February 2005

CONSULTATION NOTICE

Health Canada, in collaboration with Advertising Standards Canada (ASC), has developed draft *Consumer Advertising Guidelines for Marketed Health Products (Guidelines).* The *Guidelines* apply to consumer-directed advertising of nonprescription drugs, including natural health products, for human use. They **do not** apply to advertising of prescription drugs to consumers nor are they intended to propose any regulatory amendments related to the advertising of products to consumers for the treatment, prevention or cure of Schedule A diseases (i.e., cancer, heart disease). These guidelines, which once approved, will replace and supersede Health Canada's 1990 *Consumer Drug Advertising Guidelines*, are intended 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
Section B – Legislation, Regulations and Policies

The *Guidelines* will form the basis upon which Health Canada-endorsed preclearance agencies will review and approve advertising for products in the categories of nonprescription drugs including natural health products, and will help ensure consistency in advertising review. ASC is currently the only agency endorsed by Health Canada to review advertising material directed to consumers for nonprescription drugs and natural health products.

Health Canada has mandated ASC to collate comments received during this external stakeholder consultation period and to submit a revised draft along with a tabulation of comments to Health Canada for review and finalization of the *Guidelines*. Implementation of these guidelines once approved is proposed for January 2006.

Should you wish to provide comments or suggestions on the *Guidelines*, you are requested to do so **by April 22, 2005.** Please address comments and questions to:

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The draft *Consumer Advertising Guidelines for Marketed Health Products* are posted on ASC's Website at www.adstandards.com. They are also posted on Health Canada's Website at www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advertising_e.html with other Health Canada Advertising Policies and on the Natural Health Products Directorate home page at http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/index_e.html. Hard copies are available upon request.

Consumer Advertising Guidelines for Marketed Health Products[1]

For Nonprescription Drugs including Natural Health Products

CONSULTATION DRAFT

February 2005

Developed by:

ADVERTISING STANDARDS CANADA

Health Canada
Santé Canada

[1] This document will replace the 1990 Consumer Drug Advertising Guidelines for the purpose of helping 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.

TABLE OF CONTENTS

Section A: Advertising Guidelines

A.1 Overview
A.2 Scope
A.3 Advertising Preclearance Overview
A.4 Health Canada and Preclearance Agency Roles and Consultation Related to Advertising Review and Complaint Adjudication
A.5 Consumer and Trade Complaints about Therapeutic Aspects of Nonprescription Drug Advertisements including Natural Health Product Advertisements
A.6 Advertising Guidelines: Guiding Principles

1.0 Product Characteristics Based on *Section 9(1)* of the *Act*
- 1.1 Authorization – Terms of Market Authorization
- 1.2 Product Representation
- 1.3 Indication/Recommended Use – Single Medicinal Ingredient
- 1.4 Indication/Recommended Use – Multiple Medicinal Ingredients
- 1.5 Direction for Uses/Dosage and Administration
- 1.6 Duration of Action
- 1.7 Duration of Use
- 1.8 Efficacy
- 1.9 Medicinal vs. Non-Medicinal Ingredients
- 1.10 Onset of Action

2.0 Claims and Representations Under *Section 9(1)* of the *Act*
- 2.1 Absence of Ingredient Statements
- 2.2 Absence of Side Effect Statements
- 2.3 Children
- 2.4 Clinically Tested/Proven
- 2.5 Comparative Claims – Therapeutic Comparisons
- 2.6 Comparative Claims – Non-therapeutic Comparisons
- 2.7 Endorsements/Seals
- 2.8 Exaggeration of Product Merit
- 2.9 Extra Strength/Maximum Strength
- 2.10 Government/Health Canada Approved
- 2.11 Graphics/Schematics/Statistics/Terminology
- 2.12 Health/Healthy/Healthful
- 2.13 Implied/Indirect Claims
- 2.14 Natural
- 2.15 Natural Action/Naturally
- 2.16 Need
- 2.17 New/Improved
- 2.18 Organic
- 2.19 Potent/Potency
- 2.20 Power/Strength
- 2.21 Risk Information Communication
- 2.22 Risk Reduction Claims
- 2.23 Safe/Side Effect Free
- 2.24 Sampling
- 2.25 Scare Advertising
- 2.26 Storage Conditions
- 2.27 Structure Function Claims
- 2.28 Superscripts/Footnotes or “Supers”
- 2.29 Testimonials/Quotations
- 2.30 Therapeutic Guarantees/Absolute Claims
- 2.31 Therapeutic Claims
- 2.32 Unique
- 2.33 Withdrawal of Terms of Market Authorization

Section B: Legislation, Regulations and Policies

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

B.2 Legislation, Codes and Policies that Apply to Marketed Health Product Advertising

B.3 Appendix Material

Appendix A – *Schedule A* to the *Food and Drugs Act*
Appendix B – *Appendix 2* of *Product Licensing Guidance Document* (NHP)
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

Section A – Advertising Guidelines

A.1. Overview

The draft *Consumer Advertising Guidelines for Marketed Health Products* (the "Guidelines") apply to advertising of nonprescription drugs (NonRx drugs) including Natural Health Products (NHPs). The Guidelines, which will 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:	*Schedule A* to the *Food and Drugs Act*
Appendix B:	Appendix 2 of *Product Licensing Guidance Docum*ent (NHP)
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 the advertiser with the tools to understand drug advertising principles before advertising copy is considered and submitted for review to the Health Canada endorsed preclearance agency. The Guidelines will form the basis upon which Health Canada's endorsed preclearance agencies[2] will review and approve advertising for nonprescription drugs including natural health products, and will help ensure consistency in advertising review.

NonRx drugs including NHPs are subject to the provisions of the *Food and Drugs Act*. Drugs are subject to the *Food and Drug Regulations*. NHPs 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 *NHP Regulations* (e.g. *Section 103* of the *NHP Regulations*).

[2] Advertising Standards Canada (ASC) is the only agency endorsed by Health Canada to date to review and pre-clear broadcast and mass print advertising to consumers for nonprescription drug products including natural health products (www.adstandards.com). For more information about ASC's Roles and Responsibilities, see the Health Canada policy: *ASC and Health Canada Roles and Consultation Related to Advertising Review and Complaint Adjudication*

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 may be updated on an as-needed basis.

A.2. Scope

The Guidelines apply to all consumer-directed advertising for NonRx drugs including NHPs, in all Canadian media[3].

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 and Health Canada's endorsed preclearance agency[4] policies and procedures. The Guidelines are intended to be used in conjunction with these aforementioned provisions and policies.

The Guidelines **do not** apply to 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*)].
The Guidelines **do not** currently[5] apply to the advertising of:

- Medical devices to consumers*
- Veterinary drugs to consumers

* 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.*

The Guidelines **do not** apply to the advertising of:

- Nonprescription drugs including NHPs to health professionals[6]
- Prescription drugs to consumers
- Prescription drugs to health professionals
- Veterinary drugs to health professionals

The Guidelines **do not** apply to informational messages such as, but not limited to:

- Institutional messages
- Patient support group messages
- Help-seeking announcements
- Clinical trial recruitment messages

[3] 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
[4] Advertising Standards Canada is the only agency endorsed by Health Canada to date to review and preclear broadcast and mass print advertising to consumers for nonprescription drugs including natural health products
[5] As of date of issuance of Guidelines
[6] The Pharmaceutical Advertising Advisory Board (PAAB) preclears advertising directed to health professionals for all marketed health products

A.3. Advertising Preclearance Overview

Health Canada's endorsed 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 NonRx drugs including NHPs. 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 legislations and regulations.

Preclearance services generally include the review of advertising copy both for traditional media, including radio, television and mass print (e.g. newspaper, magazine, outdoor, transit), for other categories (e.g. flyers, point of purchase, consumer brochures) and for Internet advertising. Preclearance agencies may also offer consultation services for new product launches and new advertising concepts.

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

The specific roles of Health Canada and the endorsed preclearance agency are set out in the Health Canada Policy: *Advertising Standards Canada and the Therapeutic Products Directorate's Roles and Consultation Related to Advertising Review and Complaint Adjudication*, which can be found on the Health Canada website. (http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advertising_e.html)

This policy sets out the conditions under which the preclearance agency may consult with Health Canada on policy issues related to advertising and complaint adjudication.

A.5. Consumer and Trade Complaints about Therapeutic Aspects of Nonprescription Drug Advertisements including Natural Health Product Advertisements

Preclearance agencies are responsible for managing and administering consumer and trade complaints about therapeutic aspects of nonprescription drug advertising including natural health product 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 willful nonparticipation in, or noncompliance with the Standards and Procedures.

- Advertising complaints related to products unauthorized by Health Canada.

