INTERIM NOTIFICATION PROGRAM
LOW RISK VETERINARY HEALTH PRODUCTS

NOTIFICATION APPLICATION FORM GUIDANCE

Section #	GUIDANCE
1-2	**BRAND NAME** The brand name refers to the proprietary or product name and should be the same as on the product label. This name may, or may not, include the name of the manufacturer. This name should be unique to the manufacturer and distinguish the product from all others marketed by the firm. The brand name should not be false, misleading or deceptive or likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety. If the product is part of a specific product line, both the product line and the individual product name should be indicated here. Brand names must be in English or French only. One brand name per Notification Form. A label includes any information attached to, or accompanying a product.
2-1	**NOTIFIER** The information to be provided here pertains to the Notifier in whose name the Notification is filed and, where a Notification Number is to be issued, the company in whose name the Notification Number will be registered (i.e. the Notification Number owner whose name must be included on the product label). The Notifier is the person, including an association or partnership, who under their own name, or under a trade-, design- or word mark, trade name or other name, word or mark controlled by them, sells the product. Indicate the full legal name of the Notifier. Do not abbreviate the company name. Note that the Notifier is not necessarily the company that fabricates or imports the product. If you wish to change the Notifier name after the Notification Number has been issued, an Amendment Notification Form needs to be submitted. Provide the full mailing address of the Notifier. If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number, the city/town, the province/state, the country and the postal code or zip code. It is

	not allowed to use a Post Office (PO) Box instead of street/suite to describe the Notifier's address.
2-2	**PRINCIPAL CONTACT FOR THE NOTIFIER** Provide the name of the Principal Contact (i.e. the person who represents the Notifier) and the information needed to contact that individual, i.e. telephone and fax numbers, position/title, email address, and if applicable, language preference. The full mailing address is not required if the Principal Contact has the same address as the Notifier indicated in section A. If the Principal Contact of the Notifier company changes, the Program Administrator must be notified of this change. Note that this is NOT necessarily the contact for the subject Notification Application but the Principle Contact for the Notifier at the address given.
2-3	**CONTACT FOR THIS NOTIFICATION APPLICATION** Information provided in section C pertains to the contact specific to the subject Notification Application, i.e. the person/company to whom the Program Administrator should direct correspondence about this Notification Application and this product. This may be an employee of the Notifier, or an individual contracted from another company on behalf of the Notifier (for example a consultant). Enter the name of the company to which the Notification Application contact belongs (i.e. is a staff member). Do not abbreviate the company name. If the contact does not belong to a company, enter the name of the contact. Enter the address of the company identified in section C. If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number, the city/town, the province/state, the country and the postal code or zip code. Include the PO Box number if a post office box is used. The full mailing address is not required if the contact person has the same address as the Notifier company identified in section A. If the Principal Contact is also the contact for this Notification Application, please check the box "Contact same as B". Provide the information needed to contact that individual, i.e. telephone and fax numbers, position/title, email address, and if applicable, language preference.
2-4	**CANADIAN REPRESENTATIVE** If the Notifier (see definition below) is not located in Canada, a person located in Canada must be designated as Canadian Representative. The Canadian Representative is responsible for the product in Canada. There can only be one Canadian representative for each product. Complete section D only if the address of the Notifier identified in section A is NOT located in Canada. The Canadian representative must be located in Canada. There can only be one Canadian representative for each product. He or she can be an Importer as well. The importer(s) will be identified in Box E.

