This is **Exhibit "D"** referred to in the Affidavit of **Michael John Trebilcock** sworn before me this 23rd day of July, 2007.

A Commissioner, etc.

Health Canada | Santé Canada

Health Products and Food Branch | Direction générale des produits de santé et des aliments

October 18, 2006

Issuance of the final Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)

Further to the February 2005 and April 2006 electronic consultations with external stakeholders, as well as to the June 28, 2006 invitational roundtable on the inclusion of risk information in advertising (Section 2.21 of the Guidelines), Health Canada is pleased to issue the final *Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)*. These Guidelines were prepared in collaboration with Advertising Standards Canada (ASC) and Health Canada gratefully acknowledges their important contribution. The consultation process and the invitational roundtable have permitted stakeholders to share their viewpoints and to propose viable solutions. This important exchange of information has been crucial in the development of the Guidelines. The Marketed Health Products Directorate would like to thank all of those who participated.

The purpose of this notice is to highlight the main revisions to the Guidelines and to announce their adoption by Health Canada as of this date. These Guidelines are intended to replace and supersede the 1990 *Consumer Drug Advertising Guidelines* and the February 2005 and April 2006 consultation drafts. They are designed to help advertisers develop advertising messages that meet all the relevant provisions of the *Food and Drugs Act and Regulations*, the *Natural Health Products Regulations* and other related Health Canada Policies and Guidelines. The Guidelines form the basis upon which advertising preclearance agencies review and approve advertising for nonprescription drugs, including natural health products, and will help ensure consistency in advertising review.

These Guidelines are effective immediately however the clarifications outlined in Section 2.21 will take effect April 1, 2007 to allow industry to adjust their advertising material.

Canada

The main revisions brought to the *Guidelines* are as follows:

- The change related to Health Canada moving towards an attestation preclearance system for the consumer advertising preclearance of nonprescription drugs and natural health products, as announced on August 9, 2006, is reflected throughout the Guidelines. Once the attestation criteria will be finalized, Health Canada will update its advertising fact sheet and policies outlining the role of advertising preclearance agencies and Health Canada's role related to advertising review and complaints adjudication.

- In Section 1.1, Authorization – Terms of Market Authorization: The footnote clarifies that the Product Licence is considered to be equivalent to the terms of market authorization for natural health products.

- In Section 1.4, Indication/Recommended Use – Multiple Medicinal Ingredients: A new application for the advertising of a family of products has been added.

- Section 2.18, Organic: A statement to the effect that licence holders should consult provincial legislation with respect to the use of the term "organic" in advertising was added. The labeling requirements for organic products based on the percent certified organic content were removed.

- Section 2.21, Risk Information Communication: the section on the inclusion of risk information in advertising was revised based on comments received from various stakeholders through the April 2006 electronic consultation and the options put forward by stakeholders at the June 28, 2006 invitational Roundtable. The revised Section 2.21 reflects the areas of consensus that were reached at the Roundtable as outlined in the report available at http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/report-rapport/index_e.html . The Guidelines include new emphasis of Section 9(1) of the Food and Drugs Act (deception clause) for industry to communicate information in advertising of nonprescription drugs and natural health products about reading product labels and a general cautionary statement, if risks have been identified. If new risks have been identified and do not appear on product labels, additional requirements exist.

Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products) are available on the Health Canada Website at:

http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/index_e.html

GUIDANCE DOCUMENT

Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products)

Published by authority of the
Minister of Health

Date Adopted	2006/10/18
Effective Date	2006/10/18

Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	HPFB's Mandate is to take an integrated approach to managing the health-related risks and benefits of health products and food by: • minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

Également disponible en français sous le titre: Lignes directrices sur la publicité des produits de santé commercialisés destinée aux consommateurs (pour les médicaments en vente libre incluant les produits de santé naturels).

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The Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products) can be obtained via the internet from the Website listed below:

Health Canada
Manager, Regulatory Advertising and Risk Communications Section
Therapeutic Effectiveness and Policy Bureau
Marketed Health Products Directorate
Health Canada
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Web site: www.hc-sc.gc.ca/dhp-mps/advert-publicit/index_e.html
E-mail: mhpd_dpsc@hc-sc.gc.ca

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

ACKNOWLEDGMENT

Health Canada gratefully acknowledges Advertising Standards Canada for their important contribution and dedicated role in the successful development and implementation of this document.

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ASC NCP Advertising Standards Canada
Les normes canadiennes de la publicité

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Section A – Advertising Guidelines

A.1. Overview

The *Consumer Advertising Guidelines for Marketed Health Products* (the "*Guidelines*") apply to advertising of nonprescription drugs, including natural health products. The Guidelines, which replace and supersede the 1990 *Consumer Drug Advertising Guidelines*, are designed to help advertisers develop advertising messages that meet all the relevant provisions of the *Food and Drugs Act and Regulations*, the *Natural Health Products Regulations* and other related Health Canada Policies and Guidelines.

The Guidelines are divided into two sections:

Section A - Advertising Guidelines

1. Product Characteristics based on Section 9(1) of the *Food and Drugs Act*
2. Claims and Representations under Section 9(1) of the *Food and Drugs Act*

Section B – Legislation, Regulations and Policies

1. Definitions
2. Legislation, Codes and Policies that apply to Marketed Health Product Advertising
3. Appendix Material

Appendix A:	Health Products and Food Branch *Schedule A and Section 3 Guidance Document* (information on specific diseases/conditions with advertising prohibitions)
Appendix B:	*Regulatory Requirements Resulting from Changes to Products* from the Natural Health Products Directorate *Product Licensing Guidance Document* (Appendix 2)
Appendix C:	Excerpts from the Health Canada Policy *Changes to Marketed New Drug Products*
Appendix D:	Excerpts from the *Food and Drug Regulations*
Appendix E:	Advertising of Medical Devices

The *Guidelines* are intended to provide advertisers with the tools to understand drug advertising principles before advertising copy is considered and submitted for review to an advertising preclearance agency which has publicly attested to meeting the attestation criteria established by Health Canada. The *Guidelines* form the basis upon which advertising preclearance agencies review and approve advertising for nonprescription drugs, including natural health products, and will help ensure consistency in advertising review.

Nonprescription drugs including natural health products are subject to the provisions of the *Food and Drugs Act*. Drugs are subject to the *Food and Drug Regulations* while natural health products are subject to the *Natural Health Products Regulations* and to those provisions of the *Food and Drug Regulations* that have been incorporated by reference into the *Natural Health Products Regulations* (e.g. *Section 103* of the *Natural Health Products Regulations*).

Furthermore, the *Guidelines* form the basis for many types of consumer advertising and may be expanded in the future to include consumer advertising for other human product categories such as medical devices.

The *Guidelines* will be updated on an as-needed basis.

A.2. Scope

The *Guidelines* apply to all consumer-directed advertising for nonprescription drugs, including natural health products, in all Canadian media.[1]

The *Guidelines* present current interpretations of the advertising provisions found in the *Food and Drugs Act* and *Regulations*, the *Natural Health Products Regulations*, and other relevant Health Canada policies and procedures. The Guidelines are intended to be used by industry and advertising preclearance agencies in conjunction with these aforementioned provisions and policies.