A.6. 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*

** The guidelines set out in this section do not apply to advertisements displaying only the brand name of the product (with no embellishments). Any advertisement, which contains the name of the product and a claim, must however be in accordance with all guidelines of this section.

1.1 Authorization – Terms of Market Authorization

Guideline

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

- For NHPs:
  - Product Licence (PL)
- For NonRx Drugs:
  - Labelling Standards, Category IV Monographs, Product Monographs or Authorized Labelling (with evidence that such claims were specifically reviewed and authorized by Health Canada).

Application

- Claims found in the TMA may be paraphrased, but must remain consistent with those authorized. Claims must not directly or indirectly exceed the scope of the TMA.
- Visuals and copy must not be used to directly or indirectly suggest product benefits beyond those found in the TMA.

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

- NHPs: see Appendix 2 of the *Product Licensing Guidance Document*[7]: "Regulatory Requirements Resulting from Changes to Products".

[7] 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*.

- NonRx drugs: see Health Canada Policy: *Changes to Marketed New Drugs*[7], *or Section C.01.014.4*[8] of the *Food and Drug Regulations*.

Example
Antihistamine

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

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

✗ Unacceptable Claim:
"Got allergies? Product X will relieve/prevent them"

1.2 Product Representation

Guideline
An advertisement must not be misleading as to the product category under which it received its TMA.

Application

- The advertised product must not be directly or indirectly misrepresented as to product classification. For example, a nonprescription product must not be represented as a food, cosmetic, or medical device.

Example
Anti-dandruff Shampoo

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

✓ Acceptable Claim:
"Product X shampoo helps control flaking, scaling and itching associated with dandruff "

✗ Unacceptable Claim:
"Product X shampoo is thick, rich and smells fresh" (with no emphasis on the therapeutic claim)

[8] See Appendix D *for Section C.01.014.4*

1.3 Indication / Recommended Use – Single Medicinal Ingredient

Guideline
The advertisement must clearly communicate the intended use of the product.

Application

- An authorized clear therapeutic indication is required.
- 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"

✗ Unacceptable Claim:
"Product X may be beneficial to you" (without an indication as to the product's therapeutic use)

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

Example
Analgesic

➢ Indications / Uses:
For fever reduction and pain relief

✓ Acceptable Claim:
"Product X relieves fever" or "Product X relieves fever and pain"

✗ Unacceptable Claim:
"Product X may help you feel better" (without an indication as to one of the product's therapeutic uses)

1.4 Indication / Recommended Use – Multiple Medicinal Ingredients

Guideline
The advertisement must clearly communicate the intended uses of the product, as per the TMA.

Application

- For **multiple medicinal ingredients / multiple indication products**: At least *one* clear therapeutic indication for *each* medicinal ingredient must be presented in the advertisement (equal focus on each therapeutic indication is not required).

Example
Cough/cold preparation with 4 medicinal ingredients (guaifenesin, dextromethorphan, chlorpheniramine, acetaminophen)

➢ Indications / Uses:
Relieves chest congestion, dry cough, runny nose and fever.

✓ Acceptable Claim:
"Dry cough keeping you up at night? Product X contains DM to relieve your dry cough. It also relieves chest congestion, runny nose and fever"

✗ Unacceptable Claim:
"Dry cough keeping you up at night? Product X contains DM to relieve your dry cough"

1.5 Direction for Uses / 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 TMA.

Example
Wart remover

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

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

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

- Depictions of ingestion, e.g. graphics/visuals, 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 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”

- Duration of pharmacological action must not be equated with duration of relief unless clearly specified in the 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:
"Relieves heartburn for up to 12 hours"

1.7 Duration of Use

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

Application

- When described or depicted, the duration of use must be consistent with the 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

➢ Indication / Use:
Reduces symptom X. Use for minimum of 2 months to see beneficial effects

✓ Acceptable Claim:
"Reduces/relieves symptom X when used for at least 2 months"

✗ Unacceptable Claim:
"Reduces/relieves symptom X quickly"

1.8 Efficacy

Guideline
An advertisement must not directly or indirectly exaggerate 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 TMA.

Example
Acne medicine

➢ Indication / Use:
Treats and helps prevent acne pimples

✓ Acceptable Claim:
"Product X helps keep skin clear of 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 or non-medicinal ingredients.

Application

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

Example
Honey-flavoured Cough Syrup

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

✓ Acceptable Claim:
"Product X relieves your cough. And it contains the great taste of honey"

✗ Unacceptable Claim:
"Product X works with honey to relieve your 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 TMA, e.g., claims for action within a specific time period are only permitted if contained in the TMA.

Example
Antacid

➢ Indication / Use:
Relieves heartburn in 30-60 minutes.

➢ Pharmacology:
Starts to neutralize stomach acid in seconds.

✓ Acceptable Claim:
"Product X neutralizes stomach acid in seconds"

✗ Unacceptable Claim:
"Product X works instantly"

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

Example
Antacid

➢ Indication / Use:
Relieves heartburn in 30-60 minutes

➢ Pharmacology:
Starts to neutralize stomach acid in seconds.

✓ Acceptable Claim:
"Product X relieves my heartburn in less than an hour."

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

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.

** The requirements set out in section 2.21 (Risk Information Communication) do not apply to advertisements displaying only the brand name of a product (with no embellishments).

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.
  - For single ingredient products, the absent ingredient is of the same product class 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.

Example
Product which does not contain Phenolphthalein

✓ Acceptable Claim:
“Reformulated. Now Phenolphthalein - free”

✗ Unacceptable Claim:
“Reformulated. Now safer since phenolphthalein – free”

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.

- **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 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"

- **Sweetening Agents**

  - A product can be described as "sugar free" if it contains none of the chemical classes of sugar, including sugar alcohols.
  - However, if it is sweetened with an alternative sweetener, that sweetener must be identified. If a synthetic sweetener is used, it must be identified on the product label.

Example
Product which does not contain Sweetening Agent X

✓ Acceptable Claim:
"Product Y is sugar free, it's sweetened with sweetening agent X"

✗ Unacceptable Claim:
"Product Y is now sugar free" (without any mention of the alternative sweetener when the product is sweetened with an alternative sweetener)

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:
  - 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.

- There is a widely held consumer perception that the side effect is associated with comparable components of that class.
- No undue emphasis of statement.
- The statement provides practical information (i.e. the side effect or benefit can be readily identified by the consumer).

Example
Cold Medicine

✓ Acceptable Claim:
"Product X provides relief in a non-drowsy formula"

✗ Unacceptable Claim:
"You will feel great since product X provides relief in a non-drowsy formula"

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

Guideline
It is misleading to suggest 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.

Application
- Drug advertising must be overtly directed to adults.

Example
Cough Syrup

✓ Acceptable Depiction:
Child and father depicted with father holding product bottle and spoon

✗ Unacceptable Depiction:
Child depicted self-administering product

- 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 Claim:
Child: “My mom gave me this medicine and my throat feels better”

✗ Unacceptable Claim:
Child: “Mommy always gives me this syrup when I cough, so I’m going to take it now”.

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 product benefits that are “clinically tested/proven” are limited to those that are consistent with the TMA. Results from clinical studies that would expand the scope of permissible advertising claims cannot be used in advertising until the new claim(s) are authorized by Health Canada, and evidence of the Health Canada authorization is provided to the preclearance agency.

Example
Antihistamine

✓ Acceptable Claim:
“Clinically proven to relieve allergy symptoms.”

✗ Unacceptable Claim:
“Clinically proven to reduce allergy symptoms by 96%” (if claim not included in efficacy data reviewed by Health Canada for product authorization)

2.5 Comparative Claims – Therapeutic Comparisons

Guideline
Therapeutic superiority including superlative claims, must meet the criteria set out in the Health Canada Policy: *Therapeutic Comparative Advertising Directive and Guidance Document* (http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advertising_e.html).

Application

- Comparative claims are reviewed under the above-mentioned Health Canada Policy and *Advertising Standards Canada Therapeutic Comparative Advertising SOP*.

Example

Superiority Claims:
"Better than", "Faster than", "Unlike other products…"

Superlative Claims:
"Best", "Fastest", "most effective"

2.6 Comparative Claims – Non-therapeutic Comparisons

Guideline
Non-therapeutic comparative claims must meet the criteria set out in the Health Canada Policy: *Principles for Claims Relating to Comparison of Non-therapeutic Aspects of Non-prescription Drug Products* (http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advertising_e.html).

Application

- Non-therapeutic comparisons / claims are reviewed under the above-mentioned Health Canada policy and Advertising Standards Canada Clearance Policy *Claims about Non-Therapeutic Aspects of Nonprescription Drugs in Consumer Directed Advertising*.

Example

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 TMA.

Note: For preclearance 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 suggest that use of the advertised product is a substitute for good health practices.

