# 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	<ul> <li>Anti-dandruff products*</li> <li>Controls/Eliminates/Prevents dandruff*</li> </ul>
<ul> <li>Strengthens hair</li> <li>Repairs split ends/dry/damaged hair</li> <li>Thickens the look of/curls/lifts eyelashes</li> </ul>	<ul><li>Stimulates hair growth</li><li>Stimulates eyelash growth</li></ul>
Thickens hair	<ul><li> Prevents/Treats alopecia</li><li> Prevents hair loss/ thinning</li></ul>
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
<ul><li>Cleans/Bleaches/Whitens/Brightens/Polishes teeth</li><li>Removes stains</li></ul>	Removes permanent stains
<ul> <li>Prevents/Reduces tartar build-up/deposit (by brushing only)</li> <li>Removes/Reduces plaque (by brushing only)</li> </ul>	<ul> <li>Prevents plaque/tartar build-up/deposit/formation by chemical or antimicrobial action</li> <li>Anti-plaque / Anti-tartar</li> <li>Fights/Treats plaque/tartar</li> </ul>
<ul> <li>Kills bacteria that can cause bad breath</li> <li>Fights bad breath</li> <li>Reduces mouth odours</li> </ul>	<ul> <li>Kills germs/pathogens</li> <li>Kills odour causing germs</li> <li>Germicide</li> <li>Antiseptic</li> <li>Antiviral</li> <li>Any impression or reference to disease prevention</li> <li>Any impression or reference to pain or irritation</li> </ul>
	<ul> <li>Anti-cavity* / Anti-gingivitis / Anti-sensitivity</li> <li>Claims for fluoride effect* / Contains fluoride*</li> <li>Any implication of effect below the gum line</li> <li>Desensitizes teeth/gums</li> <li>Strengthens enamel*/teeth*/gums</li> <li>Any effect produced by product ingestion</li> </ul>

\*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	<ul> <li>Heals (unqualified)</li> </ul>
<ul><li>Repairs dry skin</li><li>Replenish/Protect the skin's moisture barrier</li></ul>	<ul><li>Repairs (damaged) skin</li><li>Repairs the skin's moisture barrier</li></ul>
<ul> <li>Protects/Relieves/Soothes dry skin</li> <li>Cools/Soothes skin after shaving/epilation</li> <li>Cleans/Cleanses skin</li> <li>Prevents/Protects against nicks/cuts/irritation during shaving</li> </ul>	<ul> <li>Calms/Protects/Relieves/Soothes abrasions/bites/insect bites/ cuts/nicks/irritated skin/ inflamed skin/rashes/ sunburns*</li> <li>Numbs</li> <li>Treats burns/infections</li> <li>Any impression or reference to pain or irritation</li> </ul>
<ul><li>Hydrates/Lubricates/Moisturizes</li><li>Reinforces/Strengthens skin (via moisturization)</li></ul>	
Improves the look of acne scars	Removes/Reduces scars
<ul> <li>Relieves redness/itching due to dryness</li> </ul>	<ul> <li>Reduces redness due to rosacea (or other circulatory-related causes)</li> <li>Reduces redness (due to sunburns)</li> <li>Any reference to rosacea</li> </ul>
Reduces the look of age spots	<ul> <li>Eliminates age spots</li> <li>Prevents new spots from appearing**</li> <li>Prevents the onset/emergence of age spots**</li> <li>Any impression or reference to skin de-pigmentation</li> </ul>
<ul> <li>Diminishes/Reduces the look or the signs of aging</li> <li>Skin looks visibly younger/revitalized/radiant/refreshed/ energised/rejuvenated/brightened</li> <li>Protects from environmental stressors (if qualified as causing dry skin)</li> </ul>	<ul> <li>Prevents photoaging and/or related damage**</li> </ul>
<ul> <li>Smoothes wrinkles</li> <li>Wrinkles appear/look reduced</li> <li>Reduces the look of dark circles</li> </ul>	
<ul> <li>Firms/Tightens/Tones/Conditions/Smoothes/Softens skin</li> <li>Improves elasticity/resiliency</li> <li>Skin feels/appears firm/lifted</li> </ul>	• Provides the effect of a medical/surgical procedure
Reduces the look of cellulite	<ul> <li>Reduces/Controls swelling/edema</li> <li>Weight management</li> <li>Weight/Fat loss</li> <li>Reduces/Removes/Treats cellulite</li> </ul>
Reduces puffiness	Reference to lipodraining
<ul><li>Sloughs off dead skin cells</li><li>Reduces ingrown hair/razor bumps (via exfoliation)</li></ul>	<ul> <li>Any reference to action at a cellular level (living) / circulation</li> <li>Reference to action on tissue/body/cells</li> </ul>
Improves the texture of skin/retextures	
<ul> <li>Deep cleans pores</li> <li>Unclogs/Tightens pores</li> <li>Makes pores smaller</li> </ul>	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\*\*\*<sup>†</sup> 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	
<ul> <li>Dermatologist tested</li> <li>Recommended/Developed by doctors/ dermatologists/ beauticians</li> </ul>	Prescription strength / Rx / Pr
<b>INGREDIENT</b> (e.g. vitamins, antioxidants, etc.)	
<ul> <li>Ingredient/Vitamin/Mineral/Antioxidant produces cosmetic benefit</li> <li>Contains vitamins which act as antioxidants to preserve product integrity or to keep product fresh</li> </ul>	<ul> <li>Active/Effective/Medicinal/Therapeutic ingredient</li> <li>Contains/Source of vitamin X (unqualified)</li> <li>Contains/Source of vitamins which act as antioxidants (unqualified)</li> <li>Any reference to therapeutic effect of vitamins/ antioxidants (e.g., free radical scavenging)</li> <li>Any reference to repairing damage</li> <li>Any reference to action at a cellular level (living)</li> <li>Any reference to dose units (e.g. IU)</li> </ul>
HEALTHY	
<ul><li>Healthy (from an appearance perspective)</li><li>Skin looks and feels healthy</li></ul>	<ul><li>Promotes health</li><li>Biological/Therapeutic action/effect</li></ul>
ORGANIC	
• Organic (product must meet a recognized standard for	

organic certification)

### For more information contact:

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