

INTERIM NOTIFICATION PROGRAM **LOW RISK VETERINARY HEALTH PRODUCTS**

CLAIMS GUIDANCE

This document is intended to provide guidance on the type of claims that can be made for a Low Risk Veterinary Health Product (LRVHP) eligible for Notification.

A claim is defined as the statement made about the expected benefits to the animal receiving the LRVHP. Limits have been set for the types of claims that can be made for products being issued a notification number. The label can only carry limited claims for possible health benefits. A label includes any legend, word, mark or tag attached to, included in, belonging to, or accompanying any LRVHP. An outer label means the label on or affixed to the outside of a package of a LRVHP. An inner label means the label on or affixed to an immediate container of a LRVHP. Leaflets or tags attached to the LRVHP are also considered labels. Notifiers, or Canadian representatives if the notifier is not located in Canada, are required to certify that there is objective and credible evidence to support a reasonable expectation of effectiveness for the claims made for the product. Information on the label must not be false, misleading or deceptive, or likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

The following information describes what types of claims are permitted and not permitted on a LRVHP product label, what evidence is needed to support the claim, as well as guidance on text content of the claim.

General Health Claims (permitted)

A General Health Claim is a claim that relates the ingredients of a veterinary health product to health maintenance. Claims should only refer to the maintenance of normal physiology, not to its modification. Claims that use the terms "help maintain", "support", "promote", "enhance", "is a factor in", "contribute", "has a role in", etc. and are not associated with a specific disease, condition or injury are generally considered to be general health claims and are acceptable. Structure-function claims are considered general health claims. These claims describe the effect of an ingredient on a structure or physiological function in the animal, or a product's support of an anatomical, physiological, or mental function. Only these types of claims are permitted for veterinary health products eligible for Notification. When a function claim is made about a benefit of a nutrient, the product should be at least a dietary source of the nutrient. See Appendix 1 for specific examples of General Health Claims.

Therapeutic Claims (not permitted)

Claims are considered therapeutic if they are intended to prevent, diagnose, cure or alleviate a disease or condition in the animal or alleviate an injury suffered by the animal, modify the physiology of the animal so as to alter its natural development, productivity, quality or reproductive capacity, or modify the effect of another veterinary drug product. Claims that use the terms "prevent", "treat", "cure", "diagnose", "reduce", "relieve", "alleviate", etc., associated with a disease, a condition or an injury are generally considered to be therapeutic claims and are not acceptable for products eligible for a notification number. Disease reduction claims are considered therapeutic claims. Products bearing therapeutic claims require rigorous evaluation and authorisation by Health Canada as a veterinary drug.

Any therapeutic claim, whether made on a label, advertisement, website or any other representation, will render the product ineligible for Notification. See Appendix 1 for specific examples of Therapeutic Claims.

Claims on Homeopathic Products

Homeopathic products containing one single ingredient can only carry the claim "Homeopathic Medicine", "Homeopathic", "Homeopathic Remedy" or "Homeopathic Preparation". Multiple ingredient homeopathic products can have general health claims based on evidence in Homeopathic Materia Medica.

Claims on Traditional Chinese Medicine Products

When a product has been used for at least 50 consecutive years within the healing paradigm of Traditional Chinese Medicine (TCM), and the product is prepared and used in the same way, a traditional use claim can be used. If the claim uses terminology specific to TCM, it should be specified in the claim (e.g. In Traditional Chinese Medicine "used to replenish Qi...").

Evidence to support claims

All claims must be true, valid and not misleading, and should not lead to unsafe or inappropriate use of the product. Evidence must relate to the whole product or the same active constituent(s) with similar dosage regime, dosage form and route of administration to the product/ingredient for which the claim is made. Sponsors must hold evidence in line with these guidelines before claiming an intended use or indication for the product. This evidence may be called in and evaluated by Health Canada where a safety concern arises, claims appear to be misleading, or in response of a complaint. See Appendix 2 for examples of useful references.

Types of evidence:

- Descriptive studies, case reports of relevant expert committees;
- Texts, such as pharmacopoeias or monographs approved by Health Canada;
- Pharmacopoeial evidence or relevant textbooks for traditional use claims;
- Other evidence based reference texts, including Homeopathic Materia Medica;
- Evidence obtained from well-designed controlled trials. In case of a homeopathic medicine, evidence from well-designed, controlled homeopathic proving;
- Evidence obtained from well-designed analytical studies preferably from more than one centre or research group, including epidemiological cohort and case-control;
- Evidence from multiple time series with or without intervention, including within country and between country population studies.