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"

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

Example
Analgesic

✓ Acceptable Claim:
"Product X provides relief of the pain of mild to moderate migraine"

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

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

Guideline
It is misleading to suggest 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 acceptable to use terms such as "extra strength" or "ultra strength" to describe items in a product line where various quantitative amounts of medicinal ingredients are available. However, 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 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 Brand X antacid. Available in 3 strengths"

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

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 government or government agencies are prohibited.
- It is acceptable to show in advertising a factual representation of a product label that bears a DIN/DIN-HM or NPN.
- It is acceptable to state the DIN, DIN-HM or NPN.
- It is not acceptable to claim the product is authorized or approved by Health Canada.

Example

✓ Acceptable Claim:
“DIN/DIN-HM/NPN XXXXXX”

✗ Unacceptable Claim:
”Has an DIN/DIN-HM/NPN 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 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

✓ Acceptable Claim:
“Reduces the risk of side-effect X from 1 in 100,000 to 1 in 200,000”

✗ Unacceptable Claim:
“Reduces the risk of side-effect X by 50%”

2.12 Health / Healthy / Healthful

Guideline
It is misleading to suggest that a product may restore, maintain or promote health, unless such claims are included in the TMA.

Application

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

Example

➢ Indication / Use:
For maintenance of good health

✓ Acceptable Claim:
“Brand X helps maintain good health”

✗ Unacceptable Claim:
“Brand X makes you healthy”

2.13 Implied / Indirect Claims

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

Application

- All elements of an advertisement will be considered when assessing conformity to the TMA, including, but not limited to: visuals, placement of text, context, graphics, special effects, music, and sounds.

Example
Analgesic

➢ Indications / Uses:
For fever reduction and pain relief

✓ Acceptable Claim:
“Product X relieves fever and pain”

✗ Unacceptable Claim:
”Product X relieves fever and pain (with a billboard in the background on which it would be written “You Need It” or a background music which would be saying “I Need You” because NonRx indications are for limited conditions that normally resolve on their own)”

2.14 Natural (See also: “2.18 Organic”)

Guideline
An advertisement must not mislead a consumer to believe that a product is “natural” or “natural source(d)” if it has undergone more than minimal processing or refinement.

Application

- **Natural:** A product can be described as "natural" if it is sold in its original state with a minimal processing or refinement, i.e. cut, dried or irradiated[9].

Example
Plant Root

✓ Acceptable Claim:
"Brand X Dried plant root is a Natural Health Product"

✗ Unacceptable Claim:
"Brand X Synthetic plant root contains the same plant root as found in nature"

- **Natural source(d):** A product can be described as "natural source" if it contains a medicinal ingredient obtained via extraction.
- Ingredients found in nature that are obtained by chemical synthesis or other means may not be referred to as "natural" or "natural source(d)" (the word synthetic is included on labels when the ingredients are synthetically manufactured).

Example
Brand Y tablets containing a processed plant root

✓ Acceptable Claim:
"Brand Y tablets are made with natural sourced plant root"

✗ Unacceptable Claim:
"Brand Y tablets are made with natural plant root"

2.15 Natural Action / Naturally

Guideline
It is misleading to claim that a product acts "naturally" since all NonRx drugs including NHPs modify the body's physiological processes.

Application

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

[9] Irradiation of some raw materials is part of Good Agricultural Practices. Declaration of irradiation is voluntary.

Example

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

✗ Unacceptable Claim:
"Product's X natural action works to…"

2.16 Need

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

Application

- It is not acceptable for an advertisement to claim that a consumer "needs" a specific product. However, it is acceptable to suggest that an individual "needs relief".

Example
Cough Syrup

✓ Acceptable Claim:
"Need relief of stubborn cough? Product X Cough Syrup may relieve it"

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

2.17 New / Improved

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

Application

- The nature of the improvement should be clearly communicated, e.g., "improved taste", "improved format".

Example

✓ Acceptable Claim:
"New Fast Dissolving Tablet"

✗ Unacceptable Claim:
"Improved" (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.

  (a) When the percent certified organic content expressed as a percentage[10] of total ingredients by mass or fluid volume, excluding water and salt, is 95% or more, the following claims and symbols are permitted:
  - Organic, and
  - All other terms above, and
  - Trademark of certification body

  (b) When the percent certified organic content is 70% or more, the following claims are permitted:
  - "Contains X% organic ingredients" or
  - "Contains X% certified organic ingredients" when the certified organic ingredients are listed; or
  - "Contains X% organic "Y"", when the actual (X) percentage of a specified ingredient "Y" constitutes 70% or more of the total ingredients.

  (c) When the percent certified organic content is less than 70%, the following claims are permitted:
  - Certified organic ingredients labelled as "organic" in the list of ingredients only.

[10] The method of calculating the percentage of organically produced ingredients can be found in *the Evidence for Quality of Finished NHPs Guidance Document*.

Example
Product X (containing 75% certified organic ingredient Y and 25% not certified organic ingredient).

✓ Acceptable Claim:
"Product X contains 75% organic Y".

✗ Unacceptable Claim:
"Product X is organic" (because product X does not contain 95% or more certified organic material).

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

Guideline
NonRx drugs: It is misleading to refer to nonprescription drugs as being "potent" or having a "potent" formulation.

NHPs: It is misleading to refer to NHPs as "potent", however claims for "potency" (as defined in the *NHP Regulations*) are permissible for NHPs when part of the PL.

DIN-HM: For homeopathic medicines, the term "potency" refers to the "quantity" as defined in the *NHP Regulations*.

Application
- All NonRx drugs are adequately medicated to be effective as per their authorized therapeutic indications. Therefore, the relief to be derived from a NonRx drug is an indicator of its effectiveness and not its "potency".

Example
NonRx Drug

✓ Acceptable Claim:
"Effective formulation"

✗ Unacceptable Claim:
"Potent Formulation"

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

Example
NHP: Plant extract
(Quantity: 1000mg, Potency: 5% hyperforin)

✓ Acceptable Claim:
"The potency of Brand X Plant extract is 5% hyperforin"

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

- The potency of homeopathic medicines is to be expressed by dilute factor expression as set out in *Evidence for Homeopathic Medicines Guidance Document*[11].

Example
DIN-HM

✓ Acceptable Claim:
"Potency:5CH"

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

Guideline
It is misleading to suggest that a particular product is more than sufficiently medicated to relieve/treat/prevent a particular condition or symptom.

It is misleading to suggest 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., are "sufficiently medicated") to be effective for the condition/symptoms they are designed to relieve/treat/prevent.
- It is thus appropriate to claim that a product is "sufficiently medicated", e.g., "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", "powerful" or "tough".

[11] The potency of homeopathic medicines is to be expressed by dilute 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

✓ Acceptable Claim:
"Has the power to relieve condition X"

✗ Unacceptable Claim:
" Your symptoms will disappear instantly with the ultra-strength formulation"

2.21 Risk Information Communication

Guideline
Consumers must be made aware of serious adverse drug reactions[12] associated with the use of the advertised product (either information already established or newly discovered information) in order to make informed decisions. Consequently, Health Canada has determined that in cases where an "Advisory/Warning" has been issued and posted on Health Canada's Website about a specific NonRx drug including a NHP, or medicinal ingredient, this information should be communicated to consumers in advertising, or, at a minimum, consumers should be directed to a source for such information.

Note: Consumer Advisories/Warnings for health products are posted on Health Canada's Website on an *ad hoc* basis to alert consumers of important new health and safety product information (http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advisories_e.html).

Application

- **Promotional material for such products should describe both the positive effects and the associated known serious adverse reactions so that the consumer can make an informed choice of medication.**
- If the advertised product, when used according to the directions has known serious adverse reactions[12] (in terms of severity and clinical importance) or is contraindicated for a known group of people because it could cause serious adverse reactions, an appropriate warning of those reactions must be given in the advertisement.
  - Such advertisements must contain the following statements (or words with the same meaning): "Always read the label" & "Use only as directed".
  - Where relevant to the product, i.e. if the indication is for symptomatic relief, or a similar indication, such advertisements must contain the following statement (or words with the same meaning): "If symptoms persist see your health care professional".

[12] ***Serious adverse drug reaction** as defined in the *Food and Drug Regulations* "means a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death"

Example
Ingredient X (which is contraindicated for patients with hypertension)

✓ Acceptable Claim:
"Product X contains Ingredient X which is contraindicated for patients with hypertension. Always read the label. Use only as directed. See your pharmacist for additional information about product use".

✗ Unacceptable Claim:
"Product X is suitable for adults over 18 years of age (when Product X contains Ingredient X which is contraindicated for patients with hypertension)."

