPD consultations with consumers, stakeholders expressed the view that this qualifier is useful but only to the niche market of Aromatherapy.

It has been noted that information about recommended dose is not always readily available for Aromatherapy products; however, It may be possible to develop standard dosage information for Aromatherapy products. Input from experts and the Aromatherapy sector will be sought in addressing these questions.

Exploring Aromatherapy claims recognizes the broad range of ingredients, reference sources and healing modalities captured under the NHP definition.

Comments from the January 2009 Workshop

Regarding the discussion examples for Aromatherapy products, participants described Aromatherapy as a small niche market (e.g., scents) and noted that the claims would only be clear or meaningful to consumers who are familiar with the healing paradigm. They would not be meaningful if used in another paradigm.

Participants described *“Used in Aromatherapy as an analgesic”* as a strong claim (analgesic) that would require more specificity and clarity on the type of pain - potentially headache, neurological pain, cancer pain, other. They commented on the need to specify the basis of support for Aromatherapy discussion examples (the above example and *“Used in Aromatherapy to promote relaxation”*) and include the mechanism of action or how the product worked on relaxation and on which structure-function. Participants suggested *“Generally recognized in Aromatherapy for ___ pain to reduce trouble related to ___”* and *“Has been used/helpful in Aromatherapy to relieve headaches”* as possible alternative phrasing.

Participants commented that while *“Used in herbal medicine”* implied stronger support than *“Used in Aromatherapy,”* both were considered unclear as there was a lack of universal definition for both. As with Aromatherapy claims, participants commented that a *“Used in herbal medicine”* claim would only be meaningful to those familiar with the healing modality. Participants noted a need to educate consumer on what traditional evidence was and where it came from (*“down the generations”*). They commented that consumers could not easily differentiate between a strictly traditional claim and *‘Used in herbal medicine’* and that the terminology may imply that there is not enough *“real”* science. It was noted that the terms would be more useful to practitioners. There was also suggestion that *“has been used for [x] number of years”* or *“used for at least 50 years”* be included, as this is the Health Canada definition of traditional medicine. It was noted that this brought more credibility to the claim.

Regarding the discussion example *“Used in herbal medicine for symptomatic relief of mild urinary tract infections,”* participants commented that it was important to distinguish symptomatic relief from treatment cure and cause of disease and concern was expressed that a consumer may use the product and *“[not treat a condition] that might require treatment.”* Regarding the discussion example, *“Used in herbal medicine as a restorative agent,”* participants described *“restorative”* as unclear and a blanket statement that did not provide sufficient precision or clarity.

Conclusion

Since the enactment of the Regulations in January 2004, Health Canada has developed a number of tools to support the product licence application review process for NHPs (e.g., Compendium of Monographs, labelling standards for homeopathic medicines).

Generalized claims were explored as a means of enhancing the rigour and comprehensiveness of the suite of existing regulatory tools. Exploring the use of generalized claims is consistent with the risk-based approach to regulating NHPs, supporting implementation of a flexible regulatory framework which considers the existing evidence and the generally low-risk nature of NHPs, in keeping with known risks, uses and benefits.

An abbreviated labelling standard for a generalized claim would include the following elements in support of informed choice for consumers: allowable generalized claim wording, information on dose, route of administration and risk (including warnings, cautions and contra-indications), and pre-cleared reference material from credible, recognized sources. Use of abbreviated labelling standards would allow Health Canada to focus on evaluation of Class II product licences.

The creation of abbreviated labelling standards, as they relate to generalized claims, is about information, that is, availability of credible evidence supporting safety and efficacy:

- there is **enough evidence** to assess risks and benefits, when looking at the totality of available evidence, for safety, efficacy and quality.
- **a balanced look** of the risk profile is possible, both for the claim sought and the information needed (contra-indications, for example).

Use of abbreviated labelling standards results in information, that is, a claim on health effect:

- **information provided** on a product label allowing consumers to have sufficient information to make an informed choice.

Comments received from stakeholders will be taken into consideration in the drafting and adoption of abbreviated labelling standards for generalized claims.