	Enter the full name of the Canadian Representative. If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number, the city/town, the province/state, the country and the postal code. Do not edit/change the country name “Canada” in section D. Provide the information needed to contact the Canadian Representative, i.e. telephone and fax numbers, position/title, email address, and if applicable, language preference.
2-5	**NAME OF THE ESTABLISHMENT(S) FABRICATING, PACKAGING, LABELLING, IMPORTING OR DISTRIBUTING THE PRODUCT** The following definitions apply to this section. **Fabricator:** A person who fabricates or processes a Low Risk Veterinary Health Product (LRVHP) for the purpose of sale, but does not include a veterinarian or a pharmacist who compounds a LRVHP for the purpose of sale to a specific animal owner. **Packager:** A person who puts a LRVHP in its immediate container. **Labeller:** A person who affixes the inner or outer label of the LRVHP. A label includes any written, electronic, or graphic communications such as legends, words or marks attached to, included in, belonging to or accompanying the LRVHP. **Importer:** A person who imports a LRVHP into Canada for the purpose of sale. This includes bulk LRVHPs. **Distributor:** A person, other than the fabricator, who sells or distributes a LRVHP to another person for the purpose of further sale by that other person. Provide the full mailing address of the establishment(s) that fabricates, packages, labels, imports or distributes LRVHP. Provide the company name and if a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number, the city/town, the province/state, the country and the postal code or zip code. Indicate the type of activity that takes place at each location. This applies to all sites, in Canada or in foreign countries.
3-1	**PRODUCT TYPE** Select the product type: **Homeopathic** Homeopathic preparations must be prepared according to the Homeopathic Pharmacopoeia of the United States (HPUS), the Homöopathische Arzneibuch (HAB), the Pharmacopée française (PhF), the European Pharmacopoeia (Ph.Eur), or the Encyclopedia of Homeopathic Pharmacopoeia (EHP) and administered at the minimum potency indicated on the List or higher. **Traditional Chinese Medicine**

	Ingredients must be prepared and used according to Traditional Chinese Medicine. **All Other Low Risk Veterinary Health Products** Excluding homeopathic and Traditional Chinese Medicines.
3-1a	**Proprietary Information** Indicate if your product contains any proprietary blends, proprietary flavourings or proprietary fragrance mixtures.
3-2	**INTENDED SPECIES (as it appears on label)** Indicate for which species the product is intended for (i.e., cats, dogs, horses not intended for food, or dairy cattle). A label includes any information attached to, or accompanying a product.
3-3	**ROUTE OF ADMINISTRATION (as it appears on label)** Indicate the recommended route of administration. Products delivered through the following routes of administration are excluded from the Interim Notification Program: Implants; Injectable; Inhalation; Intra-mammary; Intra-uterine; Ophthalmicand Transdermal patches. A label includes any information attached to, or accompanying a product.
3-4	**DOSAGE FORM (as it appears on label)** Indicate the form of the product, using the codes/descriptions set out in the list below, which best describes the product: *Code* / *Form/Description* 1 Tablet/Capsule 2 Chewable tablet 3 Liquid 4 Suspension 5 Aerosol/Pump spray 6 Powder 7 Cream 8 Lotion 9 Gel 10 Ointment 11 Bolus 12 Other_____ (Please describe) A label includes any information attached to, or accompanying a product.

3-5c	**ACTIVE (MEDICINAL) INGREDIENTS (should be the same as on the product label)** The active (medicinal) ingredients must conform to the "List of Admissible Substances" established by Health Canada and meet the conditions described on this list. List the active (medicinal) ingredient (s) that contribute to the proposed use of the product, by its/their proper name (mandatory) and common name (optional). **Standard or grade:** For homeopathic medicine indicate the relevant homeopathic pharmacopoeia (HPUS, HAB/GHP, PhF, Ph E or EHP). **Proper Name:** The Proper Name refers to the scientific name of the substance and must be identified. **For vitamins -** biotin, folate, pantothenic acid, vitamin A, thiamine, riboflavin, vitamin B_6, vitamin B_{12} and vitamins, C, E and D. **For plant or plant material, an alga, a fungus, a bacterium, an animal material (or an extract thereof) -** The Latin name of its genus and, if any, its specific epithet. (e.g. *Angelica* [genus] *archangelica* [specific epithet]). Helpful websites: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl? (for plants) http://ca.expasy.org/enzyme/enzyme_details.html (for enzymes) **For probiotics -** The proper name should include the species name (i.e. *Lactobacillus*), the specific epithet (i.e. *acidophilus*), subspecies if applicable (i.e. *Lactobacillus animalis* subs *lactis*) and the strain (i.e. *L. acidophilus* BAB1). **For other substances -** The chemical name, referred to in the International Union of Pure and Applied Chemistry Nomenclature. Helpful websites: http://www.chem.qmul.ac.uk/iupac/ http://chem.sis.nlm.nih.gov/chemidplus/ **Common Name:**