2.22 Risk Reduction Claims

Guideline
Description: 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 if it is inconsistent with the Terms of Market Authorization and if it:
    - Is related to *Schedule A* (See *Schedule A and Section 3: Guidance Document* at: http://www.hc-sc.gc.ca/hpfb-dgpsa/sched_a_gui_doc_cp_e.html)
    - Requires a prescription drug
    - Is not appropriate for self diagnosis
    - Is one that requires monitoring by a health care provider.

Example

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

✗ Unacceptable Claim:
"Product X can be used to reduce the risk of bone cancer"

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

Guideline
Claims for "safe" and "side effect free" are unacceptable.

Application
- It is misleading to suggest that a product is "safe" or "side effect free" 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 prohibited.

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 by using fear-inducing copy or dramatic devices.

Application
- An advertisement must not:
  - Suggest that the health of a consumer will suffer, or that full health cannot be attained without using the advertised product.
  - Describe 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:
"Hand Germicidal Cleanser X kills germs"

✗ Unacceptable Claim:
"Germs are everywhere! Don't be at risk. Use Hand Germicidal Cleanser 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 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
Description: 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.

Application

- It is unacceptable to make a structure function claim if it is inconsistent with the Terms of Market Authorization and if it:
    - Is related to *Schedule A* (See *Schedule A and Section 3: Guidance Document* at: http://www.hc-sc.gc.ca/hpfb-dgpsa/sched_a_gui_doc_cp_e.html)
    - Requires a prescription drug
    - Is not appropriate for self diagnosis
    - Is one that requires monitoring by a health care provider.

Example

✓ Acceptable Claim:
"Helps build strong bones"

✗ Unacceptable Claim:
"Helps improve memory."

2.28 Superscripts / Footnotes or "Supers"

Guideline
Superscripts and footnotes (also known as "supers") must 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 must appear clear, legible and be understood by the consumer
- If a super is necessary for the ad to be considered acceptable, this super must stay on screen for a sufficient length of time to be read by the average person.

Example
Audio: Relief all work day

✓ Acceptable Claim:
Super: "Provides 8 hours of relief"

Audio: Relief all day long

✗ Unacceptable Claim:
Super: "Provides 8 hours of relief"

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

Guideline
It is misleading to use a testimonial or quotation to state or imply a benefit that exceeds a product's TMA.

Application

- No claim in advertising, regardless of the source may exceed those permissible in the product's TMA.

Example
Plant X

➢ Indication / Use:
Traditionally used to relieve sore throat due to colds

✓ Acceptable Claim:
"Plant X is a traditional medicine used to relieve sore throats due to colds. It worked for me!"

✗ Unacceptable Claim:
"I tried Plant X and I just couldn't believe the results. It was amazing! It's made my immune system stronger than ever. I can resist any infection since I started taking it. You'll be amazed too"

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:
"Guaranteed 100% natural source Plant X"

✗ Unacceptable Claim:
"Plant X has been proven to be 100% effective for everyone"

2.31 Therapeutic Claims

Guideline
Description: relate to the diagnosis, treatment, and mitigation or prevention of a disease, disorder, or abnormal physical state or its symptoms in humans.

Application

- It is unacceptable to make a therapeutic claim if it is inconsistent with the Terms of Market Authorization and if it:
    - Is related to *Schedule A* (See *Schedule A and Section 3: Guidance Document* at: http://www.hc-sc.gc.ca/hpfb-dgpsa/sched_a_gui_doc_cp_e.html)
    - Requires a prescription drug
    - Is not appropriate for self diagnosis
    - Is one that requires monitoring by a health care provider.

Example

✓ Acceptable Claim:
"Product X treats bruises"

✗ Unacceptable Claim:
"Product X treats diabetes"

2.32 Unique

Guideline
It is misleading to describe a product as unique if it does not provide a unique or exclusive therapeutic benefit/effect.

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

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 and that this term is part of the market authorization for the product.

Example
Unique Therapeutic

✓ Acceptable Claim:
"Our unique antiperspirant 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 unique antiperspirant provides long lasting protection" (unacceptable since most antiperspirants provide long lasting protection)

- 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).

2.33 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 which 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/hpfb-dgpsa/tpd-dpt/index_advisories_e.html*)*.

Example
N/A

Section B
Legislation, Regulations and Policies[13]

B.1. Definitions Under the *Food and Drugs Act*, the *Food and Drug Regulations* and *the Natural Health Products Regulations*[14]

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 in Schedule 2 or a

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[13] 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*.

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

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*
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 NHPs, 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.[15,16]

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)

A **Natural Product Number** is an eight (8) digit numerical code following the acronym NPN assigned by Health Canada to a particular NHP when it is authorized for sale.

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[15] 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 Product 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.

[16] 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).

TERMS OF MARKET AUTHORIZATION / AUTHORIZED PRODUCT INFORMATION

Drugs

For drugs that are subject to the requirements of *Division 8*, *Part C* of the *Regulations* (new drugs), the Terms of Market Authorization are comprised of all information in the Product Monograph (PM) that accompanies the Notice of Compliance (NOC) and in the document that assigns a DIN and related product labelling.

For drugs that are not subject to *Division 8*, *Part C* of the *Regulations*, the Terms of Market Authorization are identified in the document that assigns a DIN and related product labelling. This information is derived from the review of information on the drug product that is required to be submitted for regulatory review and authorization, as outlined in the *Food and Drugs Act and Regulations* and interpretive guidelines and policies.

It is important to note that during the course of a screening review of Category IV Monograph and Labelling Standard products, Health Canada does not conduct a complete label review. The Health Canada review is limited to the verification of the minimum requirements related to ingredients, concentrations, basic indications, directions and warnings as outlined in the appropriate Monograph. It is the manufacturer's responsibility to ensure that all non-therapeutic claims, variations and expansions of Monograph claims and all other additional claims are consistent with the Monograph, Labelling Standard and *Food and Drugs Act and Regulations*.

Natural Health Products

For NHPs, the Product Licence (PL) constitutes the TMA.

It is important to note that an NHP that is authorized by Compendial Monograph (CM) submission may only make those claims that appear on the CM the PL are referring to. Claims found in a PL, but not authorized by Health Canada for that particular product, must be authorized by Health Canada through the appropriate regulatory submission before they may be used in advertising.

Therapeutic Claim (*Evidence for Safety and Efficacy of Finished Natural Health Products Guidance Document*)

A claim which relates to the diagnosis, treatment, mitigation or prevention of a disease, disorder, or abnormal physical state or its symptoms in humans.

Transition Period[17]

As of January 1, 2004, the *Natural Health Products Regulations* (*Regulations*) came into force and apply to all NHPs.

[17] For additional information see the following NHPD documents on the NHPD Website: *Transition Guidance Document for Natural Health Products*, *The Compliance Approach for Natural Health Products*, *Compliance and Enforcement Policy (POL-0001)*.

There is a six-year transition period for product licensing, from January 1, 2004 to December 31, 2009, for natural health products with Drug Identification Numbers (DIN) issued under the *Food and Drug Regulations*. The applicable provisions of the *Food and Drug Regulations* continue to apply for products with a DIN until they are licensed under the *Natural Health Products Regulations* at which time they will receive a Product Licence (PL) and a Natural Product Number (NPN) or an Homeopathic Medicine Number (DIN-HM).

From January 1, 2004, all NHPs (i.e. products not previously authorized for sale) that fit the natural health products definition (see Overview of the *Natural Health Products Regulations Guidance Document*) must comply with the *Natural Health Products Regulations* immediately and must be subject to the full licence application process in order to be sold in Canada.

All natural health products must comply with all the *Regulations* by January 1, 2010.

Advertising claims will be assessed against the regulatory status in effect for the advertised product at the time of submission to the Health Canada endorsed preclearance agency. As described above, if a product still has a DIN, the claims contained in the DIN authorization are permissible in advertising. If a product has an NPN or a DIN-HM, the claims contained in the PL are permissible in advertising. Products that meet the definition of a NHP, but have neither a DIN nor an NPN or a DIN-HM must obtain a PL before any advertising for that product can be approved by the Health Canada endorsed clearance agency.

