

Guidelines for the Nonprescription and Cosmetic Industry Regarding Non-therapeutic Advertising and Labelling Claims



Overview

How do you determine what advertising and labelling claims are properly representing your product according to legislative or regulatory requirements?

Which kinds of claims require pre-market authorization from Health Canada and which do not?

ASC's *Guidelines for The Nonprescription and Cosmetic Industry Regarding Non-therapeutic Advertising and Labelling Claims* (*Guidelines*) have two principal purposes:

- 1) To provide guidance to the nonprescription drug industry regarding acceptable wording for **non-therapeutic claims** that appear on the labels and in advertising of nonprescription drugs and natural health products; and
- 2) To provide guidance to the cosmetic industry regarding which claims are considered **therapeutic**, and as such cannot appear on the labels or in advertising of cosmetic products.

This guidance is based on the principle that labelling and advertising for products that modify or restore organic functions in humans, or impact human disease, are permissible only on health products supported by appropriate evidence. It is the representation of a benefit to human health that determines the difference between a therapeutic claim and a non-therapeutic/cosmetic claim.

How to Use the Guidelines

About the Format

The *Guidelines* are organized by product area and are presented in a column format.

Column I provides a non-exhaustive list of claims that can be characterized as **non-therapeutic**.

- These claims must be true and verifiable with respect to the function of the product and the brand owner must be able to substantiate any claim made on the product or its advertising of that product. However such claims do not require prior authorization from Health Canada (HC).

Column II provides a non-exhaustive list of **therapeutic/health claims** used to represent drug or natural health products.

- These claims are reviewed by the Natural and Non-prescription Health Products Directorate (NNHPD) in advance of a product receiving its Drug Identification Number (DIN) or Natural Product Number (NPN). Only those product claims that have been authorized are acceptable for use in advertising or marketing.
- The exact wording of claims listed under “Therapeutic/Health Claims” may not be acceptable for individual products bearing a DIN or NPN. The wording of claims will be assessed during product review against evidence provided and other current policies and guidelines and may require elaboration or revision.

Important Information

- The guidance provided in this document applies to products that are applied topically for local action on the skin, including the skin inside the mouth.
- The claims set out as examples in Columns I and II are included for illustrative purposes only. The lists are not exhaustive, and should be used only as a guide.
- Claims must be true, verifiable and must accurately communicate product features, characteristics and performance.
- Each claim will be evaluated within the overall context of the advertisement/label/name and net impression will be taken into account.
- The *Guidelines* are a helpful tool for those involved in advertising claims. They do not have the force of law and should be used in conjunction with the *Food and Drugs Act*, the *Food and Drug Regulations*, the *Natural Health Product Regulations*, the *Cosmetic Regulations*, the *Consumer Packaging and Labelling Act and Regulations*, the *Competition Act* and other applicable legislation, regulations and guidance documents.

Acknowledgment

The publication of these *Guidelines* represents the culmination of a collaborative effort among Advertising Standards Canada, Health Canada (HC), and other stakeholders. These *Guidelines* will be reviewed and updated regularly to reflect Canada's evolving regulatory framework and dynamic marketplace.

The claims are examples only; must be true, verifiable and accurately communicate product features, characteristics & performance; and will be evaluated within the context of the advertisement/label/name and net impression will be taken into account.

Column I – Non-therapeutic Claims

Examples of claims that are characterized as non-therapeutic that do not require prior authorization by HC
The list is not exhaustive

Column II – Therapeutic/Health Claims

Examples of claims that must be assessed by HC prior to market authorization
The list is not exhaustive

Antiperspirants

NON-THERAPEUTIC CLAIMS	THERAPEUTIC/HEALTH CLAIMS
<ul style="list-style-type: none"> Antiperspirant Any duration statement (e.g. 24, 48 hour) Helps keep you dry Protects against wetness Reduces (or provides protection against) underarm perspiration Extra effective 	<ul style="list-style-type: none"> Hyperhidrosis* Persistent protection based on a mechanism of action that modifies organic function Problem/Excessive perspiration References to perspiration from hormonal/endocrine changes or malfunction
<ul style="list-style-type: none"> Clinical (qualified as clinical testing) Clinical protection (must be qualified with “clinically proven extra effective wetness protection”) Clinically tested/proven/trials 	<ul style="list-style-type: none"> Clinical (unqualified) Clinical protection (unqualified) Clinical/Therapeutic strength/effect/action
<ul style="list-style-type: none"> Body responsive Controls odour/Anti-odorant 	

*Refer to Health Canada *Product Assessment Against Criteria: Antiperspirants*:
<http://www.hc-sc.gc.ca/cps-spc/pubs/indust/cosmet-antiperspir-sudorif/index-eng.php>

