



Health
Canada

Health Products
and Food Branch

Santé
Canada

Direction générale des produits
de santé et des aliments

October 18, 2006

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

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

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

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

Canada 

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

- The change related to Health Canada moving towards an attestation preclearance system for the consumer advertising preclearance of nonprescription drugs and natural health products, as announced on August 9, 2006, is reflected throughout the Guidelines. Once the attestation criteria will be finalized, Health Canada will update its advertising fact sheet and policies outlining the role of advertising preclearance agencies and Health Canada's role related to advertising review and complaints adjudication.
- In Section 1.1, Authorization – Terms of Market Authorization: The footnote clarifies that the Product Licence is considered to be equivalent to the terms of market authorization for natural health products.
- In Section 1.4, Indication/Recommended Use – Multiple Medicinal Ingredients: A new application for the advertising of a family of products has been added.
- Section 2.18, Organic: A statement to the effect that licence holders should consult provincial legislation with respect to the use of the term “organic” in advertising was added. The labeling requirements for organic products based on the percent certified organic content were removed.
- Section 2.21, Risk Information Communication: the section on the inclusion of risk information in advertising was revised based on comments received from various stakeholders through the April 2006 electronic consultation and the options put forward by stakeholders at the June 28, 2006 invitational Roundtable. The revised Section 2.21 reflects the areas of consensus that were reached at the Roundtable as outlined in the report available at http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/report-rapport/index_e.html . The Guidelines include new emphasis of Section 9(1) of the Food and Drugs Act (deception clause) for industry to communicate information in advertising of nonprescription drugs and natural health products about reading product labels and a general cautionary statement, if risks have been identified. If new risks have been identified and do not appear on product labels, additional requirements exist.


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

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




GUIDANCE DOCUMENT

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



Published by authority of the
Minister of Health



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Health Products and Food Branch

<p>Our mission is to help the people of Canada maintain and improve their health.</p> <p style="text-align: right;"><i>Health Canada</i></p>	<p>HPFB's Mandate is to take an integrated approach to managing the health-related risks and benefits of health products and food by:</p> <ul style="list-style-type: none"> • minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. <p style="text-align: right;"><i>Health Products and Food Branch</i></p>
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Également disponible en français sous le titre: Lignes directrices sur la publicité des produits de santé commercialisés destinée aux consommateurs (pour les médicaments en vente libre incluant les produits de santé naturels).

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

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FOREWORD

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

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

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

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

ACKNOWLEDGMENT

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

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Advertising Standards Canada
Les normes canadiennes de la publicité

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Section A – Advertising Guidelines

A.1. Overview

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

The *Guidelines* are divided into two sections:

Section A - Advertising Guidelines

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

Section B – Legislation, Regulations and Policies

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

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

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

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

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

A.2. Scope

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

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

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

- Advertising of products for which there are specific consumer-directed advertising restrictions in the *Food and Drugs Act and Regulations* and the *Controlled Drugs and Substances Act* [e.g. controlled drugs, narcotics, *Schedule F* - prescription drugs, limit dose drugs (*section C.01.021* of the *Regulations*)]
- Advertising of prescription drugs, medical devices*, vaccines, veterinary drugs to consumers and to health professionals
- Advertising of nonprescription drugs, including natural health products, to health professionals³
- Advertising of food and cosmetic products
- Advertising displaying only the brand name of a nonprescription drug or a natural health product, provided that the Terms of Market Authorization of the product have been established and that such an advertisement does not contain any direct or implied therapeutic or nontherapeutic claims. A DIN, a NPN or a DIN-HM must have been granted before any advertising can be approved by an advertising preclearance agency. As for all advertising, this type of advertising is subject to the regulatory provisions of the *Food and Drugs Act and Regulations* and the *Natural Health Products Regulations*.
- Informational messages⁴ such as, but not limited to:
 - Institutional messages
 - Patient support group messages
 - Help-seeking announcements
 - Clinical trial recruitment messages

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

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

² As of date of issuance of *Guidelines*

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

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

A.3. Advertising Preclearance Overview

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

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

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

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

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

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

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

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

A.5. Advertising Guidelines

Guiding Principles

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

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

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

1.1 Authorization – Terms of Market Authorization

Guideline

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

For natural health products:

- Product Licence (PL)⁵

For nonprescription drugs:

- Labelling Standards, Category IV Monographs, Product Monographs or Authorized Labelling

Application

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

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

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

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

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

Example

Antihistamine

➤ **Indication / Use:**

Relieves allergy symptoms: sneezing, runny nose, and itchy, watery eyes

✓ **Acceptable Claim:**

"Product X relieves sneezing, runny nose, and itchy, watery eyes due to allergies"

✗ **Unacceptable Claim:**

"Product X relieves allergies"

1.2 Product Representation

Guideline

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

Application

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

Example

Calcium Supplement (chocolate chew format)

✓ **Acceptable Claim:**

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

✗ **Unacceptable Claim:**

"Try Product X for a tasty chocolate treat"

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

⁷ See Appendix D for *Section C.01.014.4*

Application

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

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

Example

Anti-dandruff Shampoo

> Indication / Use:

Controls flaking, scaling and itching associated with dandruff

✓ Acceptable Claim:

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

✗ Unacceptable Claim:

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

1.3 Indication / Recommended Use – Single Medicinal Ingredient

Guideline

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

Application

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

Example

Cough Syrup

> **Indication / Use:**

For relief of dry coughs

✓ **Acceptable Claim:**

“Product X relieves dry coughs so that you can get on with your day”