B.2. Legislation, Codes and Policies that Apply to Marketed Health Product Advertising

Legislation	NHPs	NonRx Drugs
***Food and Drugs Act* – Umbrella Requirement**		
Sections 3(1), 3(2), 3(3) – Schedule A	*	*
Section 9(1) – Deception	*	*
Section 14 – Sampling	*	*
Food and Drug Regulations		
C.01.007 – Reference to the *Act & Regulations*		*
C.01.012 – Site, rate or extent of release to the body of a medicinal ingredient or the availability to the body of a medicinal ingredient	*[18]	*
C.01.015(2)(f) – Advertising of Tablet Disintegration Times	*[19]	*
C.01.027 – Limit Dose Drugs		*
C.01.044 – Advertising of *Schedule F* drugs to general public		*
C.01.625 – Contraceptive Drugs		*
C.08.002(1) – New Drugs		*
G.01.007 – Controlled Drugs		*
Natural Health Products Regulations		
Section 2(2) – Products required to be sold pursuant to a prescription are not natural health products	*	
Section 92 – Reference to the *Act & NHP Regulations*	*	
Section 103 – Advertising of Tablet Disintegration Times	*	
Narcotic Control Regulations		
Section 70 – Advertising to general public prohibited		*
Codes	**NHPs**	**NonRx Drugs**
Canadian Association of Broadcasters, Broadcast Code For Advertising to Children		
Clause 4(b) – Product Prohibitions	*	*
Policies	**NHPs**	**NonRx Drugs**
See page 43 below for a list of applicable Policies	*	*

The full text of sections *C.01.012, C.01.015(2)(f), C.01.044*, and *C.01.0625* can be found in Appendix D.

[18] *Section C.01.012* of the *Food and Drugs Regulations* are incorporated into the *Natural Health Products Regulations* by reference in *NHP Regulations section 98*

[19] *Section C.01.015(2)(d)* to *(f)* of the *Food and Drugs Regulations* are incorporated into the *Natural Health Products Regulations* by reference *in NHP Regulations section 103*

Food and Drugs Act – Umbrella Requirement

The *Food and Drugs Act* applies to both NHPs and NonRx drugs.

Section 3 of the *Food and Drugs Act - Schedule A*

3(1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A[20].

(2) No person shall sell any food, drug, cosmetic or device
that is represented by label, or
that the person advertises to the general public
as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.

(3) Except as authorized by regulation, no person shall advertise to the general public any contraceptive device or any drug manufactured, sold or represented for use in the prevention of conception.

Section 9(1) of the *Food and Drugs Act* - Deception

9(1) 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.

Section 14 of the *Food and Drugs Act* - Sampling

No person shall distribute or cause to be distributed any drug as a sample.

Food and Drug Regulations

Section C.01.007 - Reference to the *Act & Regulations*

No reference, direct or indirect, to the Act or to these regulations shall be made upon any label of or in any advertisement for a drug unless such reference is a specific requirement of the Act or these regulations

Section C.01.027 - Limit Dose Drugs

(1) Where a person advertises to the general public a drug for human use, the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity of the drug if it

- *a) contains a drug set out in the table to section C.01.021*[21]*; and*
- *b) carries on its label*
  - *i. a statement of the recommended single or daily adult dosage that results in a single or daily adult dosage of the drug referred to in paragraph (a) in excess of the maximum dosage set out in the table to section C.01.021 for that drug, or*
  - *ii. a statement that shows a concentration of the drug referred to in paragraph (a) in excess of the maximum limit set out in the table to section C.01.021 for that drug.*

[20] See Appendix A for *Schedule A* to the *Food and Drugs Act*
[21] See Appendix D for *C.01.021*

(2) Subsection (1) does not apply to products containing

a) acetaminophen
b) acetylsalicylic acid;
c) choline salicylate;
d) magnesium salicylate; or
e) sodium salicylate.

(3) Where a person advertises to the general public a drug for human use that contains acetylsalicylic acid, the person shall not make any representation with respect to its administration to or use by children or teenagers.

***Section C.08.002(1)* - New drugs**

No person shall advertise a new drug unless

a) the manufacturer of the new drug has filed with the Minister a new drug submission or an abbreviated new drug submission relating to the new drug that is satisfactory to the Minister;

b) the Minister has issued, pursuant to section C.08.004[22], a notice of compliance to the manufacturer of the new drug in respect of the new drug submission or abbreviated new drug submission;

c) the notice of compliance in respect of the submission has not been suspended pursuant to section C.08.006[23]; and

d) the manufacturer of the new drug has submitted to the Minister specimens of the final version of any labels, including package inserts, product brochures and file cards, intended for use in connection with that new drug, and a statement setting out the proposed date on which those labels will first be used.

***G.01.007* – Controlled Drugs**

No person shall

(a) advertise a controlled drug to the general public

Natural Health Products Regulations

***Section 2(2)* – Product is not an NHP if prescription is required**

For the purposes of these Regulations, a substance or combination of substances or a traditional medicine is not considered to be a natural health product if its sale, under the Food and Drug Regulations, is required to be pursuant to a prescription when it is sold other than in accordance with section C.01.043[24] of those Regulations.

Accordingly, with the exception of homeopathic medicines, products with ingredients required to be sold pursuant to a prescription are not natural health products, they are prescription drugs.

[22] See Appendix D for *C.08.004*
[23] See Appendix D for *C.08.006*
[24] See Appendix D for *C.01.043*

Section 92 - Reference to the *Act & Regulations*

No reference, direct or indirect, to the Act, the Food and Drug Regulations or to these Regulations shall be made on any label of or in any advertisement for a NHP unless the reference is specifically required by law.

Section 103 - Tablet Disintegration Times

Subsection C.01.015(1)[25] *and paragraphs C.01.015(2)(d) to (f) of the Food and Drug Regulations apply in respect of natural health products.*

Narcotic Control Regulations

Section 70

No person shall

(c) publish or cause to be published or furnish any advertisement to the general public respecting a narcotic;

Other Applicable Code

Canadian Association of Broadcasters (CAB) Broadcast Code for Advertising to Children

The Canadian Association of Broadcaster's Code states:

> All Children's advertising must conform to the Code, be pre-cleared in accordance with the procedures set out from time to time by the ASC and have the requisite ASC clearance number.

The Code defines **"Children's Advertising"** as:

> Any paid commercial message that is carried in or immediately adjacent to a children's program. Children's advertising also includes any commercial message that is determined by the broadcaster as being directed to children and is carried in or immediately adjacent to any other program.

Product Prohibitions - Clause 4(b)

Children's advertising is prohibited for:

> Drugs, proprietary medicines and vitamins in any pharmaceutical form, with the exception of children's fluoride toothpastes.

[25] See Appendix D for *C.01.015(1)*

Health Canada Advertising Policies

Numerous Health Canada policies and guidelines apply to the advertising of marketed health products. They may be found on the Health Canada website at http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advertising_e.html and are listed below.

Currently all Health Canada policies apply to nonprescription drugs including natural health products, without distinction. In the future, after careful examination of the current policies, the Natural Health Products Directorate may determine that specific NHP policies are required.

Health Canada Advertising Policies on the Health Canada Website at http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advertising_e.html:

- *Therapeutic Comparative Advertising: Directive and Guidance Document*
- *ASC and Health Canada Roles and Consultation Related to Advertising Review*
- *Principles for Claims Relating to Comparison of Non-Therapeutic Aspects of Nonprescription Drug Products*
- *The Distinction Between Advertising and Other Activities*
- *Fact Sheet - Overview of Drug Advertising*
- *Absence of Ingredient Statements* (http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/absence_e.html)
- *Schedule A and Section 3: Guidance Document* (http://www.hc-sc.gc.ca/hpfb-dgpsa/sched_a_gui_doc_cp_e.html)

B.3. Appendix Material

Appendix A - *Schedule A* to the *Food and Drugs Act*

Schedule A to the *Food and Drugs Act* includes a number of diseases, disorders or abnormal physical states. *Section 3* of the *Act* prohibits the advertising to the general public of any food, drug, cosmetic or device for the treatment, prevention or cure of any of the diseases listed on *Schedule A*. The section also prohibits the sale of a food, drug, cosmetic or device that is labelled in this manner.

The basis of this prohibition against claims relating to diseases listed in *Schedule A* is *Section 3* of the *Act* which states:

> *3. (1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A*
>
> *(2) No person shall sell any food, drug, cosmetic or device*
>
> *a) that is represented by label, or*
>
> *b) that the person advertises to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.*
>
> *(3) Except as authorized by regulation, no person shall advertise to the general public any contraceptive device or any drug manufactured, sold or represented for use in the prevention of conception.*

Section 3 and *Schedule A* to the *Food and Drugs Act* were originally meant to:

a. prevent fraud;
b. prohibit advertisements to the public respecting treatments for conditions where no treatments existed;
c. prohibit the advertisement of treatments where self treatment was not considered safe; and
d. encourage people to seek medical attention for serious conditions.

Alcoholism	Impetigo
Alopecia (except hereditary androgenetic alopecia)	Hypotension
Anxiety state	Kidney disease
Appendicitis	Leukemia
Arteriosclerosis	Liver disease (except hepatitis)
Arthritis	Nausea and vomiting of pregnancy
Asthma	Obesity
Bladder disease	Pleurisy
Cancer	Rheumatic fever
Convulsions	Septicemia
Depression	Sexual impotence
Diabetes	Thrombotic and Embolic disorders
Disease of the prostate	Thyroid disease
Disorder of menstrual flow	Tumor
Dysentery	Ulcer of the gastro-intestinal tract
Edematous state	Venereal disease
Epilepsy	Venereal disease
Gall bladder disease	

Gangrene	
Glaucoma	
Gout	
Heart disease	
Hernia	
Hypertension	

Schedule A and Section 3: Guidance Document available at: http://www.hc-sc.gc.ca/hpfb-dgpsa/sched_a_gui_doc_cp_e.html.