Hair Care

NON-THERAPEUTIC CLAIMS	THERAPEUTIC/HEALTH CLAIMS
<ul style="list-style-type: none"> Removes loose dandruff flakes 	<ul style="list-style-type: none"> Anti-dandruff products* Controls/Eliminates/Prevents dandruff*
<ul style="list-style-type: none"> Strengthens hair Repairs split ends/dry/damaged hair Thickens the look of/curls/lifts eyelashes 	<ul style="list-style-type: none"> Stimulates hair growth Stimulates eyelash growth
<ul style="list-style-type: none"> Thickens hair 	<ul style="list-style-type: none"> Prevents/Treats alopecia Prevents hair loss/ thinning
<ul style="list-style-type: none"> Removes hair 	<ul style="list-style-type: none"> Inhibits/Stops hair growth
<ul style="list-style-type: none"> Healthy hair 	
<ul style="list-style-type: none"> Penetrates root to tip 	
<ul style="list-style-type: none"> Revitalizes hair/hair’s beauty 	<ul style="list-style-type: none"> Any effect on living tissue (e.g. hair follicles)
<ul style="list-style-type: none"> Contains sunscreen / UV filters (for hair products only) 	

*Refer to Health Canada *Anti-Dandruff Products Monograph*:
http://webprod.hc-sc.gc.ca/nhp-id-bdipsn/atReq.do?atid=antidandruff_anitpellculaire&lang=eng

Nail Care

NON-THERAPEUTIC CLAIMS	THERAPEUTIC/HEALTH CLAIMS
<ul style="list-style-type: none"> Promotes nail growth by protecting from physical damage (abrasion, chipping, breaking) Repairs/Strengthens/Hardens nails 	<ul style="list-style-type: none"> Promotes nail growth (physiological)
	<ul style="list-style-type: none"> Antifungal

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Intimate Products

NON-THERAPEUTIC CLAIM	THERAPEUTIC/HEALTH CLAIMS
<ul style="list-style-type: none"> Enhances intimacy Enhances/Increases sex experience/sexual pleasure by lubricating 	<ul style="list-style-type: none"> Enhances sperm motility / Improves chances of conception Contains spermicide/spermicidal
<ul style="list-style-type: none"> Product is pH-balanced 	<ul style="list-style-type: none"> Helps maintain normal pH level pH-balanced to prevent infection
<ul style="list-style-type: none"> Tingling/Warm/Cool sensation Feels like natural moisture 	<ul style="list-style-type: none"> Increases libido/desire Produces/Prolongs erection/orgasm Stimulates genital tissue Vaginal tightening/contracting Desensitizing / Delays orgasm
<ul style="list-style-type: none"> Lubricates Replenishes/Restores/Replaces vaginal/personal moisture 	

Oral Care

NON-THERAPEUTIC CLAIMS	THERAPEUTIC/HEALTH CLAIMS
<ul style="list-style-type: none"> Cleans/Bleaches/Whitens/Brightens/Polishes teeth Removes stains 	<ul style="list-style-type: none"> Removes permanent stains
<ul style="list-style-type: none"> Prevents/Reduces tartar build-up/deposit (by brushing only) Removes/Reduces plaque (by brushing only) 	<ul style="list-style-type: none"> Prevents plaque/tartar build-up/deposit/formation by chemical or antimicrobial action Anti-plaque / Anti-tartar Fights/Treats plaque/tartar
<ul style="list-style-type: none"> Kills bacteria that can cause bad breath Fights bad breath Reduces mouth odours 	<ul style="list-style-type: none"> Kills germs/pathogens Kills odour causing germs Germicide Antiseptic Antiviral Any impression or reference to disease prevention Any impression or reference to pain or irritation
	<ul style="list-style-type: none"> Anti-cavity* / Anti-gingivitis / Anti-sensitivity Claims for fluoride effect* / Contains fluoride* Any implication of effect below the gum line Desensitizes teeth/gums Strengthens enamel*/teeth*/gums Any effect produced by product ingestion

*Refer to Health Canada *Oral Health Products* Monograph:
<http://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/atReq.do?atid=oral.health.sante.bucco.dentaire&lang=eng>