Adopted labelling standards will be made available for NHP licence applicants and Health Canada assessment officers to provide specificity and predictability on the purpose of generalized claim and the conditions under which they can be used. The adoption process will include the consideration and identification of the rules or principles to apply in determining whether a basic generalization can be accepted as true for a particular NHP and can be used as the basis for supporting efficacy for a product claim.

Appendix A – Workshop on Abbreviated Labelling Standards for NHPs, January 21 2009

Agenda Item	Discussion Question(s)
Generalized Health Claims: Overview (9:45 - 10:50 am)	<ol style="list-style-type: none"> 1. Is the purpose of abbreviated labelling standards, as they relate to generalized claims, clear (use, scope)? Why? Why not 2. In your view, does inclusion of <i>"Animal evidence suggests..."</i> on an NHP label provide useful information for consumers? Is animal-derived evidence sufficient for supporting efficacy of an NHP? Why or why not?
NHP claims using <i>"vitality," "immune system stimulant," "well-being"</i> (10:50 - 11:45 am)	<ol style="list-style-type: none"> 1. In your view, do these claims provide the information needed by consumers to make informed choice in selection and using an NHP? Why? Why not?
Generalized claim wording including: <i>"helps to," "promotes,"</i> and <i>"contributes to..."</i> (1:05 - 1:50 pm)	<ol style="list-style-type: none"> 1. In your view, does the claim provide meaningful information, clarity and truthfulness (translates the evidence to NHP labelling useful to a consumer)? Why? Why not? 2. In your view, does the descriptor [support, maintain, aid, contribute, promotes] meet consumer needs for NHP labelling? Why? Why not?
Generalized claims including evidence basis for efficacy: <i>"Observational studies suggest..."</i> (1:50 – 2:30 pm)	<ol style="list-style-type: none"> 1. In your view, is it useful to specify the evidence basis of a claim on an NHP label? Why? Why not? 2. The approach is in keeping with the Standing Committee on Health recommendation that "the label indicate clearly the type of evidence used to support the claim"?
Generalized claims with qualifiers: <i>"May"</i> (2:45 – 3:30 pm)	<ol style="list-style-type: none"> 1. In your view, does the claim provide meaningful information, clarity and truthfulness (translates the evidence to NHP labelling useful to a consumer)? Why? Why not? 2. What does the qualifier "may" communicate? <ol style="list-style-type: none"> a) Should it be applied to some, all risk-reduction claims? b) Is the use of "may" appropriate for non-risk reduction claims?
Generalized claims with qualifiers: <i>"Used in herbal medicine..."</i> , <i>"Used in Aromatherapy..."</i> (3:30 to 4:15 pm)	<ol style="list-style-type: none"> 1. In your view, does the claim provide meaningful information, clarity and truthfulness (specifying the health care modality translates evidence to labelling useful for consumer)? Why? Why not? 2a) Is the inclusion of "Used in herbal medicine" sufficient to distinguish the claim from a claim based solely on Traditional evidence? 2b) Is the inclusion of "Used in Aromatherapy" an aid for consumers in making informed choice about a product?

Workshop Participants List

NHP sector stakeholders included representatives from:

Advertising Standards Canada
 Allergy/Asthma Information Association
 Alliance of Cultural Communities for Equity in Health and Social Services (ACCESS)
 Best Medicines Coalition (6 participants)
 Broadcast Clearance Advisory
 Canadian Association of Naturopathic Doctors
 Canadian College of Naturopathic Medicine (2 participants)
 Canadian Federation of Medical Students (2 participants)
 Canadian Treatment Action Council
 Centre for Science in the Public Interest
 Coalition Québécoise sur la problématique du poids
 Consumer Advocare Network
 Diversified Nutrition Lifestyle (morning only)
 Jamieson Laboratories Ltd (morning only)
 NDMAC (2 participants - morning only)
 Options Consommateurs
 PSN Logistique Inc. (morning only)
 Seroyal International (morning only)
 Vitaminol Inc. (3 participants - morning only)