The Guidelines **do not apply**[2] to:

- Advertising of products for which there are specific consumer-directed advertising restrictions in the *Food and Drugs Act and Regulations* and the *Controlled Drugs and Substances Act* [e.g. controlled drugs, narcotics, *Schedule F* - prescription drugs, limit dose drugs (*section C.01.021* of the *Regulations*)]
- Advertising of prescription drugs, medical devices*, vaccines, veterinary drugs to consumers and to health professionals
- Advertising of nonprescription drugs, including natural health products, to health professionals[3]
- Advertising of food and cosmetic products
- Advertising displaying only the brand name of a nonprescription drug or a natural health product, provided that the Terms of Market Authorization of the product have been established and that such an advertisement does not contain any direct or implied therapeutic or nontherapeutic claims. A DIN, a NPN or a DIN-HM must have been granted before any advertising can be approved by an advertising preclearance agency. As for all advertising, this type of advertising is subject to the regulatory provisions of the *Food and Drugs Act and Regulations* and the *Natural Health Products Regulations.*
- Informational messages[4] such as, but not limited to:
    - Institutional messages
    - Patient support group messages
    - Help-seeking announcements
    - Clinical trial recruitment messages

* However, Appendix E gives a general guidance on the advertising of medical devices, as regulated under the *Medical Devices Regulations* and the *Food and Drugs Act.*

[1] Canadian media include, but are not limited to, television, radio, mass print (e.g., newspapers, magazines), out-of-home (e.g., billboards, transit), point-of-purchase, direct mail, and internet advertising

[2] As of date of issuance of Guidelines

[3] The Pharmaceutical Advertising Advisory Board (PAAB) preclears advertising directed to health professionals for all marketed health products

[4] For more information see Health Canada Policy *The Distinction Between Advertising and Other Activities.*

A.3. Advertising Preclearance Overview

Advertising preclearance agencies provide advertising copy review services to advertisers/advertising agencies to help ensure that their advertising, in all media, meet the relevant provisions of the *Food and Drugs Act and Regulations*, the *Natural Health Products Regulations*, and the policies that apply to nonprescription drugs, including natural health products. Copy should be submitted prior to production to avoid costly changes to final executions. "Approved" advertising is assigned a clearance number that signifies to the carrying media that the advertising has been assessed and is considered to be in compliance with the applicable Legislation and Regulations.

Preclearance services generally include the review of advertising copy for radio, television, mass print (e.g. newspapers, magazines) and out-of-home (e.g. billboards, transit). Preclearance services may also be provided on request for other categories of advertising (e.g. flyers, point of purchase, consumer brochures, internet advertising). Consultation services for new product launches and advertising concepts may also be offered.

A.4. Health Canada and Advertising Preclearance Agencies' Roles and Consultation Related to Advertising Review and Complaint Adjudication

Health Canada bears the ultimate responsibility for enforcing the *Food and Drugs Act* and related *Regulations*. The specific roles of Health Canada and the advertising preclearance agencies are set out in Health Canada Regulatory Advertising Fact Sheets and Guidance Documents which can be found on the Health Canada website: http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/index_e.html.

These documents set out the conditions under which the advertising preclearance agencies may consult with Health Canada on policy issues related to advertising and complaint adjudication.

Advertising preclearance agencies are expected to bring to the attention of Health Canada:

- Any complaints that relate to advertising which, in the preclearance agency's judgement, contravene the *Act and Regulations* and present an imminent and/or significant health hazard, or
- Any complaints that relate to advertising which, in the preclearance agency's judgement, contravene the *Act and Regulations* and for which it has been unable to bring into compliance with its standards and procedures, e.g., through wilful nonparticipation in, or noncompliance with the standards and procedures.
- Advertising complaints related to products unauthorized by Health Canada.
- Advertising complaints related to prescription drugs (Schedule F drugs) promoted to the general public.

The Compliance and Enforcement Policy describes how Health Canada delivers its national compliance and enforcement program. This policy can be found on the Health Canada website: http://hc-sc.gc.ca/dhp-mps/compli-conform/activit/index_e.html

A.5. Advertising Guidelines

Guiding Principles

- Advertising must respect *Section 9(1)* of the *Food and Drugs Act*:
  "No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety".
- Health and safety of consumers is paramount.
- To allow consumers to make an appropriate and informed choice, advertising should clearly communicate the intended use of the product in a manner that is consistent with the Terms of Market Authorization (TMA).

The following table provides guidance regarding the present interpretations of *Section 9(1)* of the *Food and Drugs Act* related to specific claims and representations. The examples provided are for guidance only. The ultimate acceptability of any claim must be evaluated within the overall context of the advertisement.

1.0 Product Characteristics Based on Section 9(1) of the Act

1.1 Authorization – Terms of Market Authorization

Guideline
Therapeutic claims must be consistent with the Terms of Market Authorization (TMA) of the product:

For natural health products:
- Product Licence (PL)[5]

For nonprescription drugs:
- Labelling Standards, Category IV Monographs, Product Monographs or Authorized Labelling

Application
- Claims found in the product's TMA may be paraphrased, but must remain consistent with those authorized. Claims must not directly or indirectly exceed the scope of the TMA.

[5] The Natural Health Products Directorate (NHPD) developed the Compendium of Monographs as a tool for the evaluation of the safety and efficacy of many commonly used medicinal ingredients that comprise natural health products (NHP). NHPD's product licensing system allows applicants to reference a monograph in support of the safety and efficacy of a product as part of their product licence application. Monographs are used as a reference tool for product licence applications. Monographs are not the terms of market authorization for NHPs. More information on monographs can be found at: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/index_e.html. The Product Licence is considered to be equivalent to the terms of market authorization for NHPs.

- Visuals and copy must not be used to directly or indirectly suggest product benefits beyond those found in the TMA.
- For claims that appear to exceed a product's TMA, the advertiser must submit evidence to the preclearance agency that the claim in question was reviewed and authorized by Health Canada.

Note: Guidance regarding regulatory requirements for changes to products may be found in the following documents:

- Natural health products: see Appendix 2 of the *Product Licensing Guidance Document*[6]: "Regulatory Requirements Resulting from Changes to Products".
- Nonprescription drugs: see Health Canada Policy: *Changes to Marketed New Drugs, or Section C.01.014.4*[7] of the *Food and Drug Regulations*.

Example
Antihistamine

➢ Indication / Use:
Relieves allergy symptoms: sneezing, runny nose, and itchy, watery eyes

✓ Acceptable Claim:
"Product X relieves sneezing, runny nose, and itchy, watery eyes due to allergies"

✗ Unacceptable Claim:
"Product X relieves allergies"

1.2 Product Representation

Guideline
An advertisement must not be misleading as to the product category under which it received its TMA, or misrepresent its therapeutic properties.

Application
- The advertised product must not be represented as a food or cosmetic.

Example
Calcium Supplement (chocolate chew format)

✓ Acceptable Claim:
"Try Product X Calcium Supplement. It's a delicious way to get extra calcium"

✗ Unacceptable Claim:
"Try Product X for a tasty chocolate treat"

[6] See Appendix B for *Appendix 2* of *Product Licensing Guidance Document* and Appendix C for an excerpt from the Health Canada Policy *Changes to Marketed New Drug Products*.
[7] See Appendix D *for Section C.01.014.4*

Application

- The advertisement must include the product's therapeutic indication. In addition, non-therapeutic and/or cosmetic* claims may be presented, providing these do not obscure the therapeutic indication or suggest a therapeutic benefit. The emphasis should always be on the therapeutic effect.