Note: In practice, the sources of most evidence will be peer-reviewed published papers and evidence based reference texts. However, other evidence that meets the requirements may also be acceptable. Websites evaluating peer-reviewed published evidence may be a source of suitable evidence.

Claims and Text Content

Absence of ingredients

Manufacturers may refer to the absence of ingredients in case the ingredient has a safety concern. This is considered only acceptable for preparations that previously contained the ingredient or that belonged to that class of products in which the ingredient could be expected (e.g. Thiaminase-free Horsetail product).

Presence of ingredients

Manufacturers can list ingredients or make a claim based on the presence of an ingredient, only if the ingredient(s) is/are present in sufficient quantities so as to likely have the expected effect in the animal.

Absence of side effects

Statements regarding the absence of a side effect are permitted provided that scientific evidence exists to support the statement, such that the incidence of a side effect is comparable to when a placebo is taken. If the evidence of a particular side effect exceeds that for the placebo, the statement regarding the absence of side effects should not be used.

Look-alike, Sound-alike Health Product Names

Look-alike, sound-alike (LA/SA) refers to names of different products that have orthographic similarities when written or similar phonetics when spoken. These similarities may pose a risk to health by causing confusion in prescribing, dispensing, or the administration of veterinary health products. It is the manufacturer's responsibility to ensure that any product name will not cause potential confusion.

Comparisons

Manufacturers are encouraged to promote health products on their own merits in a positive manner instead of by comparison with other products. Comparisons with other drugs or with the selected properties of other health products are potentially misleading. The terms "better", "stronger" implies superiority and may create an erroneous impression regarding the value and merit of the product. Efficacy comparisons are discouraged if the overall effect is considered promotional. Statements such as "...without the negative effects of pharmaceuticals" should not be used.

Endorsements, Seals of Approval, Logos

Endorsement of products by health professionals, celebrities, and others are acceptable provided that the endorsements are consistent with the expected actions of the health product and supporting data is available.

Potentially Misleading Promotional Terms

As no health product is completely safe and without potential for an adverse effect, the unqualified terms "safe", "non-toxic", "non-poisonous" or "non-allergenic" are considered to be generally misleading and unacceptable for claims. However, in the context of providing adequate directions for use, the word "safe" may be part of the directions (e.g. "for safe use, do not exceed two tablets daily"). Only products of animal or vegetable origin, obtained with a minimal of processing in order to retain most of the original constituents, may be described as "natural source". Words like "natural alternative to..." or "alternative to..." will imply that the product can be used instead of a product used for a therapeutic purpose. This is both misleading and potentially risky for the animal in that it would delay appropriate medical treatment.

APPENDIX 1:

EXAMPLES OF ACCEPTABLE AND NON-ACCEPTABLE CLAIMS FOR NOTIFIABLE LOW RISK VETERINARY HEALTH PRODUCTS

Note: These are examples only.

	General Health Claim (Acceptable for Notification)	Therapeutic Claim (Non-acceptable for Notification)
General health	"Helps maintain a healthy immune function"	"Preventing, treating, curing immune system dysfunction"
	"Supports natural defences"	"Prevents infections"
	"Helps to maintain physical performance" "For the maintenance of energy and general vitality"	"Increases physical performance"
	"A factor in the maintenance of good health"	Any statements regarding "disease resistance"
Skin health	"Helps maintain a healthy skin/coat"	"To relieve hot spots", "For wound healing"
	"Has a role in maintaining the integrity of skin, hair and hooves"	"For the prevention of laminitis"
Digestive system health	Claims referring to flatulence, odour of stool, digestibility, well-formed stools, consistency of stools, maintaining or promoting regularity.	"Prevents, treats or cures gum disease, gingivitis, periodontal disease"
		"Prevents, treats or cures diarrhea, constipation, colitis, inflammatory bowel disease, or other specific gastrointestinal diseases"
		"Relieves symptoms of gastric or duodenal ulcer" "For the relief of colic" "Treats indigestion"
		"A natural approach to bowel disease"
		"Discourages vomiting" "Acts as a laxative"
	"For the treatment of parasites"	
Prebiotics	"Promotes a healthy gut microflora"	"Helps combat digestive problems"
Probiotics	"Promotes a healthy gut flora"	"Decreases intestinal disorders"
	"For good intestinal health" "Maintains balance of healthy microflora"	"Prevents/controls diarrhea", "Helps avoid diarrhea associated with antibiotic use"