Health Canada participants were:

Alysyn Smith, Product Assessment, NHPD (afternoon only)
 Anne MacLac, Advertising Unit, Marketed Health Products Directorate
 Benjamin Mahon, Policy and Regulatory Affairs, NHPD
 Carol Toone, Office of the Executive Director, NHPD
 Diane Gagnon, Monograph Unit, NHPD
 Julie Bernier, Public Involvement, HPFB Quebec Region
 Lara Boulanger-Stewart, Product Assessment, NHPD (afternoon only)
 Laurie Chapman, Product Assessment, NHPD
 Loretta Wong, Office of the Executive Director, NHPD (afternoon only)
 Michelle Boudreau, Director General, NHPD
 Nadine McKenzie, Event Coordination, NHPD
 Nancy Richards, Senior Executive Director, NHPD
 Rebecca Bose, Policy, Office of Consumer Affairs and Public Involvement, HPFB
 Riaz Awadia, Policy Analyst, NHPD (afternoon only)
 Semir Omar, Product Assessment, NHPD (afternoon only)
 Sumehda Jogulaka, Product Assessment, NHPD (afternoon only)

Facilitation was provided by:

Raymond d'Amour, Intersol Group

Appendix B – Glossary of Terms

Note – This draft glossary is presented only as a general guide to the terms contained in this discussion paper. The NHPD recognizes the need for information on the regulatory framework for NHPs, including information on health claim definitions and labelling. It is the intention of the NHPD that the glossary will be completed and made available to consumers and others interested stakeholders.

Term	Definition
Abbreviated Labelling Standard	An approved standard label claim for identified lower-risk NHP ingredients, supported by pre-identified evidence which may include pre-approved reference material. Abbreviated labelling standards are permitted for identified (self limiting, minor) health conditions, and include dosage and risk information as well as allowable route of administration. Where an applicant attests to an Abbreviated Labelling Standard, there is no need for the applicant to submit additional evidence to support safety and efficacy of the product.
Aid	Providing an intervention to improve a health condition or be beneficial in assisting with improving a health condition; health product intended to relieve illness or injury. ^a
Amino Acids	An organic molecule containing amino and carboxylic groups attached to same carbon atom. Amino acids are building blocks of proteins (chief constituents) found in a plant or a plant material, an alga, a bacterium, a fungus, or a non-human animal material. ^b
Animal study	A laboratory experiment using animals to study the development and progression of diseases. Animal studies also test how safe and effective new treatments are before they are tested in people. ^c
Aromatherapy	Aromatherapy is the art and science of using essential oils for improving and maintaining health and beauty. ^d
Attestation	To certify by signature or oath or To certify in an official capacity ² Where NHP licence applicants point (attest) to pre-approved information, a monograph for example, to support the safety and efficacy of their product, there is no need for the applicant to submit additional safety and efficacy evidence.
Case Study	An analysis of a group or person in order to make generalizations about a larger group or society as a whole. ^e
Clinical Trial	An investigation in respect of an NHP that involves human subjects and that is intended to discover or verify its clinical, pharmacological or pharmacodynamic effects, to identify any adverse events that are related to its use, to study its absorption, distribution, metabolism and excretion, or to ascertain its safety or efficacy. ^f
Cohort Study	A scientific study that focuses on a specific subpopulation/group of individuals who share a characteristic acquired at the same time. The investigation identifies a group which have the hypothesized cause and which are free of the disease of interest, and a comparison group which are free of the hypothesized cause. Both groups are followed over time to determine the incidence rates of the disease in question in each of the two groups. ^g
Contribute	To be partly responsible for, lead to, be instrumental in, be conducive to or help improve and maintain healthy organs and systems. ^h
Descriptive Study	Involves collecting data in order to test hypotheses or to answer questions about opinions of people about a topic or issue; also called survey research. ⁱ

¹ <http://www.thefreedictionary.com>

^b Evidence for Quality of Finished Natural Health Products Guidance Document, June 2007