*For additional information regarding cosmetic claims, please refer to the *Guidelines for Cosmetic Advertising and Labelling Claims*, available at: http://www.hc-sc.gc.ca/cps-spc/legislation/pol/index_e.html

Example
Anti-dandruff Shampoo

➢ Indication / Use:
Controls flaking, scaling and itching associated with dandruff

✓ Acceptable Claim:
"Product X shampoo controls dandruff flakes and it has a moisture rich formula for shiny hair"

✗ Unacceptable Claim:
"Use Product X shampoo because it has a moisture rich formula" (with emphasis on the cosmetic attributes and no reference to the therapeutic claim)

1.3 Indication / Recommended Use – Single Medicinal Ingredient

Guideline
The advertisement must clearly communicate the intended therapeutic use of the product as per its TMA.

Application

- For **single medicinal ingredient / single indication products:** The product's sole indication must be presented in the advertisement.

Example
Cough Syrup

➢ Indication / Use:
For relief of dry coughs

✓ Acceptable Claim:
"Product X relieves dry coughs so that you can get on with your day"

✗ Unacceptable Claim:
"Product X lets you get on with your day" (without reference to the therapeutic indication)

Application

- For **single medicinal ingredient / multiple indication products**: At least one indication must be presented in the advertisement

Example
Analgesic

➢ Indication / Use:
For fever reduction and pain relief

✓ Acceptable Claim:
"Product X relieves fever so you can feel better"

✗ Unacceptable Claim:
"Product X helps you feel better" (without reference to the therapeutic indication)

1.4 Indication / Recommended Use – Multiple Medicinal Ingredients

Guideline
The advertisement must clearly communicate the symptoms that the product is intended to treat/relieve, or the intended therapeutic use as per product TMA.

Application

- For **multiple medicinal ingredients / multiple indication products**: At least *one* symptom per medicinal ingredient must be presented in the advertisement (it is acceptable to give prominence to one symptom).

Notes:

- This does not apply in cases where multiple ingredients relieve/treat a single symptom/condition.
- For multi-vitamin/multi-mineral supplements it is sufficient to include the therapeutic indication of "vitamin supplement"/"mineral supplement".

Example
Cough/Cold Preparation
3 medicinal ingredients (guaifenesin, dextromethorphan, chlorpheniramine)

➢ Indication / Use:
Relieves chest congestion, dry cough and runny nose

✓ Acceptable Claim:
"Got a miserable cold? Product X relieves your hacking cough, plus chest congestion and runny nose"

✗ Unacceptable Claim:
"Got a miserable cough? Try product X to relieve it"

Application

- For advertisements solely promoting a family of products including both single and multiple ingredient formulations, it is sufficient to include a general "symptom relief" statement.

Example
Brand X Family of Cough and Cold Products
A product line of single and multi-ingredient cough and cold liquids and capsules containing one or a combination of the following active ingredients:
Acetaminophen
Dextromethorphan
Guaifenesin
Chlorpheniramine

✓ Acceptable Claim:
Visuals: Beauty shot of various Brand X cough and cold products
"For your cough and cold symptoms, there's a Brand X product for you"

✗ Unacceptable Claim:
Visuals: Beauty shot of various Brand X cough and cold products
"For your cough there's a Brand X product for you "

1.5 Direction for Use/Dosage and Administration (See also "2.3 Children")

Guideline
An advertisement must not be misleading as to the Directions for Use/Dosage and Administration

Application

- When described or depicted, directions for use/dosage and administration must be consistent with the product's TMA.

Example
Wart Remover

➢ Directions for Use:
Apply every 2 days for 12 weeks until wart is gone

✓ Acceptable Claim:
"Removes warts. Use as directed"

✗ Unacceptable Claim:
"Removes warts in one easy step"

Application

- Depictions of ingestion must be consistent with the product's TMA.

Example
Cough Syrup

➢ Directions for Use:
Two teaspoons every 4 hours

✓ Acceptable Depiction:
Woman swallowing a teaspoon of syrup

✗ Unacceptable Depiction:
Woman drinking directly from the bottle

1.6 Duration of Action

Guideline
An advertisement must not be misleading as to the duration of action of the advertised product.

Application

- When described or depicted, the duration of action must be consistent with the product's TMA.

Example
Analgesic

➢ Indication / Use:
Relieves headache for up to 8 hours

✓ Acceptable Claim:
"Product X relieves headache for up to 8 hours"

✗ Unacceptable Claim:
"Product X relieves headache all day long"

Application

- Duration of pharmacological action must not be equated with duration of relief unless supported by the product's TMA.
- Dosing interval must not be equated with duration of action or duration of relief unless supported by the product's TMA.

Example
H2-antagonist

➢ Indication / Use:
Controls acid for up to 12 hours; relieves heartburn

✓ Acceptable Claim:
"Product X controls acid for up to 12 hours and relieves heartburn"

✗ Unacceptable Claim:
"Product X relieves heartburn for up to 12 hours"

1.7 Duration of Use

Guideline
An advertisement must not be misleading as to the recommended duration of use of the advertised product.

Application

- When described or depicted, the duration of use must be consistent with the product's TMA.
- When a product must be used for a specific period of time to obtain the desired effect, this information must be included in the advertisement.

Example
Product X Glucosamine

➢ Indication / Use:
Effective in reducing joint pain. Use for minimum of 2 months to see beneficial effects

✓ Acceptable Claim:
"Product X Glucosamine reduces joint pain when used for at least 2 months"

✗ Unacceptable Claim:
"Product X Glucosamine reduces joint pain quickly"

Application

- Products intended for short term/occasional use must not be represented for long term/chronic use.

Example
Antacid

➢ Indication / Use:
For the relief of occasional heartburn

✓ Acceptable Claim:
"When heartburn strikes, try Product X for relief"

✗ Unacceptable Claim:
"When living with daily heartburn, use Product X for relief"

1.8 Efficacy

Guideline
An advertisement must not be misleading by directly or indirectly exaggerating the degree of relief/benefit to be obtained from use of the advertised product.

Application

- When depicted or described, efficacy claims must be consistent with the product's TMA.

Example
Acne Medicine

➢ Indication / Use:
Helps treat and keep skin clear of new acne pimples

✓ Acceptable Claim:
"Product X helps keep skin clear of new acne pimples"

✗ Unacceptable Claim:
"Product X cures acne"

1.9 Medicinal vs. Non-medicinal Ingredients

Guideline
Product benefits must not be presented in a manner that misleads the consumer as to the nature of either the medicinal (therapeutic) or non-medicinal (non-therapeutic) ingredients.

Application

- No medicinal (therapeutic) benefit can be directly or indirectly attributed to a non-medicinal (non-therapeutic) ingredient

Example
Product X Cough Syrup (honey flavored)

➢ Indication / Use:
For relief of dry coughs (as per the product's TMA, honey is a non-medicinal [non-therapeutic] ingredient)

✓ Acceptable Claim:
"Product X cough syrup relieves your dry cough and the honey coats your throat to provide a soothing sensation"

✗ Unacceptable Claim:
"Try Product X cough syrup – soothing honey relieves your dry cough"

1.10 Onset of Action

Guideline
An advertisement must not be misleading as to the time to onset of action of the advertised product.

Application

- When depicted or described, the onset of action must be consistent with the product's TMA, i.e. claims for action within a specific time period are only permitted if contained in the product's TMA.

Example
Antacid

➢ Indication / Use:
Relieves heartburn in 30 minutes

✓ Acceptable Claim:
"Product X relieves heartburn in 30 minutes"

✗ Unacceptable Claim:
"Product X relieves heartburn in minutes"

Application

- Time to onset of action must not be equated with time to onset of relief, unless clearly specified in the product's TMA.