✗ **Unacceptable Claim:**

“Product X lets you get on with your day” (without reference to the therapeutic indication)

Application

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

Example

Analgesic

> **Indication / Use:**

For fever reduction and pain relief

✓ **Acceptable Claim:**

“Product X relieves fever so you can feel better”

✗ **Unacceptable Claim:**

“Product X helps you feel better” (without reference to the therapeutic indication)

1.4 Indication / Recommended Use – Multiple Medicinal Ingredients

Guideline

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

Application

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

Notes:

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

Example

Cough/Cold Preparation

3 medicinal ingredients (guaifenesin, dextromethorphan, chlorpheniramine)

> Indication / Use:

Relieves chest congestion, dry cough and runny nose

✓ Acceptable Claim:

“Got a miserable cold? Product X relieves your hacking cough, plus chest congestion and runny nose”

✗ Unacceptable Claim:

“Got a miserable cough? Try product X to relieve it”

Application

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

Example

Brand X Family of Cough and Cold Products

A product line of single and multi-ingredient cough and cold liquids and capsules containing one or a combination of the following active ingredients:

Acetaminophen

Dextromethorphan

Guaifenesin

Chlorpheniramine

✓ Acceptable Claim:

Visuals: Beauty shot of various Brand X cough and cold products

“For your cough and cold symptoms, there’s a Brand X product for you”

✗ Unacceptable Claim:

Visuals: Beauty shot of various Brand X cough and cold products

“For your cough there’s a Brand X product for you ”

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

Guideline

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

Application

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

Example

Wart Remover

> **Directions for Use:**

Apply every 2 days for 12 weeks until wart is gone

✓ **Acceptable Claim:**

“Removes warts. Use as directed”

✗ **Unacceptable Claim:**

“Removes warts in one easy step”

Application

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

Example

Cough Syrup

> **Directions for Use:**

Two teaspoons every 4 hours

✓ **Acceptable Depiction:**

Woman swallowing a teaspoon of syrup

✗ **Unacceptable Depiction:**

Woman drinking directly from the bottle

1.6 Duration of Action

Guideline

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

Application

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

Example

Analgesic

> **Indication / Use:**

Relieves headache for up to 8 hours

✓ **Acceptable Claim:**

“Product X relieves headache for up to 8 hours”

✗ **Unacceptable Claim:**

“Product X relieves headache all day long”

Application

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

Example

H2-antagonist

> **Indication / Use:**

Controls acid for up to 12 hours; relieves heartburn

✓ **Acceptable Claim:**

“Product X controls acid for up to 12 hours and relieves heartburn”

✗ **Unacceptable Claim:**

“Product X relieves heartburn for up to 12 hours”

1.7 Duration of Use

Guideline

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

Application

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

Example

Product X Glucosamine

> Indication / Use:

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

✓ Acceptable Claim:

“Product X Glucosamine reduces joint pain when used for at least 2 months”

✗ Unacceptable Claim:

“Product X Glucosamine reduces joint pain quickly”

Application

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

Example

Antacid

> Indication / Use:

For the relief of occasional heartburn

✓ Acceptable Claim:

“When heartburn strikes, try Product X for relief”

✗ Unacceptable Claim:

“When living with daily heartburn, use Product X for relief”

1.8 Efficacy

Guideline

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

Application

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

Example

Acne Medicine

> Indication / Use:

Helps treat and keep skin clear of new acne pimples

✓ Acceptable Claim:

“Product X helps keep skin clear of new acne pimples”

✗ Unacceptable Claim:

“Product X cures acne”

1.9 Medicinal vs. Non-medicinal Ingredients

Guideline

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

Application

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

Example

Product X Cough Syrup (honey flavored)

> Indication / Use:

For relief of dry coughs (as per the product’s TMA, honey is a non-medicinal [non-therapeutic] ingredient)

✓ Acceptable Claim:

“Product X cough syrup relieves your dry cough and the honey coats your throat to provide a soothing sensation”

✗ Unacceptable Claim:

“Try Product X cough syrup – soothing honey relieves your dry cough”

1.10 Onset of Action

Guideline

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

Application

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

Example

Antacid

> **Indication / Use:**

Relieves heartburn in 30 minutes

✓ **Acceptable Claim:**

"Product X relieves heartburn in 30 minutes"

✗ **Unacceptable Claim:**

"Product X relieves heartburn in minutes"

Application

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

Example

Analgesic

> **Indication / Use:**

Relieves headache in 45 minutes (TMA states tablet dissolution of 10 minutes)

✓ **Acceptable Claim:**

"Product X dissolve in 10 minutes and provides headache relief in 45 minutes"

✗ **Unacceptable Claim:**

"Product X dissolve in 10 minutes to provide fast relief"

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

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

2.1 Absence of Ingredient Statements

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

Guideline

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

Application

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

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

Example

Product which does not contain phenolphthalein

✓ **Acceptable Claim:**

“Reformulated. Now phenolphthalein-free”

✗ **Unacceptable Claim:**

“Reformulated. Now safer since phenolphthalein-free”

Application

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

Example

Product which does not contain gelatine

✓ **Acceptable Claim:**

“Gelatine-free”

✗ **Unacceptable Claim:**

“More effective since gelatine-free”

Application

- **Sweetening Agents**

- A product can be described as “sugar free” if it contains none of the chemical classes of sugar, including sugar alcohols.