^c http://www.cancer.gov/Templates/db_alpha.aspx?CdrID=454774

^d Canadian Federation of Aromatherapists - <http://www.cfacanada.com>

^e <http://www.thefreedictionary.com/case+study>

^f Overview of Natural Health Products Regulations Guidance Document

^g <http://medical-dictionary.thefreedictionary.com/cohort+study>

^h <http://www.thefreedictionary.com>

ⁱ <http://www.csus.edu/indiv/b/barricks/Ed%20Research/Descriptive%20Studies/sld002.htm>

Term	Definition
Dosage	The quantity of an active agent (substance) taken in or absorbed at any one time. ^j
Dosage Forms	The final physical form of the NHP which may be used by the consumer without requiring any further manufacturing. ^k For example, capsule, tablet, liquid extract, powder.
Enzyme	An organic catalyst, usually a protein, increasing the rate at which a specific biochemical reaction occurs. Enzymes may be derived from a plant or a plant material, an alga, a bacterium, a fungus, or a non-human animal material. ^l
Essential Oil	Plant products, usually somewhat volatile, giving the odors and tastes characteristic of the particular plant, thus possessing the essence (e.g., citral, pinene, camphor, menthane, terpenes); usually, the steam distillates of plants or oils of plants obtained by pressing out the rinds of a particular plant. ^m
Extract	A substance prepared by treating a plant or plant material, an alga, a bacterium, a fungus, or non-human animal material with solvents to remove any constituents. ⁿ
Generalized Health Claim	Generalization of a claim is about making a claim more applicable to the evidence, as well as describing that the claim draws from specific cases to more general ones.
Herbal medicine	The art or practice of using herbs and herbal remedies to maintain health and to prevent, alleviate, or cure disease. ^o
Homeopathic Medicine (HM)	To be considered an HM, a product must meet two criteria. It must be: 1) Manufactured from, or contain as medicinal ingredients, only substances referenced in a homeopathic monograph in one of the following homeopathic pharmacopoeia, as they are amended from time to time: <i>Homeopathic Pharmacopoeia of the United States</i> ; <i>Homöopathische Arzneibuch</i> (German Homeopathic Pharmacopoeia); <i>Pharmacopée française</i> (French Pharmacopoeia); <i>European Pharmacopoeia</i> (Eur. Pharm.); <i>British Homeopathic Pharmacopoeia</i> ; <i>Indian Homeopathic Pharmacopoeia</i> . 2) Prepared in accordance with the methods outlined in one of the above-mentioned pharmacopoeia.
Immune System	The body system in humans and other animals that protects the organism by distinguishing foreign tissue and neutralizing potentially pathogenic organisms or substances. The immune system includes organs such as the skin and mucous membranes, which provide an external barrier to infection, cells involved in the immune response, such as lymphocytes, and cell products such as lymphokines. ^p
In Vitro	Referring to a process or reaction occurring in an artificial environment, outside a living organism (in the laboratory), as in a test tube or culture medium. ^q
<i>In Vivo</i>	Referring to a process or reaction occurring in an artificial environment, inside a living organism. ^r
Isolate	A purified constituent of a defined molecular structure obtained from a plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material. ^s
Label	Includes any legend, word or mark attached to, included in, belonging to or accompanying a food, drug, cosmetic, device, package, or health product. ^t
Life-cycle	Refers to an approach to regulating health products which support ongoing evaluation (re-evaluation) of a

^j <http://www.thefreedictionary.com/dosage>

^k Evidence for Quality of Finished Natural Health Products Guidance Document, June 2007

^l Ibid

^m Stedman's Medical Dictionary - <http://www.stedmans.com>

ⁿ Evidence for Quality of Finished Natural Health Products Guidance Document

^o Webster Online - <http://www.merriam-webster.com>

^p <http://www.thefreedictionary.com/immune+system>

^q Stedman's Medical Dictionary - <http://www.stedmans.com>

^r <http://www.thefreedictionary.com/in+vivo>

^s Evidence for Quality of Finished Natural Health Products Guidance Document, June 2007