	<i>"Provides friendly bacteria that play an important role in basic digestion, proper metabolism and overall well-being"</i>	<i>"Helps to reduce biomarkers of allergy"</i>
	<i>"Supports the function of the immune system"</i>	<i>"Reinforces the barrier effect against pathogens"</i>
Urinary system health	<i>"Helps maintain/promote urinary tract health"</i>	<i>"Treats, cures or prevents FUS, FLUTD, struvite uroliths, etc." "Soothes bladder infections" "For urinary incontinence" "Supports the process of dissolving crystals"</i>
Circulatory system health	<i>"For the normal functioning of the heart" "Helps promote heart health"</i>	<i>"Reduces the risk of heart disease"</i>
	<i>"Support for healthy heart and arteries" "Contributes to vascular health"</i>	<i>"Prevents, treats or cures any cardiac condition"</i>
Respiratory system health	<i>"For the health of respiratory organs"</i>	<i>"For the treatment of bronchitis" "Prevents the recurrence of secondary infections"</i>
	<i>"Supports the health of the respiratory tract, helps maintain moisture balance in nose, throat and lungs"</i>	<i>"Relieves coughing, shortness of breath" "Clears sinus infections"</i>
Musculo-skeletal system health	<i>"Promotes normal/optimal growth and development of the musculo-skeletal system"</i>	<i>"Prevents, treats, or cures any musculo-skeletal disease or condition"</i>
	<i>"Supports bone health" "May help maintain joint and bone health" "Promotes joint health"</i>	<i>"For inflammation due to osteoarthritis" "To reduce swelling and lameness"</i>
	<i>"May help in the improvement of joint health and function" "helps support the function of the joints"</i>	<i>"For the treatment of degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses"</i>
Nutrition	Nutritional claims starting with <i>"has a role in..."</i> , <i>"is involved in..."</i> , <i>"required for..."</i> , or <i>"needed for..."</i> normal metabolic or physiological functions. (e.g. <i>Vitamin C has a role in maintaining healthy cartilage, tendons and bone</i> , <i>"Selenium has a role in preventing cellular oxidation"</i>)	<i>"Prevents, cures or treats the progression of renal disease, diabetes, heart disease etc."</i>
	Claims for combination vitamins and mineral supplements <i>"Factor in the maintenance of good health"</i>	<i>"Prevents, treats or cures pruritus, itchiness, allergic conditions, food allergies, fungal diseases, bacterial diseases"</i>

	<i>"For the maintenance of water and electrolyte balance"</i>	<i>"To correct electrolyte imbalances"</i> <i>"To treat hypokalemia"</i>
	<i>"Promotes satiety"</i>	
	<i>"Helps scavenging free radicals"</i> <i>"has antioxidant properties"</i>	
	<i>"Contributes to promote healthy bones"</i>	<i>"Prevents the progression, or reverses the progression, of osteoporosis"</i>
	<i>"Can help maintain healthy blood glucose levels"</i>	<i>"Regulates blood sugar levels"</i>
Behaviour	<i>"helps keep the nervous system working properly"</i>	<i>"Prevents, treats or cures primary behavioural disorders and/or aggression"</i>
Disease, injury	N/A	<i>"Prevents, treats, or cures neoplasia/cancer/tumour".</i> <i>"Prevents, treats, or cures allergy or intolerance"</i> <i>"Reduces injury from head trauma"</i> <i>"Provides relief from the effects of epilepsy"</i> <i>"Improves insulin availability and production for diabetic pets"</i> <i>"Naturally helps Cushing's disease in pets by normalizing adrenal function and balancing corticosteroid levels"</i> <i>"For hypothyroid conditions in pets"</i>

APPENDIX 2

EXAMPLES OF USEFUL REFERENCES

The following resources may be useful in the literature search for efficacy evidence.

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