Example

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

✓ **Acceptable Claim:**

“Product X cough syrup is sugar-free”

Example

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

✗ **Unacceptable Claim:**

“Product X cough syrup is sugar-free”

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

Guideline

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

Application

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

Example

Cold Medicine

> Indication / Use:

Relieves cough and nasal congestion

✓ Acceptable Claim:

“Product X relieves your cough and stuffy nose and it won’t make you sleepy”

✗ Unacceptable Claim:

“Get cough and nasal congestion relief, plus an energy boost”

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

Guideline

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

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

Application

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

Example

Cough Syrup

✓ Acceptable Depiction:

Child: “My dad gave me this medicine and my throat feels better”

Child and father depicted with father holding product bottle and spoon

✗ Unacceptable Depiction:

Child: “Daddy always gives me this syrup when I cough, so I’m going to take it now”

Child depicted self-administering product

2.4 Clinically Tested / Proven

Guideline

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

Application

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

Example

Analgesic

➤ **Indication / Use:**

Relieves arthritis pain

✓ **Acceptable Claim:**

“Clinically proven to relieve arthritis pain for up to 8 hours” (where clinical data is available to support duration of action)

✗ **Unacceptable Claim:**

“Clinically proven to relieve arthritis pain for up to 8 hours” (where clinical data does not support an 8 hour claim)

2.5 Comparative Claims – Therapeutic Comparisons

A therapeutic comparative claim is:

“A statement that compares an identified therapeutic attribute of one drug product/ingredient to that of another/other drug product(s)/ingredient(s) in terms of comparability or superiority”

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

Notes:

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

Examples

1) Claims for Superior Efficacy:

Example: Product X and Y antacids

➤ **Indication / Use:**

Both products are indicated to relieve heartburn by neutralizing stomach acid

✓ **Acceptable Claim:**

“Product X antacid relieves your heartburn 25% faster than Product Y antacid (see above note regarding required supporting evidence)”

✗ **Unacceptable Claim:**

“Product X antacid works better than Product Y antacid”

2) Claims for Superior Onset of Action:

Example: Product A and B analgesics

➤ **Indication / Use:**

Both products are indicated to relieve headaches

✓ **Acceptable Claim:**

“Product A starts to work on your headache in 10 minutes while Product B starts to work in 20 minutes (see above note regarding required supporting evidence)”

✗ **Unacceptable Claim:**

“Product A works really fast on your headache, while Product B takes a long time to start working”

3) Claims for Comparison of Side Effect Profile:

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

✓ **Acceptable Claim:**

“Product C causes less drowsiness than Product D (see above note regarding required supporting evidence)”

✗ **Unacceptable Claim:**

“Product C causes less side effects than Product D”

2.6 Comparative Claims – Non-therapeutic Comparisons

A non-therapeutic comparative claim is:

“A statement that compares an identified non-therapeutic attribute of one drug product to that of one or more drug product(s) or non-drug product(s)”

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

Examples

Non-therapeutic Claims:

“Moisturizes”, “Whitens”, “Tastes great”

Non-therapeutic Comparisons:

“Most recommended (product class) by doctors”, “Whitens better than...”, “Nothing tastes better than...”

2.7 Endorsements / Seals (See also “2.29 Testimonials / Quotations”)

Guideline

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

Application

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

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

Example

Toothpaste

✓ Acceptable Claim:

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

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

2.8 Exaggeration of Product Merit

Guideline

An advertisement must not mislead consumers by exaggerating product merit.

Application

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

Example

Analgesic

> Indication / Use:

For the relief of mild to moderate migraine pain

✓ Acceptable Claim:

“Product X provides migraine pain relief”

✗ Unacceptable Claim:

“Product X relieves severe migraine pain” (in words or depiction)

Application

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

Example

✓ Acceptable Claim:

“Effective formula/relief”

✗ Unacceptable Claim:

“Amazing formula/relief”

Application

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

Example

Antacid

✓ **Acceptable Claim:**

“Use Product X for the relief of occasional heartburn”

✗ **Unacceptable Claim:**

“Since I discovered Product X I can eat whatever I want, whenever I want”

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

Guideline

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

Application

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

Example

Antacid

200 mg tablet - Regular Strength

300 mg tablet - Extra Strength

400 mg tablet - Ultra Strength

➤ **Indication / Use (all strengths):**

For relief of occasional heartburn

✓ **Acceptable Claim:**

“When you’ve got occasional heartburn, choose Product X antacid. Available in 3 strengths”

✗ **Unacceptable Claim:**

“When you’ve got mild heartburn, choose Regular Strength Product X antacid. When you’ve REALLY overdone it and you’ve got bad heartburn, choose Ultra Strength Product X for relief of extreme heartburn”

2.10 Government / Health Canada Approved

Guideline

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

Application

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

Example

✓ **Acceptable Claim:**

"DIN 12345678"

✗ **Unacceptable Claim:**

"Has a DIN issued by Health Canada"

2.11 Graphics / Schematics / Statistics / Terminology

Guideline

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

Application

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

Example

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

✓ **Acceptable Claim:**

“Product X reduces the risk of side-effect Y from 1 in 100,000 to 1 in 200,000”

✗ **Unacceptable Claim:**

“Product X reduces the risk of side-effect Y by 50%”

2.12 Health / Healthy / Healthful

Guideline

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

Application

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

Example

Vitamin B₁

➤ **Indication / Use:**

A factor in the maintenance of good health

✓ **Acceptable Claim:**

“Product X Vitamin B₁ helps maintain good health”

✗ **Unacceptable Claim:**

“Product X Vitamin B₁ makes you healthy”

2.13 Implied / Indirect Claims

Guideline

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

Application

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

Example

Analgesic

➤ **Indication / Use:**

For arthritis pain relief

✓ **Acceptable Claim:**

“Analgesic X relieves arthritis pain”

Visuals: Woman’s gardening has been interrupted by her arthritis pain acting up. Later on we see her resume her gardening since her arthritis pain has been relieved.