	The common name refers to the name the substance is commonly known as. For example *Zingiber officinale* (proper name) is commonly known as ginger (common name). In some cases the proper and common names of a substance are identical, for example: calcium. **Source Material:** The source material is the material from which the substance was derived. When a substance is stabilized in the form of a derivative, this must be indicated, as this stabilizing agent will be present in the final product. Derivatives include salts, esters, resinates, polymers or carrier forms. For plant/animal material, the source material is the part of the plant/animal used or whole plant/organism, if applicable, and the common name of the organism if not adequately captured in the substance name. For bacteria and other unicellular organisms, the source material is the strain (if available) or a description of the cell or organism (e.g. whole, disrupted cell, filaments, colonies, etc.). For isolates, such as fatty acids and amino acids, it is important that the source is identified because the source may influence the activity of the substance. For synthetic duplicates, the source material is the derivative. If there is no derivative then use the term synthetic for source material. Table 1: Examples of source material Mineral: Calcium citrate is the source material for Calcium. Vitamin: Thiamine mononitrate is the source material for Thiamine. Plant: The roots is the source material for *Panax quinquifolius* (American ginseng). Bacteria and other unicellular organisms: Cells are the source material for *Saccharomyces cerevisiae* (Brewers yeast). Probiotics: T-134 is the source material for *Lactobacillus acidophilus.*

	Animal material or extracts thereof: The cartilage of the spiny dogfish shark is the source material for *Squalus acanthias* (Shark cartilage). Isolates: Glucosamine sulphate potassium chloride is the source material for Glucosamine sulphate. Pig pancreas is the source material for Porcine pancreatic enzymes. Fatty acids: Ethyl linoleate from safflower seed oil is the source material for Linoleic acid. Substances from multiple sources: Anchovy, sardine and mackerel oil are the source materials for Fish oil. Synthetic duplicates: Synthetic is the source material for Folate. **Synthetic:** A substance is considered synthetic if it is a semi-synthetic or synthetic duplicate of the substance. If a substance is entirely produced by a chemical process from chemical compounds or partially chemically modified by a process that chemically changes a related starting material (i.e. an isolate or extract of a plant or a plant material, an alga, a fungus or an animal material), it is considered to be synthetic. A substance is considered non-synthetic 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, extracted, isolated, and /or processing such as boiling, steaming etc.). The substance should have the same chemical identity as that in the source material. Substances found in nature that undergo chemical modification in order to increase their stability, absorbability, solubility, etc. (e.g. derivatives, salts etc.) are considered to be synthetic. Example: vitamin E (d-alpha-tocopherol) from soybean oil is non-synthetic (natural source), but d-alpha-tocopherol acetate is synthetic. **Strength/potency** (as indicated on the product label): The strength of the active ingredient(s) should be expressed as follows: Discrete dosage form - g or mg