Example
Analgesic

➢ Indication / Use:
Relieves headache in 45 minutes (TMA states tablet dissolution of 10 minutes)

✓ Acceptable Claim:
"Product X dissolve in 10 minutes and provides headache relief in 45 minutes"

✗ Unacceptable Claim:
"Product X dissolve in 10 minutes to provide fast relief"

2.0 Claims and Representations Under Section 9(1) of the Act

The following table provides guidance regarding the present interpretations of *Section 9(1)* of the *Food and Drugs Act* related to specific claims and representations. The examples provided are for guidance only. The ultimate acceptability of any claim must be evaluated within the overall context of the advertisement.

2.1 Absence of Ingredient Statements
(Reference Document: Health Canada Policy *Absence of Ingredient Statements*)

Guideline
An advertisement must not include an absence of ingredient claim in a manner that creates an erroneous impression about the advertised product or competitor product(s).

Application

- Absence of ingredient statements for medicinal and non-medicinal ingredients are acceptable under the following conditions:
- **Medicinal**
  - The statement provides useful and easily identifiable information to the consumer that reinforces existing labelling and aids consumer medication selection.
  - The statement to the effect that an ingredient has been removed from a product due to a regulatory amendment should only be used for a limited time (i.e. one year assuming continuous marketing or longer depending on circumstances, e.g. one season where products are only marketed seasonally) from the time of the application of the amendment.
  - For single ingredient products, the absent ingredient is of the same product class or has the same therapeutic effect as the actual medicinal ingredient.
  - For multiple ingredient products, the absent ingredient would likely be found in a combination product of that type.
  - There is no misleading representation as to the safety and merit of the absent ingredient.

Note: When a Canadian regulatory agency prohibits the use of a substance, it is acceptable to include a statement to the effect that the product has been reformulated to delete the prohibited ingredient or that the drug does not contain that ingredient. Such statements are acceptable for products that did or might be expected to contain the subject ingredient.

Example
Product which does not contain phenolphthalein

✓ Acceptable Claim:
"Reformulated. Now phenolphthalein-free"

✗ Unacceptable Claim:
"Reformulated. Now safer since phenolphthalein-free"

Application

- **Non-Medicinal**
  - The statement provides useful and easily identifiable information to the consumer to aid in product selection for secondary non-therapeutic attributes such as taste, odour, caloric content, allergic potential or other meaningful attribute.
  - The statement to the effect that an ingredient has been removed from a product due to a regulatory amendment should only be used for a limited time (i.e. one year assuming continuous marketing or longer depending on circumstances, e.g. one season where products are only marketed seasonally) from the time of the application of the amendment.
  - The statement is accurate.
  - There is no direct or indirect implication that the absent ingredient is medicinal.

Example
Product which does not contain gelatine

✓ Acceptable Claim:
"Gelatine-free"

✗ Unacceptable Claim:
"More effective since gelatine-free"

Application

- **Sweetening Agents**
  - A product can be described as "sugar free" if it contains none of the chemical classes of sugar, including sugar alcohols.

Example
Product X cough syrup (sweetened with aspartame – artificial sweetener)

✓ Acceptable Claim:
"Product X cough syrup is sugar-free"

Example
Product X cough syrup (sweetened with mannitol – sugar alcohol)

✗ Unacceptable Claim:
"Product X cough syrup is sugar-free"

2.2 Absence of Side Effect Statements (See also: "2.23 Safe / Side Effect Free")

Guideline
An advertisement must not include a claim for an absence of side effect in a manner that creates an erroneous impression about the advertised product or competitive product(s).

Application

- Absence of side effect statements are acceptable under the following conditions:
  - The weight of scientific evidence exists to support the statement, e.g. incidence of side effect is compared to placebo and is consistent with the product's Terms of Market Authorization.
  - The side effect is associated with comparable components of that class.
  - No undue emphasis on statement.
  - The statement provides practical information (i.e. the side effect or benefit can be readily identified by the consumer).

Example
Cold Medicine

➢ Indication / Use:
Relieves cough and nasal congestion

✓ Acceptable Claim:
"Product X relieves your cough and stuffy nose and it won't make you sleepy"

✗ Unacceptable Claim:
"Get cough and nasal congestion relief, plus an energy boost"

2.3 Children (See also "1.5 Directions for Use / Dosage & Administration)

Guideline

An advertisement must not be misleading by suggesting that a child is capable of making a rational decision regarding the use of the advertised product.

Note: Drug advertising in broadcast media directed to children is prohibited by the Canadian Association of Broadcasters Broadcast Code for Advertising to Children, with the exception of children's fluoride toothpastes.

Application

- Drug advertising must be overtly directed to adults.
- An advertisement must not depict or encourage unsupervised use of drugs by children or suggest that a child can self-diagnose and self-medicate.
- A child may approve of the taste of a medicine, but may not make recommendations concerning the use of the advertised product.
- Advertisements must not depict product storage in locations accessible to children.

Example
Cough Syrup

✓ Acceptable Depiction:
Child: "My dad gave me this medicine and my throat feels better"
Child and father depicted with father holding product bottle and spoon

✗ Unacceptable Depiction:
Child: "Daddy always gives me this syrup when I cough, so I'm going to take it now"
Child depicted self-administering product

2.4 Clinically Tested / Proven

Guideline
An advertisement must not be misleading with respect to use of the statement "clinically tested/proven".

Application

- Claims for "clinically tested/proven" with respect to the product's therapeutic attributes, are limited to those included in the product's TMA. Results from clinical studies that would expand the scope of permissible advertising claims cannot be used in advertising until such claim(s) are authorized by Health Canada, and evidence of the Health Canada authorization is provided to the advertising preclearance agency.

Example
Analgesic

➢ Indication / Use:
Relieves arthritis pain

✓ Acceptable Claim:
"Clinically proven to relieve arthritis pain for up to 8 hours" (where clinical data is available to support duration of action)

✗ Unacceptable Claim:
"Clinically proven to relieve arthritis pain for up to 8 hours" (where clinical data does not support an 8 hour claim)

2.5 Comparative Claims – Therapeutic Comparisons

A therapeutic comparative claim is:
"A statement that compares an identified therapeutic attribute of one drug product/ingredient to that of another/other drug product(s)/ingredient(s) in terms of comparability or superiority"

Therapeutic comparative claims should meet the criteria set out in Health Canada Guidance: *Therapeutic Comparative Advertising Directive and Guidance Document* available at: http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/index_e.html. To help advertisers ensure that claims are consistent with the Health Canada requirements, advertising preclearance agencies should develop Standard Operating Procedures.
Notes:

- Generally two clinical trials are required to support therapeutic comparative claims.
- Comparisons between nonprescription drugs/natural health products and prescription drugs are not permitted as per Section E - Part I of the above guidance.