✗ **Unacceptable Claim:**

“Analgesic X relieves arthritis pain”

Visuals: Woman’s gardening has been interrupted by her arthritis pain acting up. Later on we see her doing cartwheels in her backyard.

2.14 Natural (See also: “2.18 Organic”)

Guideline

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

Application

- **Natural:** An ingredient can be described as “natural” if it is obtained from a natural source material, is in a form found in nature, and has undergone only the most minimal processing (e.g. drying, grinding, powdering, chopping, encapsulating). Example: encapsulated powdered garlic.
- **Natural source(d):** An ingredient can be described as “natural source” if it is obtained via extraction, isolation and/or processing of plant, algal, fungal, bacterial, or animal material or minerals. Processing can include such steps as boiling and steaming. The ingredient must have the same chemical identity as that in the source material. Ingredients found in nature that undergo chemical modification such as derivatives and salts are considered synthetic and not natural source. Examples: Vitamin E (d-alpha-tocopherol) isolated from soybean is natural source. The derivative, d-alpha-tocopheryl acetate, produced via chemical modification of vitamin E from soybean, is not natural source, nor is the totally synthetic dl-alpha-tocopheryl acetate.
- **Multi-ingredient products:**
 - Claims that one or several ingredients in a multi-ingredient product are natural/natural source are permissible.
 - Claims about a product, as a whole, being natural/natural source are permissible if this statement is true for **all** ingredients (medicinal and non-medicinal).

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

Example

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

✓ **Acceptable Claims:**

“Product Y is a source of vitamin C for the maintenance of good health”

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

✗ **Unacceptable Claim:**

“Product Y is a natural source of vitamin C for the maintenance of good health”

2.15 Natural Action / Naturally

Guideline

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

Application

- A product’s therapeutic effect cannot be described as “natural” or “natural action/acting naturally”.

Example

✓ **Acceptable Claim:**

“Product X relieves symptom X by (authorized mechanism of action)”

✗ **Unacceptable Claim:**

“Product X acts naturally to relieve...”

2.16 Need

Guideline

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

Application

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

Example

Cough Syrup

✓ **Acceptable Claim:**

“Need relief of stubborn cough? Try Product X Cough Syrup”

✗ **Unacceptable Claim:**

“For cough relief, you need Product X Cough Syrup”

Example

Vaginal Antifungal Product X

✓ **Acceptable Claim**

“Need treatment for your yeast infection? Look to Product X”

✗ **Unacceptable Claim**

“Got a yeast infection? You need Product X”

2.17 New / Improved

Guideline

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

Application

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

Example

✓ **Acceptable Claim:**

“New and improved tablet coating”

✗ **Unacceptable Claim:**

“New and improved tablet” (unqualified)

2.18 Organic (See also: “2.14 Natural”)

NHP Reference Document: *Product Licensing Guidance Document*

Guideline

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

Application

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

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

Example

Product X

✓ Acceptable Claim:

"Product X contains organic ingredient Y"

✗ Unacceptable Claim:

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

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

Guideline

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

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

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

Application

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

Example
Nonprescription Drug

✓ **Acceptable Claim:**
“Effective formulation”

✗ **Unacceptable Claim:**
“Potent Formulation”

Application

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

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

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

✗ **Unacceptable Claim:**
“Product X Plant extract is potent”

Application

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

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

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

Example

Homeopathic Medicine

✓ **Acceptable Claim:**

"Product X has a potency of 5CH"

✗ **Unacceptable Claim:**

"Product X is potent"

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

Guideline

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

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

Application

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

Example

✓ **Acceptable Claim:**

"Product X has the power to relieve condition Y"

✗ **Unacceptable Claim:**

"Product X is powerful"

2.21 Risk/Safety Information Communication

Guideline

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

Application

Consumers should **always** :

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

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

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

Technical requirements:

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

Example

Cold Product X

✓ Acceptable Claim:

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

✗ Unacceptable Claim:

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

2.22 Risk Reduction Claims

Guideline

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

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

Application

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

Example

Calcium Supplement

> Indication / Use:

Help prevent osteoporosis

✓ Acceptable Claim:

"Product X calcium supplement may reduce the risk of developing osteoporosis"

✗ Unacceptable Claim:

"Product X calcium supplement may reduce the risk of developing bone cancer"

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

Guideline

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

Application

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

Example

✓ **Acceptable Claim:**

“Suitable for children over 12 years of age”

✗ **Unacceptable Claim:**

“Safe because it’s natural source”

2.24 Sampling

Guideline

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

Application

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

Example

✗ **Unacceptable Claim:**

“For a sample call 1-800-123-4567”

2.25 Scare Advertising

Guideline

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

Application

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

Example

Hand Germicidal Cleanser

✓ **Acceptable Claim:**

“Product X kills germs”