Appendix B – *Appendix 2* of *Product Licensing Guidance Document* (NHP)

When changes are required to information relating to *licensed natural health products*, licensees must make Natural Health Products Directorate aware of these changes. Some changes, which do not affect the safety and efficacy of the product, only require the licensee to notify NHPD within 30 days of making the change. [*Natural Health Products Regulations: section 12*] These types of changes include changes to licensee contact information or approved brand names (see *Appendix 2*).

Other changes are those that may affect the safety and efficacy of the product, and as such must be evaluated by NHPD before the change is implemented. [*Natural Health Products Regulations: section 11*] These types of changes include changes to the recommended dose or recommended use or purpose (see *Appendix 2*). When NHPD consider the changes to be acceptable, NHPD will issue an amended licence (the product number remains the same).

Some changes to a product are so fundamental that they require a complete new product licence application. In this case, NHPD issues a new product licence and product licence number. [*Natural Health Products Regulations: section 13*] These types of changes include changes to the dosage form, or addition of a medicinal ingredient (see *Appendix 2*).

Licensees must provide NHPD with information relating to the sites where it manufactures, packages, labels and, when applicable, imports the natural health product.

The licensee must maintain records of the ingredients contained in each lot or batch of the natural health product, and sufficient information to enable a recall of each lot or batch. [*Natural Health Products Regulations: section 23*]

Appendix 2: Regulatory Requirements Resulting from changes to Products

Type of Change	Regulatory Requirement
Recommended dose	
Change to amount of dosage unit	Amendment
Change to frequency	Amendment
Change to sub-population group	Amendment
Change to directions of use appearing on the label	Notification
Recommended duration of use	
Lengthening the recommended duration of use	Amendment
Shortening the recommended duration of use	Amendment
Risk information shown on any label	
Deletion of risk information	Amendment
Addition of risk information	Notification
Modification of risk information	Amendment
Recommended use or purpose	
Modification to the recommended use or purpose	Amendment
Deletion of part of the recommended use or purpose	Amendment
Addition to the recommended use or purpose New claim made using the exact same remaining conditions of use	Amendment Amendment
Source material of any medicinal ingredients	
Change to the part or tissue used	Amendment

Change to the source material from a monograph source to a source not listed on a monograph	Amendment
Change of source within a monograph	Amendment
Change from a source not listed on a monograph to a source listed on a monograph	Amendment
Change of source material to an animal-derived source	Amendment
Change to information submitted on the Animal Tissue Form	Amendment
Change to the salt or derivative used	Amendment
Change to the strain used	Amendment
Changing any of medicinal ingredients to or from being synthetically manufactured	
Change from being synthetically manufactured to a natural ingredient	Amendment
Change from a natural source to a synthetically source	Amendment
Potency of any medicinal ingredients	
Addition of a potency	Amendment
Deletion of a potency	Amendment
Change in the potency	Amendment
Change affecting safety and efficacy (other than those listed in paragraph 11(h))	
Change in manufacturing information	Amendment
Change to the quantity of a medicinal ingredient per dosage form	
Decrease in quantity	New licence
Increase in quantity	New licence
Addition or substitution of a medicinal ingredient	
Adding a medicinal ingredient	New licence
Removing a medicinal ingredient	New licence
Substituting a medicinal ingredient for one not already found in the product	New licence
Dosage form	
Changing from a discrete to a non-discrete dosage form	New licence
Changing from a non-discrete to a discrete dosage form	New licence
Changing discrete dosage forms	New licence
Recommended route of administration	
Any change in route of administration	New licence
Removal of a test method set out in the specifications	
Any removal of test methods in the specification	Amendment
Modification of a test method set out in the specifications	
Any modification to test methods in the specification	Amendment
Change to information submitted under paragraphs 5(a) and (b)	
Change in the name of the product licence holder or applicant	Notification
Change in ownership of the product licence	Notification
Mergers between companies	Notification
Change of senior official	Notification
Change of title, phone number, fax number, e-mail address or mailing address of senior official	Notification
Change of contact person for the application	Notification
Change of title, phone number, fax number, e-mail address or mailing address of the contact person for application	Notification
Change of company name for Regulatory Affairs Information in Canada	Notification
Change to contact information for Regulatory Affairs Information in Canada	Notification

Information provided under *section 22*	
Addition of a manufacturer, packager, labeller, importer or distributor	Notification
Removal of a manufacturer, packager, labeller, importer or distributor	No need to communicate with the Natural Health Products Directorate

Addition or substitution of a non-medicinal ingredient	
Changing from an ingredient on the "acceptable" list to one not on that list	Amendment
Changing to a different ingredient on the "acceptable" list	Notification
Change in nominal concentration for an ingredient on the acceptable list	Nothing required as long as the restrictions are still being adhered to
Change in nominal concentration for an ingredient not on the acceptable list	Notification
Sale under a brand name other than one submitted under paragraph 5(e)	
Adding a brand name to those already authorized	Notification
Removing a brand name under which the product is sold	Notification
Common name or proper name of any medicinal ingredients	
Change in proper name following scientific revisions	Notification
Change in proper name following more precise identification techniques (i.e. the species is the same, but was improperly identified previously)	Notification
Change to the common name of a medicinal ingredient, when the species remains the same	Notification
Change in proper name that results from changing species, genus, chemical name or vitamin name but not from a change listed above	New licence

Appendix C – Excerpts from the Health Canada Policy *Changes to Marketed New Drug Products*

When changes are required to information relating to *marketed new drug products*, manufacturers must make Health Canada aware of these changes. Changes to marketed drug products have been grouped into 4 categories (Level 1, 2, 3 and 4) based on the significance of the change and therefore the potential impact on safety and efficacy.

Level 1 – Supplemental New Drug Submission

Level 1 changes are those for which a supplemental new drug submission must be filed pursuant to *C.08.003*. A Notice of Compliance is required before proceeding with such a change.

Level 1 changes are those made:

1. in the identifying name of the drug product or the brand name;
2. in the dosage form or strength of the drug product;
3. in the formulation, method of manufacture, equipment, or process control of the drug product that requires supporting clinical or bioequivalence data;
4. in the case of *Schedule C* and *D* drugs, in the production site, method of manufacture, equipment and process control of the drug substance or in the formulation, method of manufacture, equipment, process control or production site of the drug product;
5. in the labelling including package inserts, product brochures, file cards, and product monographs of the drug product respecting, either explicitly or implicitly:
    i) the recommended route of administration of the drug product,
    ii) the dosage of the drug product, and
    iii) the claims, including indications, made for the drug product;
6. for sterile drug products, in the specifications to remove the sterility test and replace it with process parametric release.

Level 2 – Notifiable Change (Notice of Intention to Change)

Level 2 changes are those considered to be notifiable. Changes identified in Level 2 require the preparation and filing of the same level and detail of information and scientific justification as is currently required in a supplemental new drug submission. This information and material must be filed prior to the institution of the change. Unless a written objection is received from the Branch within 90 days, the manufacturer may proceed with the change.

Level 2 changes are those made:

1. subject to Level 1 (4), in the production site or method of manufacture of the drug substance;
2. subject to Level 1 (6) and Level 3 (3) & (4), in the specifications of the drug product or the drug substance or the non-medicinal ingredients in the drug product. Provided the conditions of the notice of compliance are not affected, this does not apply to changes in specifications that are required to comply with a standard contained in any publication referred to in *Schedule B* to the *Act*;

3. subject to Level 1 (3) & (4), in the formulation, method of manufacture, equipment, process control, or production site of the drug product;
4. subject to Level 3 (1), in the specifications or composition of packaging materials which are either in direct contact with the drug product or help to ensure the stability, sterility or delivery of the drug product;
5. subject to Level 1 (5), in the location of text in the labelling or an addition to the labelling, including package inserts, product brochures, file cards and product monographs, respecting;

i) overdose symptoms, treatment and related toxicological information,
ii) side effects, contra-indications, warnings and precautions, where no direct or indirect new claim is made, and
iii) references cited;

6. subject to Level 3 (5), in the conditions of storage and expiration period of the drug product;
7. in the case of parenteral drug products, in the container size of the product.

Level 3 – Notice of Change

Level 3 changes are those for which a written notice of change is required. Although supporting data should not be submitted, the data must be available on the manufacturer's premises. The manufacturer may proceed immediately to make the change, but should submit a compilation of all level 3 changes for each of their products in one annual update to be filed with the annual (DIN) notification.