Examples

1) Claims for Superior Efficacy:

Example: Product X and Y antacids

➢ Indication / Use:
Both products are indicated to relieve heartburn by neutralizing stomach acid

✓ Acceptable Claim:
"Product X antacid relieves your heartburn 25% faster than Product Y antacid (see above note regarding required supporting evidence)"

✗ Unacceptable Claim:
"Product X antacid works better than Product Y antacid"

2) Claims for Superior Onset of Action:

Example: Product A and B analgesics

➢ Indication / Use:
Both products are indicated to relieve headaches

✓ Acceptable Claim:
"Product A starts to work on your headache in 10 minutes while Product B starts to work in 20 minutes (see above note regarding required supporting evidence)"

✗ Unacceptable Claim:
"Product A works really fast on your headache, while Product B takes a long time to start working"

3) Claims for Comparison of Side Effect Profile:

Example: Product C and D antihistamines (both products include drowsiness as known side effect)

✓ Acceptable Claim:
"Product C causes less drowsiness than Product D (see above note regarding required supporting evidence)"

✗ Unacceptable Claim:
"Product C causes less side effects than Product D"

2.6 Comparative Claims – Non-therapeutic Comparisons

A non-therapeutic comparative claim is:
"A statement that compares an identified non-therapeutic attribute of one drug product to that of one or more drug product(s) or non-drug product(s)"

Non-therapeutic comparative claims should meet the criteria set out in Health Canada Guidance: *Principles for Claims Relating to Comparison of Non-Therapeutic Aspects of Nonprescription Drug Products* (http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/index_e.html). To help advertisers meet the criteria of the Health Canada policy, advertising preclearance agencies should develop Standard Operating Procedures.

Examples

Non-therapeutic Claims:
"Moisturizes", "Whitens", "Tastes great"

Non-therapeutic Comparisons:
"Most recommended (product class) by doctors", "Whitens better than...", "Nothing tastes better than..."

2.7 Endorsements / Seals (See also "2.29 Testimonials / Quotations)

Guideline
Seals and endorsements must not be used in a manner that creates an erroneous impression regarding product merit.

Application

- Endorsements by, or seals of recognized groups are acceptable, providing the terms of the endorsement/recognition are consistent with the product's TMA.

Note: For preclearance agency evaluations of such claims, the advertiser should provide written material from the endorsing agency describing the nature and scope of the endorsing agency, and the nature and scope of the product recognition.

Example
Toothpaste

✓ Acceptable Claim:
"Brand X toothpaste contains sodium monofluorophosphate which is, in our opinion, an effective decay preventative agent and is of significant value when used in a conscientiously applied program of oral hygiene and regular professional care – Canadian Dental Association & logo"

✗ Unacceptable Claim: "All dentists always recommend using Brand X toothpaste because it is the best decay preventative agent"

2.8 Exaggeration of Product Merit

Guideline
An advertisement must not mislead consumers by exaggerating product merit.

Application

- It is unacceptable to exaggerate the severity of the condition that can be relieved with the advertised product.

Example
Analgesic

➢ Indication / Use:
For the relief of mild to moderate migraine pain

✓ Acceptable Claim:
"Product X provides migraine pain relief"

✗ Unacceptable Claim:
"Product X relieves severe migraine pain" (in words or depiction)

Application

- It is unacceptable to use superlative terminology to exaggerate therapeutic properties of a product unless supported by its TMA.

Example

✓ Acceptable Claim:
"Effective formula/relief"

✗ Unacceptable Claim:
"Amazing formula/relief"

Application

- It is unacceptable to suggest that use of the advertised product is a substitute for good health practices and a healthy lifestyle.

Example
Antacid

✓ Acceptable Claim:
"Use Product X for the relief of occasional heartburn"

✗ Unacceptable Claim:
"Since I discovered Product X I can eat whatever I want, whenever I want"

2.9 Extra Strength / Maximum Strength (See also: "2.20 Power / Strength")

Guideline
An advertisement must not be misleading by suggesting that an "extra" strength product provides a greater benefit than a "regular" strength product in cases where both are indicated for the same condition.

Application

- It is not acceptable to suggest that there is a correlation between the amount of medicinal ingredient and degree of efficacy unless this is part of the product's TMA.

Example
Antacid
200 mg tablet - Regular Strength
300 mg tablet - Extra Strength
400 mg tablet - Ultra Strength

➢ Indication / Use (all strengths):
For relief of occasional heartburn

✓ Acceptable Claim:
"When you've got occasional heartburn, choose Product X antacid. Available in 3 strengths"

✗ Unacceptable Claim:
"When you've got mild heartburn, choose Regular Strength Product X antacid. When you've REALLY overdone it and you've got bad heartburn, choose Ultra Strength Product X for relief of extreme heartburn"

2.10 Government / Health Canada Approved

Guideline
An advertisement must not make any direct or indirect reference to the *Act* or *Regulations*, as per *Section C.01.007* of the *F&D Regulations*, and *Section 92* of the *NHP Regulations*.

Application

- Claims that state or imply product endorsement or authorization by Health Canada or any other government agency are prohibited.
- It is acceptable to depict a product label that bears a DIN, DIN-HM or NPN.
- It is acceptable to include the actual DIN, DIN-HM or NPN in an advertisement.

Example

✓ Acceptable Claim:
"DIN 12345678"

✗ Unacceptable Claim:
"Has a DIN issued by Health Canada"

2.11 Graphics / Schematics / Statistics / Terminology

Guideline
Graphics, language, schematics, statistics, and terminology used to present product features or characteristics must not do so in a manner that will mislead the consumer as to the therapeutic merits of the product.

Application

- Risk information authorized for the consumer labelling including labels and consumer information documents should be presented to the consumer in absolute rather than relative terms.
- Scientific or technical information should be presented in terminology suitable for the target audience.

Example
Product X Authorized Risk Information: Incidence of side effect Y is reduced from 1 in 100,000 to 1 in 200,000

✓ Acceptable Claim:
"Product X reduces the risk of side-effect Y from 1 in 100,000 to 1 in 200,000"

✗ Unacceptable Claim:
"Product X reduces the risk of side-effect Y by 50%"

2.12 Health / Healthy / Healthful

Guideline
An advertisement must not be misleading by suggesting that a product may restore, maintain or promote health, unless such claims are included in the product's TMA.

Application
- It is unacceptable to make claims regarding health or promotion of health, unless such claims are included in the product's TMA.

Example
Vitamin B_1

➢ Indication / Use:
A factor in the maintenance of good health

✓ Acceptable Claim:
"Product X Vitamin B_1 helps maintain good health"

✗ Unacceptable Claim:
"Product X Vitamin B_1 makes you healthy"

2.13 Implied / Indirect Claims

Guideline
Implied or indirect claims must be consistent with the product's TMA.

Application
- All elements of an advertisement will be considered when assessing conformity to the product's TMA, (e.g. audio, visuals, placement of text, context, graphics, special effects).

Example
Analgesic

➢ Indication / Use:
For arthritis pain relief

✓ Acceptable Claim:
"Analgesic X relieves arthritis pain"
Visuals: Woman's gardening has been interrupted by her arthritis pain acting up. Later on we see her resume her gardening since her arthritis pain has been relieved.

✗ Unacceptable Claim:
"Analgesic X relieves arthritis pain"
Visuals: Woman's gardening has been interrupted by her arthritis pain acting up. Later on we see her doing cartwheels in her backyard.

2.14 Natural (See also: "2.18 Organic")

Guideline
An advertisement must not mislead a consumer to believe that a nonprescription drug or a natural health product is "natural" or "natural source(d)" if it is synthetically derived.

Application

- **Natural:** An ingredient can be described as "natural" if it is obtained from a natural source material, is in a form found in nature, and has undergone only the most minimal processing (e.g. drying, grinding, powdering, chopping, encapsulating). Example: encapsulated powdered garlic.

- **Natural source(d):** An ingredient can be described as "natural source" if it is obtained via extraction, isolation and/or processing of plant, algal, fungal, bacterial, or animal material or minerals. Processing can include such steps as boiling and steaming. The ingredient must have the same chemical identity as that in the source material. Ingredients found in nature that undergo chemical modification such as derivatives and salts are considered synthetic and not natural source. Examples: Vitamin E (d-alpha-tocopherol) isolated from soybean is natural source. The derivative, d-alpha-tocopheryl acetate, produced via chemical modification of vitamin E from soybean, is not natural source, nor is the totally synthetic dl-alpha-tocopheryl acetate.