^t Overview of Natural Health Products Regulations Guidance Document

Term	Definition
approach	product's risk-benefit profile as knowledge about the product grows, including availability of evidence on product safety and efficacy.
Longitudinal Study	A study that follows the same persons over time, evaluating the effects of one or more variables on a process over time. Examples include: cohort, case-control, cross-sectional and horizontal studies. ^u
May	Used to indicate a certain measure of likelihood or possibility. ^v
Meta-analysis	A quantitative statistical analysis of several separate but similar experiments or studies in order to test the pooled data for statistical significance. ^w
Mineral	A naturally occurring solid, inorganic substance with a definite and predictable chemical composition and physical properties. Synthetic minerals are produced by synthesis. ^x
Monograph	A treatise on a particular subject or specific aspect of a subject. ^y A written description of particular elements on an identified topic. ^z
Natural Health Product (NHP)	A substance set out in Schedule 1 of the National Health Product Regulations or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, an HM or a traditional medicine, that is manufactured, sold or represented for use in <ul style="list-style-type: none"> (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; (b) restoring or correcting organic functions in humans; or (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health. <p>However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.^{aa}</p>
NHP Health Claim	A statement that indicates the intended beneficial effect of an NHP when used in accordance with the recommended dose, duration of use, and route of administration. ^{bb}
Naturopathy/ Naturopathic Medicine	A distinct primary health care system that blends modern scientific knowledge with traditional and natural forms of medicine. The art and science of disease diagnosis, treatment and prevention using natural therapies including botanical medicine, clinical nutrition, hydrotherapy, homeopathy, naturopathic manipulation, traditional Chinese medicine / acupuncture, and lifestyle counselling. ^{cc}
Nutrient	A constituent of food necessary for normal physiologic function. ^{dd}
Observational Study	A type of study in which individuals are observed or certain outcomes are measured. No attempt is made to affect the outcome (e.g., no treatment is given). ^{ee}
Oral	Given or taken through or by way of the mouth. ^{ff}

^u <http://medical-dictionary.thefreedictionary.com/longitudinal+study>

^v <http://www.thefreedictionary.com/may>

^w Webster Online - - <http://www.merriam-webster.com>

^x Evidence for Quality of Finished Natural Health Products Guidance Document, June 2007

^y Stedman's Medical Dictionary - <http://www.stedmans.com>

^z Health Canada Website

^{aa} *Natural Health Product Regulations*

^{bb} Discussion Paper on Abbreviated Standard Labelling Indications for Generalized NHP Health Claims, Natural Health Products Directorate, January 2009