Level 3 changes are those made:

1. with respect to solid drug products, in the specifications of packaging materials which are either in direct contact with the drug product or help to ensure the stability, sterility or delivery of the drug product;
2. with the exception of parenteral drug products, in the container size of the product which do not affect conformity with the conditions of the notice of compliance;
3. in analytical methods that maintain or increase precision, accuracy, specificity and sensitivity;
4. in the specifications which add a test or tighten existing limits or test criteria;
5. subject to the Policy on Extension of Expiration Dates (Dec. 24, 1991), in the expiration period of the drug product when the original expiration period is 2 years or more.

Level 4

Changes not listed in Levels 1-3 may be made without notification. Manufacturers are expected to maintain a list of level 4 changes.

Appendix D – Excerpts from the *Food and Drug Regulations*

C.01.012

A manufacturer who makes representations on the label of a drug in oral dosage form, or in any advertisement, with respect to the site, rate or extent of release to the body of a medicinal ingredient of the drug, or the availability to the body of a medicinal ingredient of the drug shall,
(a) before making the representations, conduct such investigations, using an acceptable method, as may be necessary to demonstrate that the site, rate or extent of release to the body of the medicinal ingredient of the drug and the availability to the body of the medicinal ingredient of the drug, correspond to the representations; and
(b) on request submit the record of such investigations to the Director

C.01.014.4

If the information referred to in subsection C.01.014.1(2) in respect of a drug is no longer correct owing to a change in the subject matter of the information,
(a) in the case of a change in the subject matter of any of the information referred to in paragraphs C.01.014.1(2)(a) to (f)
(i) that occurs prior to the sale of the drug, a new application shall be made, or
(ii) that occurs after the sale of the drug, no further sale of the drug shall be made until a new application for a drug identification number in respect of that drug is made and a number is assigned; and
(b) in the case of a change in the subject matter of any of the information referred to in paragraphs C.01.014.1(2)(g) to (k)
(i) that occurs prior to the sale of the drug, the particulars of the change shall be submitted with the return of the document referred to in section C.01.014.3, or
(ii) that occurs after the sale of the drug, the person to whom the drug identification number in respect of that drug was issued shall, within 30 days of the change, inform the Director of the change.

C.01.015(1)

Subject to subsection (2), no person shall sell for human use a drug in the form of a tablet that is intended to be swallowed whole unless, when tested by the official method DO-25, Determination of the Disintegration Time of Tablets, dated July 5, 1989,
(a) in the case of an uncoated tablet, the tablet disintegrates in not more than 45 minutes;
(b) in the case of a plain coated tablet, the tablet disintegrates in not more than 60 minutes; and
(c) in the case where the label of the drug indicates that the tablet carries an enteric coating or a coating designed to serve a purpose similar to that of an enteric coating, the tablet does not disintegrate when exposed for 60 minutes to simulated gastric fluid, but when it is subsequently exposed for a continuous period to simulated intestinal fluid, the tablet disintegrates in not more than 60 minutes.
(2) Subsection (1) does not apply in respect of a drug in the form of a tablet where
(a) a notice of compliance in respect of the drug in the form of a tablet has been issued pursuant to section C.08.004;
(b) [Repealed, SOR/98-423, s. 7]
(c) a dissolution or disintegration test for the drug in the form of a tablet is prescribed in Division 6 of this Part;
(d) the drug is labelled as complying with a standard contained in a publication referred to in Schedule B to the Act;
(e) the drug has been demonstrated by an acceptable method to be available to the body; or
(f) representations regarding the drug are made on its label, or in any advertisement, with respect to the site, rate or extent of release to the body of a medicinal ingredient of that drug, or the availability to the body of a medicinal ingredient of that drug.

C.01.015(2)(f)

Subsection (1)[26] does not apply in respect of a drug in the form of a tablet where
(f) representations regarding the drug are made on its label, or in any advertisement, with respect to the site, rate or extent of release to the body of a medicinal ingredient of that drug, or the availability to the body of a medicinal ingredient of that drug.

C.01.021

Except as provided in these Regulations, no person shall sell a drug for human use listed in the following table unless both the inner and outer labels other than the inner label of a single dose container carry a statement of

(a) the quantitative content of the drug, and
(b) the recommended single and daily adult dose designated as such, except for
  (i) preparations solely for external use, or
  (ii) preparations solely for children's use, and
(c) adequate directions for use when the drug is recommended for children which shall be either
  (i) the statement, "CHILDREN: As directed by a physician", or
  (ii) a suitably reduced maximum single and daily dose which shall not exceed the following:

Age in Years	***Proportion of adult dose***
10-14	*one-half*
5-9	*one-fourth*
2-4	*one-sixth*
under 2 years	*as directed by physician.*

[26] See Appendix D for *C.01.015(1)*

Table of limits of drug dosage for adults

Item	External Use -- Maximum Limit	Internal Use – Maximum Dosage Unless otherwise stated, doses are in milligrams		
		Percent	Single	Daily
Acetaminophen		--	650	4.0 g
Acetanilide and derivatives (except N-Acetyl-p-amino phenol)		--	65	195
Acetylsalicylic Acid		--	650	4.0 g
Aconitine, its preparations and derivatives		0.2	0.1	0.1
Adonis vernalis		--	65	195
Amylocaine, its salts and derivatives when sold or recommended for opthalmic use		0.0	0.0	0.0
Amylocaine Hydrochloride, except when sold or recommended for ophthalmic use		1.0	0.0	0.0
Antimony, compounds of		--	3.3	13
Atropine, Methylatropine, and their salts		1.0	0.13	0.44
Belladonna and its preparations, on the basis of belladonna alkaloids		0.375	0.13	0.44
Benzene (Benzol)		--	--	--
Benzocaine		8.0	195	585
Beta-Naphthol		--	195	585
Butacaine, its salts and derivatives when sold or recommended for ophthalmic use		0.0	0.0	0.0
Butacaine Sulphate, except when sold or recommended for opthalmic use		1.0	0.0	0.0
Cadexomer Iodine		0.0	0.0	0.0
Cantharides, cantharidin, and their preparations, on the basis of cantharidin, except blisters		0.03	0.0	0.0
Cantharides, blisters only		0.2	0.0	0.0
Cedar Oil		25.0	0.0	0.0
Chlorbutol (not more often than every 4 hours)		--	325	975
Choline Salicylate		--	870	5.22 g
Cinchocaine Hydrochloride, except suppositories		1.0	0.0	0.0
Cinchocaine Hydrochloride, suppositories only		--	11	11
Colchicine and its salts		--	0.55	1.65
Colchicum and its preparations, on the basis of colchicine		--	0.27	0.81
Croton Oil		10.0	0.0	0.0
Cyproheptadine and its salts—when sold or recommended for the promotion of weight gain		--	0.0	0.0
Ephedrine and its salts		--	11	32.5
Ephedrine and its salts, sprays		1.0	--	--
Epinephrine and its salts, sprays		1.0	--	--
Gelseminine (Gelsemine) and its salts (not to be repeated within 4 hours)		--	0.55	1.65
Gelsemium and its preparations, on the basis of the crude drug		--	16.2	48.6
Hydrocyanic (Prussic) Acid as 2 per cent solution		--	0.062 ml	0.31 ml
Hydroquinone		2.0	--	--
Hyoscine (Scopolamine) and its salts		0.5	0.325	0.975
Hyoscine aminoxide hydrobromide		0.5	0.325	0.975
Hyoscyamine and its salts		--	0.325	0.975
Hyoscyamus and its preparations, on the basis of hyoscyamus alkaloids		--	0.073	0.22
Lobelia and its preparations, on the basis of the crude drug		--	130	390
Lobeline and its salts		--	2.0	6.0
Magnesium Salicylate		--	650	4.0 g
Methyl Salicylate		30	--	--
Methylene Blue		--	130	390
Phenacetin		--	650	1.95 g
Phenazone and compounds thereof		--	325	975
Phenol		2.0	32.5	260
Phenylpropanolamine when sold or recommended as an appetite depressent		--	0.0	0.0
Phosphorus		--	0.0	0.0
Podophyllin		0.0	0.0	0.0

Potassium Chlorate	--	325	975
Potassium Chlorate, gargle	2.5	--	--
Procaine and its salts	--	--	--
Proxymetacaine, its salts and derivatives when sold or recommended for ophthalmic use	0.0	0.0	0.0
Salicylamide	--	975	2.925 g
Santonin	--	65	130
Selenium and its compounds	2.5	0.0	0.0
Sodium Chlorate	--	325	975
Sodium Fluoride	--	0.1	0.1
Sodium Salicylate	--	650	4.0 g
Squill and its preparations, on the basis of crude drug	--	32.5	97.5
Stramonium and its preparations, on the basis of stramonium alkaloids	--	0.16	0.65
Strychnine and its salts	--	0.0	0.0
Tannic Acid	--	150	1 000
Tetracaine, its salts and derivatives when sold or recommended for ophthalmic use	0.0	0.0	0.0
Thiocyanates	0.0	0.0	0.0
Urethane	0.0	0.0	0.0

Where drugs having similar physiological actions occur in combination, the dosage of each shall be proportionately reduced. Accurate dosages may be expressed in either metric units or imperial units. If the dosage is expressed in both systems, then an approximation may be used for one expression, but such approximation must precede or follow the accurate statement by which the product will be judged and must be in brackets.

