INTERIM NOTIFICATION PROGRAM
LOW RISK VETERINARY HEALTH PRODUCTS

LABELLING REQUIREMENTS

This document is intended to provide guidance on the label requirements for a Low Risk Veterinary Health Product (LRVHP) eligible for Notification.

. Once a notification number is issued, the label should be updated within a maximum period of six (6) months unless otherwise recommended by Health Canada Placing a new label on top of an existing label on a LRVHP is permitted when done according to this guidance and Good Manufacturing Practices Guidelines.

"Label" includes any legend, word, mark or tag attached to, included in, belonging to, or accompanying a 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 and must comply with the outer label requirements. The principal display panel is the main product display surface visible to the user under normal or customary conditions of display or use.

All information required to appear on a label must be in both official languages (i.e., English and French) and clearly and prominently displayed (type size, color contrast, position and spacing, etc*.).* Bilingual information may be affixed on a separate panel or sticker.

Any information on the label must not be false, misleading or deceptive, or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

The label text must be identical to the information provided in the Notification application. Any changes to the proposed label text require the Notifier to submit a Notification amendment application to the Third Party Administrator.

The following is a description of the information that must be included (in both official languages) on a LRVHP product label:

Principal Display Panel (inner and outer label)

- **Statement "For Veterinary Use Only", "Veterinary Use Only", "Animal Use Only " or "For Animal Use Only"**
    - Must immediately precede or follow the brand name, proper name or common name in type not less than half the size of the largest type on the label.
    - If "For Animal Use Only" or "Animal Use Only" is used, the species for which the product is intended must be stated, e.g. "For Cats and Dogs"

- **Brand name**
    - Does not need to be translated.
    - Must not be false, misleading or deceptive, or likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

- **Dosage form**
    - Tablets, syrup, capsules, powder, etc.
    - This information needs to be added only if it is not readily apparent from the Brand name, common name(s) or proper name(s) or indications.

- **Net contents**

  - Net amount (metric) in the immediate container in terms of weight, measure or number (e.g. 500 g of powder, 100 capsules, 500 ml syrup).
  - The following metric symbols are considered bilingual: mg, mcg, µg, l, or L.

- **Notification Number**
  - The Notification Number should be preceded by "NN" and must be displayed on the Principal panel of the label.
  - NN is considered bilingual.

- **Warnings as applicable**
  - These refer to human hazards (e.g. "keep out of reach of children").
  - All products intended for use in horses **MUST** display one of the following statements on the label: "**Not for use in horses intended for food" or "Not for use in horses intended for food as a withdrawal period has not been established**".

Any Other Panel (Inner and outer label)

- **Recommended Use or Purpose (Health Claims)**
  - Homeopathic products containing only one single ingredient can carry the claim "Homeopathic Medicine", "Homeopathic", "Homeopathic Remedy" or "Homeopathic Preparation".
  - Multi-ingredient homeopathic products can have general health claims based on evidence in Homeopathic Materia Medica.
  - For more information about acceptable health claims see the *Claims Guidance* document.

- **Quantity of each active (medicinal) ingredient per dosage unit**
  - It is recommended that the active (medicinal) ingredients be listed in descending order of quantity as follows: proper name (common name), (source), quantity, extract ratio and quantity dried equivalent (as applicable).
  - For tablets and capsules: g or mg per dosage form (e.g. tablet) or dosage unit (e.g. scoop)
  - For oral liquids: g or mg per dosage unit or per mL.
  - For creams, lotions, ointments: mg or mL per g per mL or % (w/w, w/v, v/v as applicable).
  - Potency can be used to express the activity of an active ingredient if applicable (e.g. Fish oil: 180 mg EPA and 120 mg DHA per 1000 mg, Vitamin E: 22.5 IU per 15 mg).
  - For Probiotics: Colony Forming Units (CFUs) per dosage form
  - For homeopathic medicines: the homeopathic potency (CH, C, X, D, M, K, MK, LM, Q).

- **List of Excipients (Non-medicinal ingredients)**
  - Listing the excipients on the label is not mandatory but it is highly recommended.
  - Common names should be used.

- **Adequate directions for Use**
  - Intended species, recommended dose, route of administration, duration of treatment, etc.
  - Statement such as "Can be given during or after meal time" and "Administer orally on a full stomach" are acceptable.

- **Risk Information**
  - Cautions, known adverse reactions and contraindications (e.g. "Do not administer to animals with thyroid disease", "Not for use in pregnant or lactating animals ").

- **Recommended storage conditions**, if any

- **Notifier's name and business address**

- 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 LRVHP.
- The Notifier does not need to be the actual fabricator or the importer.
- The address must be sufficiently complete to permit postal delivery.

- **Contact for Product Information**
  - A toll free telephone number must appear on the label in case of product related questions

- **Contact for Reaction Reporting**
  - In order for end users to be able to report adverse events associated with the use of the product, one of three options must be complied with:
    - the English and French web links www.lrvhp.ca / www.pvsfr.ca and toll-free number 1-866-574-1718 of the Program Administrator (North American Compendiums) must appear on the label (see Label example) OR
    - for Canadian Notifiers the Notifier's adverse event reporting contact information must appear on the lable OR
    - for Notifiers located outside Canada the Canadian Representative's coordinates must appear on the label, along with the Notifier's Adverse Event reporting contact information

- **Production Lot Number**
  - The number should be preceded by one of the following: Lot number, Lot No, Lot, or (L).

- **Expiry Date or Shelf Life**
  - The term "Expiration" or the abbreviations "EXP" or Exp" are considered bilingual.