^{cc} Canadian Association of Naturopathic Doctors - <http://www.cand.ca>

^{dd} Stedman's Medical Dictionary - <http://www.stedmans.com>

^{ee} <http://www.cancer.gov>

Term	Definition
Paradigm	A world view which underlies the theories and methodology in science in a particular period of history or within a particular culture. ⁹⁹
Probiotic	A monoculture or mixed culture of live microorganisms, which when administered in adequate amounts, confers a health benefit in humans. ^{hh} (i.e. <i>Lactobacillus acidophilus</i> ; <i>Bifidobacterium longum</i>).
Risk Reduction Claim	Describes the relationship between a medicinal ingredient and the reduction in the risk of developing a disease or abnormal physiological state, possibly by significantly altering a major risk factor or other contributing factor recognized to be involved in the development of disease. ⁱⁱ A risk reduction claim is supported by well-designed observational studies, such as prospective cohort studies. Risk reduction claims are based on the relationship. For example: "Use of [product xyz] may decrease the risk of developing osteoporosis."
Route of Administration	The path by which the NHP is brought into contact with the body; for example, oral, topical, nasal. Only one route may be chosen for a product. ^{jj} For example, oral or topical.
Stimulant	An agent, especially a chemical agent such as caffeine, which temporarily arouses or accelerates physiological or organic activity, especially of the nervous or cardiovascular systems. ^{kk}
Support	To keep from weakening or failing; to strengthen. The activity of providing for or maintaining by supplying with necessities. ^{ll}
Supplemental evidence	Refers to evidence provided by a product licence applicant to support the safety or efficacy evidence provided through other reference sources or evidence levels. For example, an in vivo study provided to corroborate efficacy evidence provided through references on marketing use and a small clinical trial study.
Structure-Function Claim	Describes the effect or support of an NHP ingredient on the structure or anatomical, physiological, or mental function in the human body, or a product's support of an anatomical, physiological, or mental function. Where adequately supported by evidence, structure-function claims may include broad statements related to the promotion of overall health. ^{mmm} For example, "Maintains healthy gums."
Tonic	Medicinal preparations used to restore normal tone to tissues or to stimulate the appetite. ⁿⁿ
Topical	Designed for or involving application to or action on the surface of a part of the body. ^{oo}
Traditional Medicine	The sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness. Traditional medicine has a long history (50 consecutive years) of use. ^{pp}
Treatment Claim	Relates to the diagnosis, treatment, mitigation or prevention of a disease, disorder, or abnormal physical state or its symptoms in humans. ^{qq} These claims must be supported by a weight of evidence. These claims, described as curative, medical and medicinal, are prohibited by regulations in many countries. ²⁰
Vitality	Physical or mental vigour or energy. ^{rr}

^{ff} Webster Online - <http://www.merriam-webster.com>

⁹⁹ Overview of Natural Health Products Regulations Guidance Document

^{hh} Evidence for Quality of Finished Natural Health Products Guidance Document, June 2007

ⁱⁱ Overview of Natural Health Products Regulations Guidance Document

^{jj} Product Licensing Guidance Document, v.2 December 2006

^{kk} <http://www.thefreedictionary.com/stimulant>

^{ll} <http://www.thefreedictionary.com/support>

^{mmm} Overview of Natural Health Products Regulations Guidance Document

ⁿⁿ Ibid

^{oo} Webster Online - <http://www.merriam-webster.com>

^{pp} Overview of Natural Health Products Regulations Guidance Document

^{qq} Ibid

^{rr} <http://www.thefreedictionary.com/vitality>

Term	Definition
Vitamin	A naturally occurring organic substance required in small amounts by the body to maintain health. ^{ss}
Well-being	The state of being healthy. ^{tt} A healthy state of wellbeing free from disease. ^{uu}

^{ss} Evidence for Quality of Finished Natural Health Products Guidance Document, June 2007

^{tt} <http://www.merriam-webster.com/dictionary/well-being>

^{uu} <http://www.thefreedictionary.com/well-being>

Appendix C – Abbreviated Labelling Standards for NHPs (Discussion Examples)

Information		Discussion Example
1. NHP “helps to”		
1.1	Ingredient	Lutein
	Route of administration	Oral
	Claim	Contributes to eye health or Helps maintain eye health
	Duration of use	Ongoing
	Risk information	No known adverse reactions
	Dose	10 mg/day
	Evidence source	Human in-vivo studies, Prospective cohort trials (observational)
1.2	Ingredient	Choline
	Route of administration	Oral
	Claim	Helps support and/or maintain liver health
	Duration of use	Ongoing
	Risk information	No known adverse reactions
	Dose	25 mg/day
	Evidence source	Institute of Medicine (IOM), 2 randomized clinical trials
1.3	Ingredient	Bromelain
	Route of administration	Oral
	Claim	Digestive aid; helps improve nutrient availability
	Duration of use	None
	Risk information	Appropriate risk information is still under investigation
	Dose	Effective dose is still under investigation
	Evidence source	Double-blind placebo-controlled and crossover studies, in vitro
1.4	Ingredient	Methionine
	Route of administration	Oral
	Claim	Contributes to healthy liver function
	Duration of use	None
	Risk information	No known adverse reactions
	Dose	Yet to be determined
	Evidence source	Institute of Medicine (IOM), nutrition textbook references
1.5	Ingredient	Vitamin D
	Route of administration	Oral
	Claim	Assists with the absorption and use of calcium and phosphorus
	Duration of use	None
	Risk information	No known adverse reactions
	Dose	Information is available