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Skin Care/Makeup

NON-THERAPEUTIC CLAIMS	THERAPEUTIC/HEALTH CLAIMS
<ul style="list-style-type: none"> • Heals dry skin 	<ul style="list-style-type: none"> • Heals (unqualified)
<ul style="list-style-type: none"> • Repairs dry skin • Replenish/Protect the skin’s moisture barrier 	<ul style="list-style-type: none"> • Repairs (damaged) skin • Repairs the skin’s moisture barrier
<ul style="list-style-type: none"> • Protects/Relieves/Soothes dry skin • Cools/Soothes skin after shaving/epilation • Cleans/Cleanses skin • Prevents/Protects against nicks/cuts/irritation during shaving 	<ul style="list-style-type: none"> • Calms/Protects/Relieves/Soothes abrasions/bites/insect bites/ cuts/nicks/irritated skin/ inflamed skin/rashes/ sunburns* • Numbs • Treats burns/infections • Any impression or reference to pain or irritation
<ul style="list-style-type: none"> • Hydrates/Lubricates/Moisturizes • Reinforces/Strengthens skin (via moisturization) 	
<ul style="list-style-type: none"> • Improves the look of acne scars 	<ul style="list-style-type: none"> • Removes/Reduces scars
<ul style="list-style-type: none"> • Relieves redness/itching due to dryness 	<ul style="list-style-type: none"> • Reduces redness due to rosacea (or other circulatory-related causes) • Reduces redness (due to sunburns) • Any reference to rosacea
<ul style="list-style-type: none"> • Reduces the look of age spots 	<ul style="list-style-type: none"> • Eliminates age spots • Prevents new spots from appearing** • Prevents the onset/emergence of age spots** • Any impression or reference to skin de-pigmentation
<ul style="list-style-type: none"> • Diminishes/Reduces the look or the signs of aging • Skin looks visibly younger/revitalized/radiant/refreshed/ energised/rejuvenated/brightened • Protects from environmental stressors (if qualified as causing dry skin) 	<ul style="list-style-type: none"> • Prevents photoaging and/or related damage**
<ul style="list-style-type: none"> • Smooths wrinkles • Wrinkles appear/look reduced 	
<ul style="list-style-type: none"> • Reduces the look of dark circles 	
<ul style="list-style-type: none"> • Firms/Tightens/Tones/Conditions/Smooths/Softens skin • Improves elasticity/resiliency • Skin feels/appears firm/lifted 	<ul style="list-style-type: none"> • Provides the effect of a medical/surgical procedure
<ul style="list-style-type: none"> • Reduces the look of cellulite 	<ul style="list-style-type: none"> • Reduces/Controls swelling/edema • Weight management • Weight/Fat loss • Reduces/Removes/Treats cellulite
<ul style="list-style-type: none"> • Reduces puffiness 	<ul style="list-style-type: none"> • Reference to lipodraining
<ul style="list-style-type: none"> • Sloughs off dead skin cells • Reduces ingrown hair/razor bumps (via exfoliation) 	<ul style="list-style-type: none"> • Any reference to action at a cellular level (living) / circulation • Reference to action on tissue/body/cells
<ul style="list-style-type: none"> • Improves the texture of skin/retextures 	
<ul style="list-style-type: none"> • Deep cleans pores • Unclogs/Tightens pores • Makes pores smaller 	<ul style="list-style-type: none"> • Cleans wounds

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Skin Care/Makeup (Cont'd)

NON-THERAPEUTIC CLAIMS	THERAPEUTIC/HEALTH CLAIMS
<ul style="list-style-type: none"> Removes/Absorbs oil Cleanser for acne-prone skin Covers blemishes/acne 	<ul style="list-style-type: none"> Anti-blemish Clears skin (acne)*** Heals/Prevents/Stops/Treats acne***† <p>†Acne = blemishes, zits, spots, blackheads, comedones, pimples, breakouts, etc</p>
<ul style="list-style-type: none"> Covers / Conceals Bronzed, suntanned look 	<ul style="list-style-type: none"> SPF/ UV/UVA/UVB** Sunburn protectant** (Contains) Sunscreen** Protects sun damaged skin**
<ul style="list-style-type: none"> Kills odour causing bacteria 	<ul style="list-style-type: none"> Kills pathogens/germs/ bacteria (other than odour causing bacteria) Antibacterial action Antiseptic (Cleanser)/Disinfectant/Sanitizer Fungicide Any impression or reference to disease prevention Reference to disease causing organisms Reference to disease control/healing

*Refer to Health Canada's *Medicated Skin Care Products* Monograph:
http://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/atReq.do?atid=skin_peau&lang=eng

**Refer to Health Canada's *Sunscreen* Monograph:
<http://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/atReq.do?atid=sunscreen-ecransolaire&lang=eng>

***Refer to Health Canada's *Acne Therapy* Monograph:
http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/mono_acne-eng.php

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Other Claims

NON-THERAPEUTIC CLAIMS

THERAPEUTIC/HEALTH CLAIMS

ENDORSEMENT

- Dermatologist tested
- Recommended/Developed by doctors/ dermatologists/ beauticians

- Prescription strength / Rx / Pr

INGREDIENT (e.g. vitamins, antioxidants, etc.)

- Ingredient/Vitamin/Mineral/Antioxidant produces cosmetic benefit
- Contains vitamins which act as antioxidants to preserve product integrity or to keep product fresh

- Active/Effective/Medicinal/Therapeutic ingredient
- Contains/Source of vitamin X (unqualified)
- Contains/Source of vitamins which act as antioxidants (unqualified)
- Any reference to therapeutic effect of vitamins/ antioxidants (e.g., free radical scavenging)
- Any reference to repairing damage
- Any reference to action at a cellular level (living)
- Any reference to dose units (e.g. IU)

HEALTHY

- Healthy (from an appearance perspective)
- Skin looks and feels healthy

- Promotes health
- Biological/Therapeutic action/effect

ORGANIC

- Organic (product must meet a recognized standard for organic certification)

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