	Powder for oral use - g or mg/mL, g or mg/dosage unit (e.g./5 mL) Liquid for oral use - g or mg/mL, g or mg/dosage unit (e.g./5 mL) Cream ointment, lotion, etc. - mg or mL/g or mg/mL or % Powder for solution - units/dosage units (e.g./20 mL vial) Potency can be used to express the activity of an active ingredient, including the activity of enzymes, herbs or vitamins. Examples of expressions of potency: Echinacea: 2% cichoric acid per 500 mg Fish oil: 180 mg EPA and 120 mg DHA per 1000 mg Bromelain: 2000 GDU/gram per 300 mg (GDU = gelatine digesting units) Vitamin E: 22.5 IU per 15 mg (IU = International units) Cellulase: 50 FPU/g per 50 mg (FPU = Filter paper units) Note that the term potency as used here is not applicable to homeopathic medicines. In the case of homeopathic medicines, this column may be left blank. The homeopathic potency (e.g. 12CH) must be listed in the Quantity per dosage unit field. **Quantity per dosage unit:** The dosage unit refers to the tablet, capsule etc. Quantity of the medicinal ingredient in the dosage unit should be based on the proper name of the medicinal ingredient. For example, the quantity of Vitamin E in a product should be the quantity of RRR-alpha-tocopherol and not of RRR-alpha-tocopherol succinate (i.e. the source). Quantity units for vitamins, amino acids, fatty acids, minerals and isolates are milligrams, micrograms or grams (or other appropriate metric equivalent). Quantity units for probiotics are colony forming units (cfu). Quantity units for homeopathic medicines are CH, C, X, D, M, CK, K, M, MK, LM, Q. The unit should be listed in one of the acceptable homeopathic pharmacopoeia. Quantity for extracts is the amount of the extracted medicinal ingredient contained in each dosage unit. If the extract is non-standardized, the extract ratio and quantity crude equivalent must also be provided. **Extract Ratio:** The extract ratio is always expressed as the quantity of crude material (fresh or dry) to extract, regardless of whether it is a liquid or a solid. For example, a tincture (liquid) ratio of 1:5 means that 1 g of crude dried material was used to

	prepare 5 mL of extract. In a solid extract, a ratio of 5:1 means that 5 g of crude material was used to prepare 1 g of extract. **Quantity Crude Equivalent (QCE):** The quantity crude equivalent is the amount of crude dried or fresh, material (amount of original material) from which the ingredient was extracted (per dosage unit). When stating the quantity crude equivalent, it must be indicated whether the amount of the original starting material being referred to is the fresh or dry amount. For example, when 1 g of dried material was dissolved in 5 mL, the quantity per dosage form is 5 mL, the extract ratio is 1:5, and the QCE (dry) is 1 g.
3-6	**EXCIPIENTS (NON-MEDICINAL)** An excipient is any substance added to confer a suitable consistency or form to active substances that are present in a veterinary health product. It refers to any component of a finished dosage form other than the active substances. They may also be called non-medicinal ingredients (NMIs), inerts, additives, and include dyes, flavours, binders, emollients, fillers, lubricants, preservatives etc. It is mandatory to enter the common name of excipients, the proper name is optional. The quantity of excipients present in the product should be expressed in metric units. The purpose of adding the excipient should be entered.
4-1	**RECOMMENDED USE OR PURPOSE (health claim(s) as it appears on label)** Indicate the intended benefit of the product when used according to the recommended dose, duration of use and route of administration. Only products with general health claims are eligible for the Interim Notification Program. Specific therapeutic claims (claims to diagnose, prevent, treat, or cure a disease or abnormal physiological condition) are not allowed. For example, a product could carry the claim that it "may help in the improvement of joint health and function," but not that it is "for the treatment of osteoarthritis". For more information, see the guidance document on permitted health claims. Homeopathic medicines containing one single ingredient can only carry the claim "Homeopathic Medicine", "Homeopathic", "Homeopathic remedy" "Homeopathic Preparation". Multiple ingredient homeopathic medicines can have general health claims based on evidence in Homeopathic Materia Medica. A label includes any information attached to, or accompanying a product.
4-2	**RECOMMENDED DOSE (as it appears on label)**