✗ **Unacceptable Claim:**

“Germs are everywhere! Don’t be at risk. Use Product X to prevent SARS”

2.26 Storage Conditions

Guideline

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

Application

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

Example

➤ **Authorized Storage Conditions:**

“Store between 15-30 degrees Celsius”

✓ **Acceptable Depiction:**

“Product stored in medicine cabinet”

✗ **Unacceptable Depiction:**

“Product depicted as being stored in glove box of car during a snow storm”

2.27 Structure Function Claims

Guideline

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

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

Application

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

Example

Product X Glucosamine

> Indication / Use:

A factor in the building of healthy cartilage

✓ Acceptable Claim:

"Product X Glucosamine is a factor in building healthy cartilage"

✗ Unacceptable Claim:

"Product X Glucosamine will treat your arthritis"

2.28 Superscripts / Footnotes or "Supers"

Guideline

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

Application

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

Example

TMA: Provides 8 hours of relief

✓ **Acceptable Claim:**

Audio: "Relief all work day"

Super: "Provides 8 hours of relief"

✗ **Unacceptable Claim:**

Audio: "Around the clock relief"

Super: "Provides 8 hours of relief"

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

Guideline

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

Application

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

Example

Product Y Echinacea

➤ **Indication / Use:**

Traditionally used for the relief of sore throat due to colds

✓ **Acceptable Claim:**

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

✗ **Unacceptable Claim:**

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

2.30 Therapeutic Guarantees / Absolute Claims

Guideline

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

Application

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

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

Example

✓ **Acceptable Claim:**

"Product X provides effective relief"

✗ **Unacceptable Claim:**

"Product X is proven 100% effective for everyone, 100% of the time"

2.31 Unique

Guideline

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

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

Application

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

Example

Unique (Therapeutic)

✓ **Acceptable Claim:**

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

✗ **Unacceptable Claim:**

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

Application

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

Example

Unique (Non-therapeutic)

✓ **Acceptable Claim:**

“Shampoo X fights dandruff and has a unique shine enhancing ingredient” (advertiser would have to provide attestation that no other shampoo contains this shine ingredient)

2.32 Withdrawal of Terms of Market Authorization

Guideline

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

Application

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

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

Section B: Legislation, Regulations and Policies⁹

B.1. Definitions Under the Food and Drugs Act, the Food and Drug Regulations and the Natural Health Products Regulations¹⁰

Advertisement (Food and Drugs Act Section 2):

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

Drug (Food and Drugs Act Section 2):

'drug' includes any substance or mixture of substances manufactured, sold or represented for use in

- a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals,
- b) restoring correcting or modifying organic functions in human beings or animals, or
- c) disinfection in premises in which food is manufactured, prepared or kept

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

'brand name' means, with reference to a drug, the name, whether or not including the name of any manufacturer, corporation, partnership or individual, in English or French,

- (a) that is assigned to the drug by its manufacturer,
- (b) under which the drug is sold or advertised, and
- (c) that is used to distinguish the drug

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

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

- a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
- b) restoring or correcting organic functions in humans; or
- c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out

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

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

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

Schedule 1: INCLUDED NATURAL HEALTH PRODUCT SUBSTANCES

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

Schedule 2: EXCLUDED NATURAL HEALTH PRODUCT SUBSTANCES

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

Product Licence (NHP Regulations Section 14(1))

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

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

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

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

OTHER DEFINITIONS

Brand Name (NHP Regulations Section 1(1))

“Brand name” means a name in English or French, whether or not it includes the name of a manufacturer, corporation, partnership or individual

- (a) that is used to distinguish the natural health product; and
- (b) under which a natural health product is sold or advertised

Drug Identification Number (DIN)

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

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

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

Homeopathic Medicine Number (DIN-HM)

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

Natural Product Number (NPN)

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

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

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.

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.¹³

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 natural health products, 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 submitted in the PL application that have not been authorized by Health Canada, cannot be used in advertising. The Natural Health Products Directorate (NHPD) developed the Compendium of Monographs as a tool for the evaluation of the safety and efficacy of many commonly used medicinal ingredients that comprise natural health products (NHP). NHPD's product licensing system allows applicants to reference a monograph in support of the safety and efficacy of a product as part of their product licence application. Monographs are used as a reference tool for product licence applications. Monographs are not the terms of market authorization for NHPs. More information on monographs can be found at:

¹³ Label includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic device or package (*Section 2* of the *Food and Drugs Act*)

http://www.hc-sc.gc.ca/dhp-mpps/prodnatur/applications/licen-prod/monograph/index_e.html

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 Period¹⁴

As of January 1, 2004, the *Natural Health Products Regulations* came into force and apply to all natural health products.

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 natural health products (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 *NHP 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 advertising preclearance agencies. 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 advertising preclearance agencies.

¹⁴ 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)*.

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

Legislation	Natural Health Products	Nonprescription 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	* ¹⁵	*
C.01.015(2)(f) – Advertising of Tablet Disintegration Times	* ¹⁶	*
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	Nonprescription Drugs
Canadian Association of Broadcasters, Broadcast Code For Advertising to Children		
Clause 4(b) – Product Prohibitions	*	*
Policies	Natural health products	Nonprescription Drugs
See 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.

¹⁵ 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

¹⁶ 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 natural health products and nonprescription 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 A¹⁷.

(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.01.021¹⁸; 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

¹⁷ See Appendix A for Schedule A to the *Food and Drugs Act*

¹⁸ See Appendix D for C.01.021

- 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.