- **Multi-ingredient products:**
  - Claims that one or several ingredients in a multi-ingredient product are natural/natural source are permissible.
  - Claims about a product, as a whole, being natural/natural source are permissible if this statement is true for **all** ingredients (medicinal and non-medicinal).

- Claims can also be made to the effect that a "product contains X% natural/natural source 'Y' " where X is the actual percentage of ingredient Y in the product that is natural/natural source.

Example
Product Y that contains 40% synthetic and 60% natural source vitamin C (ascorbic acid)

✓ Acceptable Claims:
"Product Y is a source of vitamin C for the maintenance of good health"

"Product Y contains 60% natural source vitamin C for the maintenance of good health"

✗ Unacceptable Claim:
"Product Y is a natural source of vitamin C for the maintenance of good health"

2.15 Natural Action / Naturally

Guideline
An advertisement must not be misleading by claiming that a product acts "naturally" since all nonprescription drugs, including natural health products, modify the body's physiological processes.

Application
- A product's therapeutic effect cannot be described as "natural" or "natural action/acting naturally".

Example

✓ Acceptable Claim:
"Product X relieves symptom X by (authorized mechanism of action)"

✗ Unacceptable Claim:
"Product X acts naturally to relieve..."

2.16 Need

Guideline
An advertisement must not mislead consumers by suggesting that the advertised product is needed.

Application

- It is not acceptable for an advertisement to claim that a consumer "needs" a specific product or ingredient. However, it is acceptable to suggest that an individual "needs relief" or treatment in cases where the condition will not resolve on its own.

Example
Cough Syrup

✓ Acceptable Claim:
"Need relief of stubborn cough? Try Product X Cough Syrup"

✗ Unacceptable Claim:
"For cough relief, you need Product X Cough Syrup"

Example
Vaginal Antifungal Product X

✓ Acceptable Claim
"Need treatment for your yeast infection? Look to Product X"

✗ Unacceptable Claim
"Got a yeast infection? You need Product X"

2.17 New / Improved

Guideline
The terms "new" and "improved" may be used for a period of one year from the date of marketing a new formulation.

Application

- The product attribute that is "new" or "improved" must be clearly specified, e.g., "improved taste", "improved format".

Example

✓ Acceptable Claim:
"New and improved tablet coating"

✗ Unacceptable Claim:
"New and improved tablet" (unqualified)

2.18 Organic (See also: "2.14 Natural")

NHP Reference Document: *Product Licensing Guidance Document*

Guideline

An advertisement must not mislead a consumer to believe a product is "organic" unless it is certified according to organic standards.

Application

- Advertisers must provide evidence of certification, i.e. copy of Organic Certificate. Certification according to any standard reference by a certification body is acceptable.
- Products that are certified organic or contain certified organic ingredients may display the following terms and symbols:
  - Organic
  - Organically grown
  - Organically raised
  - Organically produced
  - Trademark of the certification body

Note: It is recommended that licence holders consult relevant provincial legislation as specific requirements with respect to the use of the term "organic" and its derivatives may vary in each province.

Example
Product X

✓ Acceptable Claim:
"Product X contains organic ingredient Y"

✗ Unacceptable Claim:
"Product X is organic" (if a number of ingredients in product X are not organic)

2.19 Potent / Potency (See also: 2.20 Power / Strength)

Guideline

Nonprescription drugs: An advertisement must not be misleading by referring to a nonprescription drug as being "potent" or having a "potent" formulation.

Natural health products: An advertisement must not be misleading by referring to a natural health product as "potent". However claims for "potency" (as defined in the *NHP Regulations*) are permissible for natural health products when included in the PL and expressed in a manner consistent with the product's TMA.

Homeopathic medicines: For homeopathic medicines, the term "potency" refers to the "quantity" as defined in the *Evidence for Homeopathic Medicines Guidance Document.* Statements regarding potency express the serial dilution and succession of the medicinal ingredient, consistent with the product's TMA.

Application

- All nonprescription drugs and natural health products contain sufficient medicinal ingredients to be effective as per their authorized therapeutic indications. Therefore, the relief to be derived from such products is an indicator of their effectiveness and not their "potency".

Example
Nonprescription Drug

✓ Acceptable Claim:
"Effective formulation"

✗ Unacceptable Claim:
"Potent Formulation"

Application

- As per Section 5(c)(iii) of the *NHP Regulations*: "Potency": amount per dosage unit of the standardized component which further characterizes the quantity -- "Quantity": amount of medicinal ingredient per dosage unit.

Example
Natural Health Product
Plant Extract
Quantity: 1000mg, Potency: 5% hyperforin

✓ Acceptable Claim:
"The potency of Product X Plant extract is standardized to contain 5% hyperforin"

✗ Unacceptable Claim:
"Product X Plant extract is potent"

Application

- The potency of homeopathic medicines is expressed by a dilution factor (e.g. 10M) as set out in *Evidence for Homeopathic Medicines Guidance Document*[8].

[8] The potency of homeopathic medicines is to be expressed by a dilution factor as follows:

Designation	Scale	Method of Attenuation
X or D	Decimal (1/10)	Hahnehamannian
CH or C	Centesimal (1/100)	Hahnehamannian
CK or K	Centesimal (1/100)	Korsakovian
M or MK	Millesimal (1/1000)	Korsakovian
LM or Q	fifty Millesimal (1/50,000)	Hahnehamannian

Example
Homeopathic Medicine

✓ Acceptable Claim:
"Product X has a potency of 5CH"

✗ Unacceptable Claim:
"Product X is potent"

2.20 Power / Strength (See also: "2.19 Potent / Potency" and "2.9 Extra Strength / Maximum Strength")

Guideline
An advertisement must not be misleading by suggesting that a particular product contains more than sufficient medicinal ingredient to relieve/treat/prevent a particular condition or symptom.

An advertisement must not be misleading by suggesting that there is a correlation between the amount of medicinal ingredient and degree of efficacy unless this is part of the TMA.

Application

- All drugs are formulated (i.e., contain sufficient medicinal ingredient) to be effective for the condition/symptoms they are designed to relieve/treat/prevent.
- It is thus appropriate to claim that a product is "effective", "strong enough", or "tough enough", for the condition or symptoms it is designed to relieve/treat/prevent. It is unacceptable to suggest that the product, in and of itself, is "strong" or "powerful".

Example

✓ Acceptable Claim:
"Product X has the power to relieve condition Y"

✗ Unacceptable Claim:
"Product X is powerful"

2.21 Risk/Safety Information Communication

Guideline
In order to make informed decisions about their health, consumers should be provided with fair and balanced information about the benefits and the risks associated with the use of the advertised product.

Application
Consumers should **always** :

- Be advised to read the label and follow directions of use for the advertised product.
- Where there are known risks, be provided with a general risk/cautionary statement that the advertised product may pose risks and may not be suitable for everyone (or similar wording).
- Be provided with an easily accessible source of additional, appropriate information. This function may be fulfilled through the advice to always read the label if the label is fully up-to-date. Other sources of information (websites, phone numbers, reference to print material, etc.) may also be referenced in an advertisement in order to provide relevant balanced information consistent with the TMA.