Information	Discussion Example
Evidence source	Institute of Medicine (IOM), textbook references
1.6 Ingredient	Theanine
Route of administration	Oral
Claim	Promotes relaxation
Duration of use	None
Risk information	No known adverse reactions
Dose	Information is available
Evidence source	Clinical trials
2. Claim specifying the evidence basis for efficacy of the NHP	
2.1 Ingredient	Lycopene
Route of administration	Oral
Claim	Observational studies show lycopene contributes to prostate health
Duration of use	None
Risk information	No known adverse reactions
Dose	6 mg/day
Evidence source	In vitro; prospective cohort (47,894 healthy men); observational (4,770 1994-2003)
2.2 Ingredient	Colostrum
Route of administration	Oral
Claim	Pilot study suggests that Colostrum reduces risk of complications due to flu
Duration of use	None
Risk information	Appropriate risk information is still under investigation
Dose	Effective dose is still under investigation
Evidence source	In vitro
2.3 Ingredient	Vitamin D
Route of administration	Oral
Claim	Observational studies show vitamin D supports colorectal health
Duration of use	None
Risk information	No known adverse reactions
Dose	10 mcg/day
Evidence source	Pacebo-controlled randomized trial, case-control, prospective cohort, comparative, in vitro
2.4 Ingredient	Yeast beta-glucan
Route of administration	Oral
Claim	Early studies suggest that use of Yeast Beta-glucan may reduce the risk of developing colds and flus
Duration of use	None
Risk information	Appropriate risk information is still under investigation
Dose	Effective dose is still under investigation
Evidence source	Discussion example

Information		Discussion Example
2.5	Ingredient	Multi-ingredient product (can include vitamin, mineral, herbal, enzyme...)
	Route of administration	Oral
	Claim	The individual ingredients in this product have been shown to relieve symptoms of congestion associated with colds. The combination of ingredients has not been assessed
	Duration of use	As per medicinal ingredients
	Risk information	As per medicinal ingredients
	Dose	As per medicinal ingredients
	Evidence source	Two separate references, as per medicinal ingredients
3. NHPs with claim qualifier “may”		
3.1	Ingredient	Zeaxanthin
	Route of administration	Oral
	Claim	May reduce the risk of developing age-related macular degeneration
	Duration of use	Information is not available
	Risk information	No known adverse reactions
	Dose	Information is not available
	Evidence source	Human in vivo trials, observational study (380 elderly men and women)
3.2	Ingredient	Calcium and vitamin D
	Route of administration	Oral
	Claim	Calcium intake, when combined with sufficient vitamin D, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis
	Duration of use	Information is not available
	Risk information	For an adult subpopulation only (when calcium HAP or HVP chelate used as source material)
	Dose	Information is available
	Evidence source	Textbook references, National Institute of Health
3.3	Ingredient	Pectinase (<i>A.niger</i>)
	Route of administration	Oral
	Claim	May improve symptoms of maldigestion; enzyme catalyzes breakdown of fibre
	Duration of use	None
	Risk information	Appropriate risk information is still under investigation
	Dose	Effective dose is still under investigation
	Evidence source	Discussion example