	Indicate the number of dosage units **(in metric measurements)** and frequency of administration. For example, 2 capsules three times daily. If the dosage form is not discrete (e.g. powder, liquid), the dosage unit may be expressed as teaspoon, tablespoon, ml, grams, scoop, dropper etc. For ointment and creams, where the amount is variable, the medicinal ingredient should be expressed as a percentage and the recommended dose may be stated as "apply sparingly, "apply liberally", or "apply as needed". A label includes any information attached to, or accompanying a product.
4-3	**DURATION OF USE (as it appears on label)** Indicate the duration of use if applicable. A label includes any information attached to, or accompanying a product.
4-4	**PACKAGE SIZES** Identify the package size(s), e.g. bottle - 100 tablets; Tube - 50g.
4-5	**EXPIRY/SHELF LIFE** The expiry/shelf life is the length of time to which the product maintains its labelled potency, purity and physical characteristics.
4-6	**CAUTIONS/ CONTRAINDICATIONS (as it appears on label)** Indicate the cautions/contraindications that will be included on the label. Cautions refer to animal hazards. An example of a caution is: "Do not use in pregnant or lactating animals". An example of a contraindication is: "Not for use in animals with clotting disorders or animals being treated with anticoagulant medication". A label includes any information attached to, or accompanying a product.
4-7	**WARNINGS (as it appears on label)** Indicate the warnings that will be included on the label. Warnings relate to human hazards. An example of a warning is: "Keep out of reach of children".

	A label includes any information attached to, or accompanying a product.

INTERIM NOTIFICATION PROGRAM

LOW-RISK VETERINARY HEALTH PRODUCTS

NOTIFICATION APPLICATION FORM

1-2 BRAND NAME (proprietary or product name, as it appears on the label)

2-1 NOTIFIER (this will be the Notification Number Holder)

Company/Notifier Name (Full Legal Name – no abbreviations)	**Address:** Number-Street/Suite/Post Office Box City/Town Province/State Country Postal/Zip code Telephone Number: Ext.: FAX Number: E-mail:

2-2 PRINCIPAL CONTACT FOR THE NOTIFIER (Person Attesting)

Name of the Principal Contact :	**Address:**
	☐ Same as **A** ☐ Other, specify below
Title:	Number-Street/Suite/Post Office Box
	City/Town
Company Name (if different from Notifier):	
	Province/State
	Country
	Postal/Zip code
	Telephone Number:
	Ext.:
	FAX Number:
	E-mail:

2-3 CONTACT FOR THIS NOTIFICATION APPLICATION

☐ Contact same as "**B"**

Name	**Address:**
	☐ Same as "**A"** ☐ Other, specify below

Title **Company name** (if different from Notifier)	Number-Street/Suite/Post Office Box City/Town Province/State Country Postal/Zip Code Telephone Number: Ext: FAX Number: Email:

2-4 CANADIAN REPRESENTATIVE (Complete ONLY where Address in "**A**" is not in Canada)

Name of Representative (Full Name – no Abbreviations **Title**	**Address:** ☐ Same as "**C**" ☐ Other, specify below Number - Street/Suite/P.O.Box

Company Name (if different from Notifier)	City/Town Province/State Postal/Zip code **CANADA** Telephone Number: Ext: FAX Number: E-mail:

2-5 NAME OF THE ESTABLISHMENT(S) FABRICATING, PACKAGING, LABELLING, IMPORTING OR DISTRIBUTING THE PRODUCT

Company Name: Number-Street/Suite/Post Office Box City Province/State Postal/Zip Code Country	☐ Fabricator ☐ Packager ☐ Labeller ☐ Importer ☐ Distributor
Company Name: Number-Street/Suite/Post Office Box City Province/State	☐ Fabricator ☐ Packager ☐ Labeller ☐ Importer

Postal/Zip Code Country	□ Distributor

3-1. Product Type

- Homeopathic
- Traditional Chinese Medicine
- All Other Low Risk Veterinary Health Products

3-1a. Proprietary Information

- Does your product contain a Proprietary Active Blend?
- Does your product contain a Proprietary Excipient Blend?
- Does your product contain a Proprietary Flavouring Mixture?
- Does your product contain a Proprietary Fragrance Mixture?