C.01.043

(1) A person may sell a Schedule F Drug, without having received a prescription therefor, to
(a) a drug manufacturer;
(b) a practitioner;
(c) a wholesale druggist;
(d) a registered pharmacist;
(e) a hospital certified by the Department of National Health and Welfare;
(f) a Department of the Government of Canada or of a province, upon receipt of a written order signed by the Minister thereof or his duly authorized representative; or
(g) any person, upon receipt of a written order signed by the Director.
(2) Where a person makes a sale authorized by paragraph (1)(f) or (1)(g), he shall retain the written order for the drug for a period of at least two years from the date of filling the order.

C.01.044

(1) Where a person advertises to the general public a Schedule F Drug, the person shall not make any representation other than with respect to the brand name, proper name, common name, price and quantity

C.01.625

Contraceptive drugs that are manufactured, sold or represented for use in the prevention of conception and that are not listed in Schedule F may be advertised to the general public.

C.08.004.1

(1) Where a manufacturer files a new drug submission, an abbreviated new drug submission, a supplement to a new drug submission or a supplement to an abbreviated new drug submission for the purpose of establishing the safety and effectiveness of the new drug for which the submission or supplement is filed, and the Minister examines any information or material filed with the Minister, in a new drug submission, by the innovator of a drug that contains a chemical or biological substance not previously approved for sale in Canada as a drug, and the Minister, in support of the manufacturer's submission or supplement, relies on data contained in the

information or material filed by the innovator, the Minister shall not issue a notice of compliance in respect of that submission or supplement earlier than five years after the date of issuance to the innovator of the notice of compliance or approval to market that drug, as the case may be, issued on the basis of the information or material filed by the innovator for that drug.
(2) Subsection (1) does not apply where the manufacturer of a new drug for which a notice of compliance was issued pursuant to section C.08.004 gives written permission to another manufacturer to rely on the test or other data filed in respect of that new drug.
(3) Subsection (1) does not apply where the data relied upon by the Minister was contained in information or material filed by the innovator before January 1, 1994.

C.08.006

(1) For the purposes of this section, evidence or new information obtained by the Minister includes any information or material filed by any person pursuant to Division 5 or Section C.08.002, C.08.002.1, C.08.003, C.08.005 or C.08.005.1.

(2) The Minister may, by notice to a manufacturer, suspend, for a definite or indefinite period a notice of compliance issued to that manufacturer in respect of a new drug submission or an abbreviated new drug submission or a supplement to either submission, in the Minister considers

(a) that the drug is not safe for the use represented in the submission or supplement, as shown by evidence obtained from

(i) clinical or other experience not reported in the submission or supplement or not available to the Minister at the time the notice of compliance was issued, or

(ii) tests by new methods or tests by methods not reasonably applicable at the time the notice of compliance was issued;

(b) that, upon the basis of new information obtained after the issuance of the notice of compliance, there is lack of substantial evidence that the drug will have the effect it is represented to have under the conditions of use prescribed, recommended or proposed by the manufacturer;

(c) that the submission or supplement contained an untrue statement of material fact;

(d) that the manufacturer has failed to establish a system for maintaining required records or has repeatedly or deliberately failed to maintain such records;

(e) that, on the basis of new information obtained after the issuance of the notice of compliance, the methods, equipment, plant and controls used in the manufacturing, processing and packaging of the drug are inadequate to assure and preserve the identity, strength, quality or purity of the new drug; or

(f) that, on the basis of new information obtained after the issuance of the notice of compliance, the labelling of the drug is false or misleading or incomplete in any particular and that this defect was not corrected by the manufacturer upon receipt of a written notice from the Director specifying the respect in which the labelling is false or misleading or incomplete.

Appendix E – Advertising of Medical Devices

Since the repeal of the *Broadcasting Act*, there is no requirement for preclearance of advertising copy for medical devices. However, manufacturers and advertisers are reminded that devices are subject to the provisions of the *Food and Drugs Act* and the *Medical Devices Regulations*, as they pertain to advertising.

If the Application information submitted by the manufacturer complies with the regulatory requirements for that device, Health Canada issues a Medical Device Licence to the device manufacturer, which authorizes the sale of that device for the indications for use which are outlined in the licence application.

For advertising purposes, manufacturers are expected to comply with the requirements of *Section 27* of the *Medical Devices Regulations*. Additionally, the requirements of *Part I, Sections 3. (1)(2)(3); 20.(1)(2); 21*., of the *Food and Drugs Act* apply.

Any labelling or advertising claims which exceed or embellish the market authorization are not permitted. Advertising of products for conditions listed in *Schedule A* of the *Food and Drugs Act* is not permitted. Complaints related to false or misleading advertising are addressed by the Health Products and Foods Branch Inspectorate.

Regulatory Requirements for Medical Device Advertising

Requirements under the *Medical Devices Regulations*

Under *Part 1*, *section 27* restricts the advertising of class II, III and IV devices to those devices which have licences. However, there is a provision for advertising of unlicensed devices in catalogues if a suitable disclaimer is present. The advertising of devices for investigational testing is restricted under *section 87* which requires that the device have authorization and the advertisement indicates the device is the subject of investigational testing along with the purpose of the testing.

There are also special requirements for the advertising of contraceptive devices under *section 24*. This section interprets how the requirements of *section 3(1)* and *(2)* of the *Act* apply to these devices.

Requirements under the *Food and Drugs Act*

Section 3 (1) places restrictions on the advertisement of devices to the general public for conditions listed in *Schedule A*. *Section 3(3)* restricts the advertising of contraceptive devices to those permitted under the *Regulations* (see *section 24* of the *MDR*). Advertisements targeted to healthcare professionals are not subject to these restrictions.

Section 20 regulates misleading or false advertising. Class II, III and IV devices are licensed for particular indications and conditions. The advertising of licensed devices for indications or conditions which are not specified on the licence application upon which the licence was issued can be considered misleading. In cases where the manufacturer does not have any evidence of effectiveness for the indications, the advertising may even be considered false. Note this can also apply to class 1 devices since they also require evidence of effectiveness under *section 12* of the *MDR*.

The advertising of the **use** of devices by clinics or other facilities does not fall under the scope of the *Act* or *Regulations*.

Compliance Assessment

The compliance of importers, distributors and some manufacturers is assessed through the inspection programme conducted by the Inspectorate. In addition, the Inspectorate will investigate, on a risk management basis, complaints of alleged violations. Information on how to register a complaint can be found on the Health Products and Food Branch Inspectorate Website at http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/index_e.html.

References

Chapter F-27 *Food and Drugs Act*

"**device**" means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, 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 human beings or animals,

(b) restoring, correcting or modifying a body function or the body structure of human beings or animals,

(c) the diagnosis of pregnancy in human beings or animals, or

(d) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring,

and includes a contraceptive device but does not include a drug;

Part I - Foods, Drugs, Cosmetics and Devices

General

3. *(1) No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.*

(2) No person shall sell any food, drug, cosmetic or device
(a) that is represented by label, or
(b) that the person advertises to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A.

(3) Except as authorized by regulation, no person shall advertise to the general public any contraceptive device or any drug manufactured, sold or represented for use in the prevention of conception.
R.S., 1985, c. F-27, s. 3; 1993, c. 34, s. 72(F).

Devices

19. No person shall sell any device that, when used according to directions or under such conditions as are customary or usual, may cause injury to the health of the purchaser or user thereof.
R.S., c. F-27, s. 19.

20. (1) No person shall label, package, treat, process, sell or advertise any device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its design, construction, performance, intended use, quantity, character, value, composition, merit or safety.

(2) A device that is not labelled or packaged as required by, or is labelled or packaged contrary to, the regulations shall be deemed to be labelled or packaged contrary to subsection (1).
R.S., c. F-27, s. 20; 1976-77, c. 28, s. 16.

21. Where a standard has been prescribed for a device, no person shall label, package, sell or advertise any article in such a manner that it is likely to be mistaken for that device, unless the article complies with the prescribed standard.
R.S., c. F-27, s. 21