(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.08.004¹⁹, 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.08.006²⁰; 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.01.043²¹ of those Regulations.

¹⁹ See Appendix D for C.08.004

²⁰ See Appendix D for C.08.006

²¹ See Appendix D for C.01.043

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.

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)²² 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.

²² See Appendix D for C.01.015(1)

Health Canada Advertising Policies

Numerous Health Canada policies and guidance documents apply to the advertising of marketed health products. They may be found on the Health Canada website at http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/index_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/dhp-mps/advert-publicit/pol/index_e.html:

- *Therapeutic Comparative Advertising: Directive and Guidance Document*
- *Advertising Preclearance Agencies 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/dhp-mps/prodpharma/applic-demande/pol/index_e.html)
- *Schedule A and Section 3: Guidance Document* (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/activit/index_e.html)

B.3. Appendix Material

Appendix A – Health Products and Food Branch Schedule A and Section 3: Guidance Document

Guidance Document issued in February 2003

I. PURPOSE

This document helps clarify the intent and applicable interpretations of section 3 and Schedule A to the *Food and Drugs Act* for stakeholders, Health Canada enforcement officers, and inspectors of the Canadian Food Inspection Agency (CFIA) with respect to the assessment of label claims and advertisements. All assessments must be on a case-by-case basis, taking account of the circumstances particular to each case. Consideration should also be given to sections 5, 9, and 20 of the *Food and Drugs Act* (see Appendix A) which require that label claims and advertisements be truthful.

When referring to label and advertising information, this document uses the term “claims” which should be considered synonymous with “indications.” Please refer to Appendix B for definitions of some phrases used in this document. It should be noted that the term “disease” in this document is used as a general term to include “diseases, disorders or abnormal physical states”.

II. CLARIFICATION OF THE PROHIBITION

Section 3 of the *Food and Drugs Act* 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 publicas 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 thus prohibits any label claim or advertisement that has *both of the following characteristics*:

- is aimed at the general public;
- contains treatment, preventative, or cure claims and refers to a Schedule A disease.

Understanding the scope of Schedule A and assessing whether a label claim or advertisement would violate section 3 is a challenging task that is best done on a case by case basis. The compliance checklist in Appendix D provides a list of questions to help assist the assessment of a claim.

It is useful to note that information packages, brochures and other material may be considered to be advertising for a drug product when displayed in close proximity to or distributed with products containing the same ingredient, in the same retail outlet. (See the Therapeutic Products Directorate policy “The distinction between Advertising and other Activities” for more details.)

1. General Public

“General public” does not include health care professionals. Consequently, advertising to these individuals - as well as health professional associations such as the Canadian Pharmacists Association, the Canadian Medical Association and the Canadian Veterinary Medical Association - through a print ad in a professional journal for example, is permitted.

2. Treatment, Preventative, or Cure

Section 3 uses the specific words “treatment,” “preventative,” and “cure.” However, it also prohibits certain claims that do not include these exact words. For example, the following phrases are among those that would be considered preventative or treatment claims:

- 1) “this product may assist in the management of disease X”;
- 2) “this product may be used as an adjunct in the treatment of disease X”;
and
- 3) “this product may help reduce the risk of disease X.”

However, reference to a Schedule A disease may be made in the context of precautions or contraindications as part of directions for use.

3. References to Schedule A Diseases

Section 3 prohibits claims that refer to any of the Schedule A diseases. However, some claims

that do not expressly mention a Schedule A disease may also violate section 3. The following must be considered to determine whether a claim is acceptable: a) diseases considered synonyms or subsets of Schedule A diseases; b) certain symptoms and signs of Schedule A diseases; and c) risk factors for Schedule A diseases.

a) Synonyms and subsets

Some diseases were not well characterized when the Schedule was first drafted but are generally understood today to fall under the terms used in Schedule A. They are considered synonyms or subsets of the diseases listed in Schedule A. For example, a claim with respect to “angina” would be synonymous with the Schedule A disease “heart disease” and thus prohibited. Similarly, “syphilis” is a subset of venereal disease, and “hardening of the arteries” is a synonym for arteriosclerosis.

Appendix C provides some synonyms and subsets for Schedule A diseases. This list has been used for some time in assessing advertisement and label claims, but is not meant to be comprehensive. It continues to be used in guiding the enforcement of section 3.

b) Symptoms and signs

Many Schedule A diseases are closely associated with symptoms or signs. A claim to treat, prevent or cure these signs or symptoms of a Schedule A disease is considered to be a claim to treat, prevent, or cure the disease itself. Accordingly, such a claim is prohibited by section 3.

The prohibition against advertising to the general public products for the treatment of arthritis has historically not applied to products designed to relieve the pain associated with this disease. Therefore, claims such as “for the relief of pain due to/or associated with arthritis” are permissible, because the treatment of “pain” is not considered to be a claim to treat the disease. This distinction is sustained when representations clearly indicate that these products only relieve the pain due to or associated with arthritis. Also, the distinction is further affirmed when the representations give an equal prominence to the relief of pain statements and to any reference to the disease itself. The distinction between symptoms and disease would not be sustained, and therefore a claim would be prohibited if it implies that the arthritic condition itself will be relieved or that the functioning of the articulations will be improved.

c) Risk factors

Section 3 should be interpreted to allow references to risk factors to Schedule A diseases. In other words, a label or advertisement stating a product addresses a risk factor associated with a listed disease without expressly mentioning the disease name itself (or a synonym) would not be considered to violate section 3. For example, claims such as “this product helps maintain healthy cholesterol levels” or “this product does not raise blood sugar levels” may not necessarily relate to arteriosclerosis and diabetes respectively, and therefore would not be prohibited.