3-2 INTENDED SPECIES (As it appears on the label)

- Dogs
- Cats
- Horses (not intended for food)
- Dairy cattle

3-3 ROUTE OF ADMINISTRATION (as it appears on the label):

- Oral
- Topical
- Otic
- Dental/Periodontal

3-4. DOSAGE FORM (as it appears on the label):

Description

Other

3-5c ACTIVE (MEDICINAL) INGREDIENTS (should be the same as on the product label)

Ingredient Number	Standard or grade (*for homeopathic medicines only)*	Proper Name	Common Name (optional)	Source Material	Synthetic	
					Yes	No
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

Ingredient number	Strength (including units)	Quantity per dosage unit	If extract, state Ratio or Quantity Crude Equivalent (for non-standardized extracts)	
			Fresh	Dry
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

3-6. EXCIPIENTS (NON-MEDICINAL) INGREDIENTS (should be the same as on the product label)

Common Name	Proper Name (optional)	Quantity	Purpose

4.1 RECOMMENDED USE OR PURPOSE (Health Claim (s), as it appears on the label):

4-2 RECOMMENDED DOSE (as it appears on the label)

4-3 DURATION OF USE (as it appears on the label)

○ N/A (not required)

○ Specify

4-4 PACKAGE SIZES

4-5 EXPIRY/SHELF LIFE

4-6 CAUTIONS/ CONTRAINDICATIONS (as it appears on label)

4-7 WARNINGS (as it appears on the label)

ATTESTATION

I attest that:

a) There is objective and credible evidence demonstrating that the product is safe;
b) There is objective and credible evidence to support a reasonable expectation of effectiveness when the product is used as intended;
c) The manufacturing practices and quality control systems used to manufacture, package, label, distribute and store this product will comply with the Good Manufacturing Practices requirements described in the relevant guideline and are similar to the requirements for Natural Health Products used in humans;
d) Labelling shall comply with the Labelling Guidance and will appear in the two official languages, English and French;
e) Product labelling information and any other information supplied to the users will match the information provided on the Notification Form (e.g. Health Claims) and comply with the conditions of the List of Admissible Substances (e.g. contraindications, cautions and warnings);
f) No specified risk materials (SRMs) are used for manufacturing and/or in the processing of this product. (SRMs are the skull, brain, trigeminal ganglia (nerves attached to the brain), eyes, tonsils, spinal cord and dorsal root ganglia (nerves attached to the spinal cord) of cattle aged 30 months or older; the distal ileum of cattle of all ages. This does not apply to material originating from a country that is designated as being free from Bovine Spongiform Encephalopathy(BSE) in accordance with the Health of Animals Regulations;
g) If the product is intended for food producing animals (including horses and dairy cattle), the product is not be added to feed in circumstances where the Feeds Regulations would apply;
h) If the product is intended for horses, the label will state either " Do not use in horses intended for food" or "Do not use in horses intended for food as a withdrawal period has not been established";
i) A post-market surveillance program will be established and any adverse event or product recall will be documented and reported to the Program Administrator according to the Adverse Event Reporting Guidance. Also, an adverse event report will be provided yearly when renewing the notification;
j) All the conditions of the Interim Notification Program are met;
k) All information presented in the notification form is true and correct; and
l) Either the Notifier or the Canadian Representative will inform Health Canada of any change concerning the information provided in this notification form or of any change that would relate to any of the above attestations.

Name of Author	**Title** **Company**
Signature	**Date**

ATTESTATION FOR CANADIAN REPRESENTATIVE (To be completed by the Canadian Representative ONLY when a Canadian Representative is assigned in section D)

This notification form for a low risk veterinary health product has been submitted and you are designated as the Canadian Representative.

This is to confirm that you accept to be the Canadian Representative for this product.

If the Notifier is not located in Canada, a person located in Canada must be designated as Canadian Representative. There can only be one Canadian Representative for each product. The Canadian Representative is responsible for the sale of the product in Canada and ensuring it meets the requirements of the Interim Notification Program (INP) as outlined in the Overview and other associated documents. The Canadian Representative must have systems in place to be able to effect a recall or take corrective actions in a timely manner for all products in Canada. This includes taking corrective action should Health Canada consider that the product does not meet the requirements of the INP and the relevant regulatory provisions or that it is unsafe or likely to cause the public to be deceived.

By signing below, you confirm that you accept to act as the Canadian Representative for the product.

Name of Canadian Representative	**Title** **Company**
Signature	**Date**