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 Health Products Directorate (NHPD) 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.

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**

Antiperspirants

NON-THERAPEUTIC CLAIMS

- Antiperspirant
- 24 hour antiperspirant effect (products that demonstrate 20% sweat reduction within a 24-hour period)
- Helps keep you dry
- Protects against wetness
- Reduces (or provides protection against) underarm perspiration
- Extra effective (products that demonstrate 30% or more sweat reduction within a 24-hour period)
- Clinical (qualified as clinical testing)
- Clinical protection (must be qualified with "clinically proven extra effective wetness protection", and must demonstrate 30% or more sweat reduction within a period of 24 hours)
- Clinically tested/proven/trials
- Body responsive
- Controls odour/Anti-odorant

Hair Care

NON-THERAPEUTIC CLAIMS	THERAPEUTIC/HEALTH CLAIMS
Removes loose dandruff flakes	 Anti-dandruff products* Controls/Eliminates/Prevents dandruff*
 Strengthens hair Repairs split ends/dry/damaged hair Thickens the look of/curls/lifts eyelashes 	Stimulates hair growthStimulates eyelash growth
Thickens hair	 Prevents/Treats alopecia Prevents hair loss/ thinning
Removes hair	Inhibits/Stops hair growth
Healthy hair	
Penetrates root to tip	

- Revitalizes hair/hair's beauty
- Contains sunscreen / UV filters (for hair products only)
- Any effect on living tissue (e.g. hair follicles)

*Refer to Health Canada *Anti-Dandruff Product*s Monograph: <u>http://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq.do?atid=antidandruff_anitpelliculaire&lang=eng</u>

Nail Care

NON-THERAPEUTIC CLAIMS

- Promotes nail growth by protecting from physical damage (abrasion, chipping, breaking)
- Repairs/Strengthens/Hardens nails

THERAPEUTIC/HEALTH CLAIMS

• Promotes nail growth (physiological)

• Antifungal

Column II – Therapeutic/Health Claims Examples of claims that must be assessed by HC prior to market authorization **The list is not exhaustive**

THERAPEUTIC/HEALTH CLAIMS

- Hyperhidrosis
- Persistent protection (usually significantly greater than 24 hours) based on a mechanism of action that modifies organic function
- Problem /Excessive perspiration
- References to perspiration from hormonal/endocrine changes or malfunction
- Clinical (unqualified)
- Clinical protection (unqualified)
- Clinical/Therapeutic strength/effect/action

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**

Intimate Products

NON-THERAPEUTIC CLAIM

- Enhances intimacy
- Enhances/Increases sex experience/sexual pleasure by lubricating
- Product is pH-balanced
- Tingling/Warm/Cool sensation
- Feels like natural moisture

Column II – Therapeutic/Health Claims Examples of claims that must be assessed by HC prior to market authorization **The list is not exhaustive**

THERAPEUTIC/HEALTH CLAIMS

- Enhances sperm motility / Improves chances of conception
- · Contains spermicide/spermicidal
- Helps maintain normal pH level
- pH-balanced to prevent infection
- Increases libido/desire
- Produces/Prolongs erection/orgasm
- Stimulates genital tissue
- Vaginal tightening/contracting
- Desensitizing / Delays orgasm

- Lubricates
- Replenishes/Restores/Replaces vaginal/personal moisture

Oral Care

NON-THERAPEUTIC CLAIMS	THERAPEUTIC/HEALTH CLAIMS
Cleans/Bleaches/Whitens/Brightens/Polishes teethRemoves stains	Removes permanent stains
 Prevents/Reduces tartar build-up/deposit (by brushing only) Removes/Reduces plaque (by brushing only) 	 Prevents plaque/tartar build-up/deposit/formation by chemical or antimicrobial action Anti-plaque / Anti-tartar Fights/Treats plaque/tartar
 Kills bacteria that can cause bad breath Fights bad breath Reduces mouth odours 	 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
	 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/nhpid-bdipsn/atReq.do?atid=oral.health.sante.bucco.dentaire&lang=eng

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

Skin Care/Makeup	
NON-THERAPEUTIC CLAIMS	THERAPEUTIC/HEALTH CLAIMS
Heals dry skin	 Heals (unqualified)
Repairs dry skinReplenish/Protect the skin's moisture barrier	Repairs (damaged) skinRepairs the skin's moisture barrier
 Protects/Relieves/Soothes dry skin Cools/Soothes skin after shaving/epilation Cleans/Cleanses skin Prevents/Protects against nicks/cuts/irritation during shaving 	 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
Hydrates/Lubricates/MoisturizesReinforces/Strengthens skin (via moisturization)	
Improves the look of acne scars	Removes/Reduces scars
 Relieves redness/itching due to dryness 	 Reduces redness due to rosacea (or other circulatory-related causes) Reduces redness (due to sunburns) Any reference to rosacea
Reduces the look of age spots	 Eliminates age spots Prevents new spots from appearing** Prevents the onset/emergence of age spots** Any impression or reference to skin de-pigmentation
 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) 	 Prevents photoaging and/or related damage**
 Smoothes wrinkles Wrinkles appear/look reduced Reduces the look of dark circles 	
 Firms/Tightens/Tones/Conditions/Smoothes/Softens skin Improves elasticity/resiliency Skin feels/appears firm/lifted 	• Provides the effect of a medical/surgical procedure
Reduces the look of cellulite	 Reduces/Controls swelling/edema Weight management Weight/Fat loss Reduces/Removes/Treats cellulite
Reduces puffiness	Reference to lipodraining
Sloughs off dead skin cellsReduces ingrown hair/razor bumps (via exfoliation)	 Any reference to action at a cellular level (living) / circulation Reference to action on tissue/body/cells
Improves the texture of skin/retextures	
 Deep cleans pores Unclogs/Tightens pores Makes pores smaller 	Cleans wounds

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

Skin Care/Makeup (Cont'd)

NON-THERAPEUTIC CLAIMS THERAPEUTIC/HEALTH CLAIMS Removes/Absorbs oil Cleanser for acne-prone skin Anti-blemish Covers blemishes/acne Clears skin (acne)*** • Heals/Prevents/Stops/Treats acne***[†] Acne = blemishes, zits, spots, blackheads, comedones, pimples, breakouts, etc Covers / Conceals • Bronzed, suntanned look SPF/ UV/UVA/UVB** Sunburn protectant** (Contains) Sunscreen** Protects sun damaged skin** Kills odour causing bacteria Kills pathogens/germs/ bacteria (other than odour ٠ • 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/nhpid-bdipsn/atReq.do?atid=skin_peau&lang=eng

**Refer to Health Canada's *Sunscreen* Monograph:

http://webprod.hc-sc.gc.ca/nhpid-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

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**

Other Claims

Column II – Therapeutic/Health Claims Examples of claims that must be assessed by HC prior to market authorization **The list is not exhaustive**

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 healthBiological/Therapeutic action/effect
ORGANIC	
• Organic (product must meet a recognized standard for	

organic certification)

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