III. RESPONSIBILITIES

The enforcement decisions based on this interpretive guide are the responsibility of the staff of the various programs within Health Canada and the Canadian Food Inspection Agency (CFIA).

IV. APPLICATION DATE AND FURTHER REVIEW

This guidance document reflects the current interpretation and enforcement of Section 3 and Schedule A. It will be reviewed 6 months after its issuance and may be supplemented further to the work of the Working Group.

APPENDIX A – Statutory Provisions

Section 3, *Food and Drugs Act*

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 publicas 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 5, *Food and Drugs Act*

5. (1) No person shall label, package, treat, process, sell or advertise any food 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 9, *Food and Drugs Act*

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 20, Food and Drugs Act

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 character, value, quantity, composition, merit or safety.

Schedule A, Food and Drugs Act

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

APPENDIX B -- Definitions

The following, except as otherwise indicated, are taken from the *Food and Drugs Act* or *Regulations*

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;

Cosmetic:

includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes;

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

- (b) abnormal physical state, or its symptoms, in human beings or animals, 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;

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 or 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;

Food:

includes any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever;

Health Care Professionals: (defined in the *Medical Devices Regulations*)

persons who are entitled under the laws of a province to provide health services in the province;

Label:

includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package;

Natural Health Product: (defined in the proposed *Natural Health Product Regulations* published in the *Canada Gazette*, Part I on December 22, 2001).

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 preparation 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) maintaining or promoting health or otherwise modifying organic functions in humans.

However, a natural health product does not include a substance set out in Schedule 2 or any combination of substances that includes a substance set out in Schedule 2. (*produit de santé naturel*)

Schedule 1 - Included Natural Health Product Substances

1. A plant or a plant material, an alga, 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, their salts or their derivatives:
 - biotin
 - folic acid
 - niacin
 - pantothenic acid
 - vitamin A
 - vitamin B₁ or thiamine
 - vitamin B₂ or riboflavin
 - vitamin B₆ or pyridoxine
 - vitamin B₁₂ or cyanocobalamin
 - vitamin C or ascorbic acid
 - vitamin D
 - vitamin E
 - vitamin K
4. An amino acid or any of its salts
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

1. An antibiotic prepared from a micro-organism or a synthetic duplicate of that antibiotic
2. A substance set out in Schedule C or D to the Act
3. A substance regulated under the *Tobacco Act*
4. A substance intended to be administered by injection

Sell:

includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is for consideration.

EXCERPT FROM THE THERAPEUTIC PRODUCTS COMPLIANCE GUIDE

APPENDIX C – Claims Synonymous with Schedule A diseases/disorders

This section lists some frequently encountered claims that would be considered synonymous with the diseases, disorders or abnormal physical states referred to in Schedule A to the *Food and Drugs Act*.

ALCOHOLISM

Synonymous claims: Liquor or drinking habit.

ANXIETY STATES

Synonymous claims: Apprehension, worry, concern, fear and tension.

Note: An acceptable drug may be promoted for the treatment of edgy nerves, nervous headaches, nervousness, edginess, jitteriness, insomnia or sleeplessness.

ARTERIOSCLEROSIS

Synonymous claims: Coronary artery disease, arteriosclerotic ulcer, hardening of the arteries, circulatory troubles.

ARTHRITIS

Note: Suitably medicated products may be represented as aids in alleviating the pain of arthritis or as being for the relief of arthritic pain.

BLADDER DISEASE

Synonymous claims: Inflammation of the bladder, bladder trouble

CONVULSIONS

Synonymous claims: Anticonvulsant.

DEPRESSION

Synonymous claims: Feelings of sadness, dejection, hopelessness, unhappiness, or apathy; phobic attitude, neurosis.

DISEASE OF THE PROSTATE

Synonymous claims: Prostatism, urinary incontinence, prostatic problems.

DISORDER OF THE MENSTRUAL FLOW

Synonymous claims: Amenorrhea, delayed menstruation, menstrual irregularity. Note : Suitable products may be advertised as being helpful to relieve the pain associated with menstruation, premenstrual tension, symptoms associated with menopause, and premenstrual syndromes.

EDEMATOUS STATE

Synonymous claims: Bloating, water retention, puffiness, swelling, pitting, dropsy.

Note : Appropriately medicated product may be represented for temporary water retention, bloating, swelling, and/or full feeling associated with the premenstrual and menstrual periods.

EPILEPSY

Synonymous claims: Anticonvulsant, antiepileptic, petit mal or grand mal seizures.

GALL BLADDER DISEASE

Synonymous claims: Gall stones, biliary dyskinesia, gall bladder troubles, biliary tract antispasmodic.

GOUT

Synonymous claims: Gouty arthritis, gouty disease.

HYPERTENSION

Synonymous claims: Antihypertensive agent, high blood pressure, poor circulation.

HYPOTENSION

Synonymous claims: Hypertensive agent, low blood pressure, poor circulation, diminished tension, sluggish blood.

IMPETIGO

Note: Acceptable drugs may be promoted as providing relief from, or treatment for minor skin infections.

KIDNEY DISEASE

Synonymous claims: Kidney troubles, flush out the kidney.