Where a safety advisory related to the advertised product or ingredient has been issued and when the label information may not be up-to-date, consumers should be:

- Made aware of the new risk information through an additional source of information (supplemental advertisement, updated advertisement including new information, reference to Health Canada's Website to access new safety information about the advertised product or ingredient, etc.) until the label of the advertised product is revised to reflect the new information.
- Invited to contact a health professional for up-to-date information.

Technical requirements:

- Visual disclosures (supers) in broadcast advertisements shall always be of a size, shade and duration sufficient for an average person to read and comprehend it.
- The general risk/cautionary statement should be verbally communicated in television and radio messages in a clear and understandable manner.
- Disclosures in print advertisements shall always be in a type size and location sufficiently noticeable for an average person to read and comprehend it, in print that contrasts with the background against which it appears.

Example
Cold Product X

✓ Acceptable Claim:
"Product X is suitable for adults over 18 years of age looking for relief of cough, cold and flu symptoms". Product X may pose risks and may not be suitable for everyone. Read the label and follow directions of use. Additional balanced information may be obtained by calling 1-800-xxx-xxxx or by consulting the Website xxxx.

✗ Unacceptable Claim:
"Product X is suitable for adults over 18 years of age looking for relief of cough, cold and flu symptoms".

2.22 Risk Reduction Claims

Guideline
An advertisement must not mislead consumers through inappropriate use of a risk reduction claim.

Definition – Risk Reduction: describes the relationship between using a medicinal ingredient and reducing risk of developing a specific disease or abnormal physiological state, by significantly altering a major risk factor or factors recognized to be involved in the development of the chronic disease or abnormal physiological state.

Application

- It is unacceptable to make a risk reduction claim that is inconsistent with a product's TMA and/or that involves a condition that:
  - Is related to *Schedule A* (See *Schedule A and Section 3: Guidance Document* at: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/activit/index_e.html or Appendix A in Section B of the *Guidelines*)
  - Is not appropriate for self diagnosis
  - Requires monitoring by a health care provider.

Example
Calcium Supplement

➢ Indication / Use:
Help prevent osteoporosis

✓ Acceptable Claim:
"Product X calcium supplement may reduce the risk of developing osteoporosis"

✗ Unacceptable Claim:
"Product X calcium supplement may reduce the risk of developing bone cancer"

2.23 Safe / Side Effect Free (See also: "2.2 Absence of Side Effect Statements")

Guideline
Claims stating "safe", "side effect free" and "no known side effects" are unacceptable.

Application

- It is misleading to suggest that a product is "safe", "side effect free" or has "no known side effects" since all products carry some degree of risk.
- It is misleading to suggest that a product is "safe" or that it can be used without harm or without side effects because it is derived from nature.

Example

✓ Acceptable Claim:
"Suitable for children over 12 years of age"

✗ Unacceptable Claim:
"Safe because it's natural source"

2.24 Sampling

Guideline
In accordance with *Section 14* of the *Food and Drugs Act*, which prohibits the distribution of drugs as samples to the general public, advertising for drug sampling is unacceptable.

Application
- Advertisements must not include offers for samples to the general public.

Example

✗ Unacceptable Claim:
"For a sample call 1-800-123-4567"

2.25 Scare Advertising

Guideline
An advertisement must not create an erroneous impression regarding the merit of a product through use of fear-inducing copy or visuals.

Application
- An advertisement should not:
  - Suggest that the health of a consumer will suffer, or that full health cannot be attained without using the advertised product.
  - Exaggerate the possible consequences of not treating a condition or disorder.
  - Describe more serious diseases or effects that may result from the original condition if left untreated.

Example
Hand Germicidal Cleanser

✓ Acceptable Claim:
"Product X kills germs"

✗ Unacceptable Claim:
"Germs are everywhere! Don't be at risk. Use Product X to prevent SARS"

2.26 Storage Conditions

Guideline
An advertisement must not mislead consumers regarding the safe and appropriate storage conditions of a product.

Application
- When depicted or described, the storage conditions must be consistent with the product's TMA.

Example

➢ Authorized Storage Conditions:
"Store between 15-30 degrees Celsius"

✓ Acceptable Depiction:
"Product stored in medicine cabinet"

✗ Unacceptable Depiction:
"Product depicted as being stored in glove box of car during a snow storm"

2.27 Structure Function Claims

Guideline
An advertisement must not mislead consumers through inappropriate use of a structure function claim.

Definition – Structure Function: describes the effect of a medicinal ingredient on a structure or physiological function in the human body, or a medicinal ingredient's support of an anatomical, physiological, or mental function. A structure Function claim is considered to be included in the definition of a drug in *Section 2* of the *Food and Drugs Act.*

Application

- It is unacceptable to make a structure function claim that is inconsistent with a product's TMA and/or that involves a condition that:
  - Is related to *Schedule A* (See *Schedule A and Section 3: Guidance Document* at: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/activit/index_e.html or Appendix A in Section B of the *Guidelines*)
  - Is not appropriate for self diagnosis
  - Requires monitoring by a health care provider.

Example
Product X Glucosamine

➢ Indication / Use:
A factor in the building of healthy cartilage

✓ Acceptable Claim:
"Product X Glucosamine is a factor in building healthy cartilage"

✗ Unacceptable Claim:
"Product X Glucosamine will treat your arthritis"

2.28 Superscripts / Footnotes or "Supers"

Guideline
Superscripts and footnotes (also known as "supers") should not be used to correct an otherwise misleading impression about a product.

Application

- Superscripts or footnotes may be used to provide clarification or additional information about a product.
- Superscripts/Footnotes shall appear clear, legible and be understood by the consumer
- If a super is necessary for the ad to be considered acceptable, this super should stay on screen for a sufficient length of time to be read by the average person.

Example
TMA: Provides 8 hours of relief

✓ Acceptable Claim:
Audio: "Relief all work day"
Super: "Provides 8 hours of relief"

✗ Unacceptable Claim:
Audio: "Around the clock relief"
Super: "Provides 8 hours of relief"

2.29 Testimonials / Quotations (See also: "2.7 Endorsements / Seals")

Guideline
An advertisement must not be misleading by using a testimonial or quotation to state or imply a benefit that exceeds a product's TMA.

Application
- Testimonials are acceptable, provided the claims do not exceed the product's TMA.

Example
Product Y Echinacea

➢ Indication / Use:
Traditionally used for the relief of sore throat due to colds

✓ Acceptable Claim:
"Product Y Echinacea is traditionally used to relieve sore throats due to colds. Product Y contains echinacea. It worked for me!"

✗ Unacceptable Claim:
"I tried Product Y Echinacea and I just couldn't believe the results. It was amazing! It's made my immune system stronger than ever"

2.30 Therapeutic Guarantees / Absolute Claims

Guideline
Some individuals may respond to a particular medication and others may not, part of the inherent variability of drug action in a population. Therefore, an advertisement must not be misleading as to the merits of a product by directly or indirectly suggesting that it will be effective for all individuals, or that it will be effective every single time it is used.

Application

- When depicted or described, an advertisement must realistically present the product's efficacy.

Note: Guarantees of purity, quality or physical characteristics are acceptable (i.e., guarantees about non-therapeutic attributes) if true and supportable

Example

✓ Acceptable Claim:
"Product X provides effective relief"

✗ Unacceptable Claim:
"Product X is proven 100% effective for everyone, 100% of the time"

2.31 Unique

Guideline

An advertisement must not be misleading by describing the therapeutic aspects of a product as unique if the product does not provide a unique therapeutic benefit/effect.