Information		Discussion Example
4. NHP with qualifier specifying healing modality		
Used in Herbal Medicine, Aromatherapy		
4.1	Ingredient	Pumpkin seed oil
	Route of administration	Oral
	Claim	Used in herbal medicine for relief of symptoms associated with enlarged prostate
	Duration of use	None
	Risk information	This medication relieves symptoms without reducing the enlargement. Consult a health care practitioner at regular intervals.
	Dose	Information is not available
	Evidence source	British Herbal Compendium Vol. 2, Commission E (2000)
4.2	Ingredient	Lavender
	Route of administration	Topical
	Claim	Used in Aromatherapy as an analgesic
	Duration of use	None
	Risk information	No known adverse reactions
	Dose	Not specified/may not be readily available
	Evidence source	Two Aromatherapy textbook references
4.3	Ingredient	Chamomile
	Route of administration	Oral
	Claim	Used in Aromatherapy to promote relaxation
	Duration of use	None
	Risk information	No known adverse
	Dose	Not specified/may not be readily available
	Evidence source	Two Aromatherapy textbook references
4.4	Ingredient	Panax ginseng
	Route of administration	Oral
	Claim	Used in herbal medicine as a restorative agent
	Duration of use	None
	Risk information	No known adverse
	Dose	Not specified/may not be readily available
	Evidence source	World Health Organization, Commission E, ESCOP (Experiment Station Committee on Organization and Policy)
4.5	Ingredient	Barberry leaf
	Route of administration	Oral
	Claim	Used in herbal medicine for symptomatic relief of mild urinary tract infection
	Duration of use	None
	Risk information	No known adverse
	Dose	Information is available

Information	Discussion Example
Evidence source	WHO, Commission E, ESCOP
4.6 Ingredient	Sage leaf
Route of administration	Oral
Claim	Used in herbal medicine as an aid for excessive perspiration
Duration of use	Not for prolonged use
Risk information	Do not take if pregnant or breastfeeding.
Dose	Information is available
Evidence source	Commission E, ESCOP

References

- 1 <http://www.hc-sc.gc.ca/dhp-mps/prodnatu>
- 2 NHP - substances (e.g., herbal ingredients, vitamins, minerals, amino acids) or combination of substances in which all the medicinal ingredients are substances set out in NHPR Schedule 1, a homeopathic medicine or a traditional medicine. See Schedule 1, NHPR <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/acts-lois/prodnatur/index-eng.php>
- 3 Baseline Natural Health Products Survey Among Consumers, March 2005 http://www.hc-sc.gc.ca/dhp-mps/pubs/natur/eng_cons_survey-eng.php
- 4 Natural Health Products: 53 Recommendations of the Standing Committee on Health http://www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/53_recommen_nhp-cps-eng.php
- 5 Blueprint for Renewal: Transforming Canada's Approach to Regulating Health Products and Food <http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/blueprint-plan/index-eng.php>
- 6 Charting A Course: Refining Canada's Approach to Regulating Natural Health Products http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/blueprint-plan/chart-course_tracer-voie-eng.php
- 7 Health Canada, 2004b. About Natural Health Product Regulations in Canada. http://www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/index_e.html
- 8 <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/efe-paie-eng.php>
- 9 <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/efe-paie-eng.php>
- 10 <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/index-eng.php>
- 11 <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/efe-paie-eng.php>
- 12 Alternative medicine: Evaluate claims of treatment success - <http://www.mayoclinic.com/health/alternative-medicine/SA00078>, Herbal Supplements, University of Arizona - <http://ag.arizona.edu/pubs/health/az1227.pdf>
- 13 Health claims warmly welcomed by consumers, July 2007, <http://www.foodfromfinland.com>
- 14 ACCLAIM - Promoting consumers' health literacy
- 17 Thorne S, Best A, Balon J, Kelner M, Rickhi B. Ethical dimensions in the borderland between conventional and complementary/alternative medicine. *Journal of Alternative and Complementary Medicine*. [link shows: Unable to open] 2002 Dec; 8(6):907-15.
- 16 Ibid
- 18 Consumer acceptance and trust: Recommendations for using health-related claims in marketing, ACCLAIM Project, Nordic Innovation Centre - <http://virtual.vtt.fi/virtual/acclaim>

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- 19 Hooker NH, Teratanavat R. Dissecting qualified health claims: evidence from experimental studies. *Critical Review of Food Science and Nutrition*. [link shows: Unspecified error] 2008 Feb;48(2):160-76.
- 20 Singh, Amrit Pal (October 2007), Ethics in Herbal Medicine, *Ethnobotanical Leaflets* 11: 206-211. 2007
- 27 Hawkes, Corinna (2004). *Nutrition labels and health claims: the global regulatory environment*. World Health Organization