Note: Sufficiently medicated drugs may claim to be mild diuretics or to increase the flow of urine.

LIVER DISEASE

Synonymous claims: Jaundice, cirrhosis, inactive or congested liver, liver troubles.

NAUSEA AND VOMITING DUE TO PREGNANCY

Synonymous claims: Morning sickness, drowsiness, vertigo, dizziness occurring during pregnancy. Note: Anti-emetic agents may be represented for relief of motion sickness, but no suggestion for use during pregnancy may be made.

OBESITY

Synonymous claims: Anti-obesity agent.

Note: The promotion of over the counter (OTC) drugs to assist in weight loss is acceptable under the following conditions :

The drug is marketed in conjunction with a reducing plan, program, diet, or course that promotes a reduced intake of dietary calories with a possible increase in physical activity.

It should be clearly indicated to the consumer that it is the modification of dietary intake and physical activity that will be the instrument of weight loss.

The purpose of the drug in the weight-loss plan should be clearly identified as being an aid in curbing hunger and in improving program compliance.

SEPTICEMIA

Synonymous claims: Systemic anti-infective, blood purifiers.

SEXUAL IMPOTENCE

Synonymous claims: Frigidity, decreasing virility or manly power, aphrodisiac.

THYROID DISEASE

Synonymous claims: Thyroid problems, hypothyroidism, hyperthyroidism, goitre.

ULCER OF THE GASTROINTESTINAL TRACT

Synonymous claims: Peptic ulcer, ulcerative colitis, duodenal ulcer.

Note: Products that are appropriately medicated may be promoted for hyperacidity, excess acid or gas, heartburn, upset stomach or acid indigestion, or hypermobility of the gastrointestinal tract.

VENEREAL DISEASE

Note: Acquired immune deficiency syndrome (AIDS) is considered to fall under the scope of Schedule A through this listing.

APPENDIX D – Compliance Checklist

Generally, section 3 would prohibit a claim that, taking into account its target audience and intent, would likely lead a member of the general public to understand that it is a treatment, preventative, or cure for a Schedule A disease.

Claims ought to be assessed in the above holistic manner, and the following checklist should assist this assessment. If the answer to at least one question from each of the following categories is “yes”, section 3 would likely prohibit the claim in question:

CATEGORIES	QUESTIONS
#1: General Public	Is the claim aimed at the general public?
#2: Type of Claim	<p>Does the claim* refer expressly to "treatment, preventative or cure?"</p> <p>Does the claim refer to therapeutic benefit that is equivalent to "treatment, preventative or cure," for example risk reduction or management of the disease?</p>
#3: Disease Reference	<p>Does the claim refer expressly to a disease as written in Schedule A?</p> <p>Does the claim refer indirectly to a Schedule A disease by referring to a synonymous disease?</p> <p>Does the claim refer to a subset of a Schedule A disease?</p> <p>Does the claim refer to a symptom or sign of a Schedule A disease?</p>

* “Claim” includes the product name.

Appendix B – Regulatory Requirements Resulting from Changes to Products from the Natural Health Products Directorate Product Licensing Guidance Document (Appendix 2)

When changes are required to information relating to licensed natural health products, licensees must make the 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	Amendment
New claim made using the exact same remaining conditions of	

use	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.01.014.1

(1) A manufacturer of a drug, a person authorized by a manufacturer or, in the case of a drug to be imported into Canada, the importer of the drug may make an application for a drug identification number for that drug

(2) An application under subsection (1) shall be made to the Director in writing and shall set out the following information:

- (a) the name of the manufacturer of the drug as it will appear on the label;
- (b) the pharmaceutical form in which the drug is to be sold;
- (c) in the case of any drug other than a drug described in paragraph (d), the recommended route of administration;
- (d) in the case of a drug for disinfection in premises, the types of premises for which its use is recommended;
- (e) a quantitative list of the medicinal ingredients contained in the drug by their proper names or, if they have no proper names, by their common names;
- (f) the brand name under which the drug is to be sold;
- (g) whether the drug is for human use, veterinary use or disinfection in premises;
- (h) the name and quantity of each colouring ingredient that is not a medicinal ingredient;
- (i) the use or purpose for which the drug is recommended;
- (j) the recommended dosage of the drug;
- (k) the address of the manufacturer referred to in paragraph (a) and, where the address is outside the country, the name and address of the importer of the drug;
- (l) the name and address of any individual, firm, partnership, or corporation, other than the names and addresses referred to in paragraphs (a) and (k), that will appear on the label of the drug;
- (m) the written text of all labels and package inserts to be used in connection with the drug and of any further prescribing information stated to be available on request; and
- (n) the name and position of the person who signed the application and the date of signature.

(3) In the case of a new drug, a new drug submission or an abbreviated new drug submission filed pursuant to section C.08.002 or C.08.002.1 shall be regarded as an application for a drug identification number.

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)²³ 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:

²³ See Appendix D for C.01.015(1)

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.

Table of limits of drug dosage for adults

Item	External Use	Internal Use	
	Maximum Limit	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 ophthalmic 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, Methyلاتropine, 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 ophthalmic 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	--	150.0	1000.0
Tetracaine, its salts and derivatives when sold or recommended for ophthalmic use	--	0.0	0.0
Thiocyanates	--	0.0	0.0
Urethane	--	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 Food 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 Health Canada's Website at http://www.hc-sc.gc.ca/dhp-mps/compli-conform/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