Note: Any claims for "unique" that meet the Health Canada definition of a comparative therapeutic claim should meet the requirements set forth in Health Canada's Directive and Guidance Documents regarding Comparative Therapeutic Advertising

Application

- It is unacceptable to claim that a product has a unique therapeutic formulation or provides a unique therapeutic benefit unless the product is unique in both therapeutic formulation and effect.

Example
Unique (Therapeutic)

✓ Acceptable Claim:
"Our antiperspirant is unique because it provides 48 hours of continual wetness protection" (acceptable if the only antiperspirant authorized by HC for a 48 hr duration of action)

✗ Unacceptable Claim:
"Our antiperspirant is unique because it provides long lasting protection" (unacceptable since most antiperspirants provide long lasting protection)

Application

- The term unique is acceptable when used to accurately describe non-therapeutic/cosmetic product features, e.g. unique fragrance.

Example
Unique (Non-therapeutic)

✓ Acceptable Claim:
"Shampoo X fights dandruff and has a unique shine enhancing ingredient" (advertiser would have to provide attestation that no other shampoo contains this shine ingredient)

2.32 Withdrawal of Terms of Market Authorization

Guideline

Advertising is not permitted for products for which the TMAs have been withdrawn by Health Canada for health and safety reasons, or for products that have voluntarily been withdrawn or discontinued by the manufacturer.

Application

- In the case of a product for which the TMAs have been withdrawn, or products voluntarily discontinued by the manufacturer, the preclearance agency will immediately revoke any previously assigned approval numbers.

Note: Product Advisories and Warnings are posted on Health Canada's website (http://www.hc-sc.gc.ca/dhp-mps/advisories-avis/index_e.html).

Section B:
Legislation, Regulations and Policies[9]

B.1. Definitions Under the Food and Drugs Act, the Food and Drug Regulations and the Natural Health Products Regulations[10]

Advertisement (*Food and Drugs Act Section 2*):

> ***'advertisement'*** *includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device*

Drug (*Food and Drugs Act Section 2*):

> ***'drug'*** *includes any substance or mixture of substances manufactured, sold or represented for use in*
>
> *a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals,*
> *b) restoring correcting or modifying organic functions in human beings or animals, or*
> *c) disinfection in premises in which food is manufactured, prepared or kept*

Brand name (*Food and Drug Regulations Section C.01.001(1)*)

> *'**brand name**' means, with reference to a drug, the name, whether or not including the name of any manufacturer, corporation, partnership or individual, in English or French,*
> *(a) that is assigned to the drug by its manufacturer,*
> *(b) under which the drug is sold or advertised, and*
> (c) *that is used to distinguish the drug*

Natural Health Product (*NHP Regulations Section 1(1)*)

> ***"natural health product"*** *means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in*
>
> *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.*
>
> *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*

[9] This section is to be used as a complement to *Section A – Advertising Guidelines of the Consumer Advertising Guidelines for Marketed Health Products For Nonprescription Drugs including Natural Health Products.*

[10] Definitions in the *Food and Drugs Act* apply to *the Food and Drug Regulations* as well as to the *Natural Health Products Regulations.*

in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.

Schedule 1: INCLUDED NATURAL HEALTH PRODUCT SUBSTANCES

Item	Substances
1	A plant or plant material, an alga, a bacterium, a fungus or a non-human animal material
2	An extract or isolate of a substance described in item 1, the primary molecular structure of which is identical to that which it had prior to its extraction or isolation
3	Any of the following vitamins: biotin, folate, niacin, pantothenic acid, riboflavin, thiamine, vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin E, vitamin K1 and K2 (120 micrograms daily or less)
4	An amino acid
5	An essential fatty acid
6	A synthetic duplicate of a substance described in any of items 2 to 5
7	A mineral
8	A probiotic

Schedule 2: EXCLUDED NATURAL HEALTH PRODUCT SUBSTANCES

Item	Substances
1	A substance set out in Schedule C to the Act
2	A substance set out in Schedule D to the Act, except for the following: (a) a drug that is prepared from any of the following micro-organisms, namely, an alga, a bacterium or a fungus; and (b) any substance set out on Schedule D when it is prepared in accordance with the practices of homeopathic pharmacy
3	A substance regulated under the Tobacco Act
4	A substance set out in any of Schedules I to V of the Controlled Drugs and Substances Act
5	A substance administered by puncturing the dermis
6	An antibiotic prepared from an alga, a bacterium or a fungus or a synthetic duplicate of that antibiotic

Product Licence (*NHP Regulations Section 14(1)*)

*A **product licence** shall set out the following information:*

a) the name and address of the licensee;
b) the product number of the natural health product;
c) the dosage form that is authorized for the natural health product;
d) the recommended route of administration that is authorized for the natural health product;
e) the recommended dose that is authorized for the natural health product;
f) the recommended duration of use, if any, that is authorized for the natural health product;
g) in respect of each medicinal ingredient of the natural health product
  (i) its authorized quantity per dosage unit,
  (ii) its authorized potency, if any, and
  (iii) its authorized source material;

h) the recommended use or purpose that is authorized for the natural health product; and
i) the date on which the licence was issued

Note: For natural health products, the Product Licence constitutes the Terms of Market Authorization.

OTHER DEFINITIONS

Brand Name (*NHP Regulations Section 1(1)*)

*"**Brand name**" means a name in English or French, whether or not it includes the name of a manufacturer, corporation, partnership or individual*
(a) that is used to distinguish the natural health product; and
(b) under which a natural health product is sold or advertised

Drug Identification Number (DIN)

A **Drug Identification Number** is an eight (8) digit numerical code following the acronym DIN assigned by Health Canada to a particular drug when it is authorized for sale.

Homeopathic Medicine (*Evidence for Homeopathic Medicines Guidance Document*)

Medicines that are manufactured from or contain as medicinal ingredients only those substances or sources referenced in the Homeopathic Pharmacopoeia of the United States (HPUS), the Homoopathische Arzneibuch (HAB), the Pharmacopée francaise (PhF) or the European Pharmacopoeia, as they are amended from time to time, and that are prepared in accordance with these pharmacopoeias.[11,12]

Homeopathic Medicine Number (DIN-HM)

A **Homeopathic Medicine Number** is an eight (8) digit numerical code following the acronym DIN-HM assigned to each homeopathic medicine authorized to be marketed under the *Natural Health Products Regulations*.

Natural Product Number (NPN)

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[11] Substances listed on Schedules I to V of the *Controlled Drugs and Substances Act* (CDSA), the *Tobacco Act* and classified *as Schedule C* (radiopharmaceuticals) to the *Food and Drugs Act* are excluded from the Natural Health Product definition, and therefore not subject to the *Natural Health Products Regulations*. Therefore, medicines containing or manufactured from substances listed on these schedules, which are listed on *Appendix 1* of the *Evidence for Homeopathic Medicines Guidance Document* (EHM-GD), are not acceptable in HMs. Please note that *Appendix 1* of the EHM-GD may be used as a guide but is not necessarily all inclusive.

[12] The *Natural Health Products Regulations* allow homeopathic medicines manufactured from or containing substances listed on *Schedule D* to the *Food and Drugs Act* or the *Schedule F* to the *Food and Drugs Regulations*. Please refer to *Appendix 2* of *the Evidence for Homeopathic Medicines Guidance Document* (EHM-GD) for additional information. Medicines containing or manufactured from substances listed on *Appendix 2* of the EHM-GD are acceptable in homeopathic medicines but are not covered in the *Evidence for Homeopathic Medicines Guidance Document*. The approach to these particular homeopathic medicines will be covered in a separate appendix of the EHM-GD (under development).