INTERIM NOTIFICATION PROGRAM
LOW RISK VETERINARY HEALTH PRODUCTS (LRVHPs)
(GOOD MANUFACTURING PRACTICES GUIDELINES)

Introduction

This document is intended to provide guidance on the Good Manufacturing Practices (GMP) requirements for a Low Risk Veterinary Health Product eligible for Notification.

The following is a list of GMP requirements applicable to manufacturers, packagers, labelers, importers or distributors, as the case may be. These requirements are quite similar to the requirements applicable to Natural Health Products used in humans.

You will find a list of definitions in Appendix A

Prohibition

1. (1) Subject to subsection (2), no person shall sell a LRVHP unless it is manufactured, packaged, labelled, imported, distributed or stored, as the case may be, in accordance with this Guideline.

(2) A person may sell a LRVHP that is manufactured, packaged, labelled, imported, distributed or stored, as the case may be, in accordance with requirements that are equivalent to those set out in this Guideline if the LRVHP is imported.

Premises

2. (1) Every LRVHP shall be manufactured, packaged, labelled and stored in premises that are designed, constructed and maintained in a manner that permits the activity to be conducted under sanitary conditions, and in particular that

(*a*) permits the premises to be kept clean and orderly;

(*b*) permits the effective cleaning of all surfaces in the premises;

(*c*) permits the LRVHP to be stored or processed appropriately;

(*d*) prevents the contamination of the LRVHP; and

(*e*) prevents the addition of an extraneous substance to the LRVHP.

(2) Every LRVHP shall be stored under conditions that will maintain the quality and safety of the LRVHP.

Equipment

3. Every LRVHP shall be manufactured, packaged, labelled and stored using equipment that is designed, constructed, maintained, operated and arranged in a manner that

(*a*) permits the effective cleaning of its surfaces;

(*b*) permits it to function in accordance with its intended use;

(*c*) prevents it from contaminating the LRVHP; and

(*d*) prevents it from adding an extraneous substance to the LRVHP.

Personnel

4. Every LRVHP shall be manufactured, packaged, labelled and stored by personnel who are qualified by education, training or experience to perform their respective tasks.

Sanitation Program

5. Every LRVHP shall be manufactured, packaged, labelled and stored in accordance with a sanitation program that sets out

(*a*) procedures for effectively cleaning the premises in which the activity is conducted;

(*b*) procedures for effectively cleaning the equipment used in the activity;

(*c*) procedures for handling any substance used in the activity; and

(*d*) all requirements, in respect of the health, the hygienic behaviour and the clothing of the personnel who are involved in the activity, that are necessary to ensure that the activity is conducted in sanitary conditions.

Operations

6. Every LRVHP shall be manufactured, packaged, labelled and stored in accordance with standard operating procedures that are designed to ensure that the activity is conducted in accordance with the requirements of this Guideline.

7. Every manufacturer, packager, labeller, importer and distributor shall establish and maintain a system of control that permits the rapid and complete recall of every lot or batch of the LRVHP that has been made available for sale.

Quality Assurance

8. (1) Every manufacturer, packager, labeller, importer and distributor shall

(*a*) have a quality assurance person who

(i) is responsible for assuring the quality of the LRVHP before it is made available for sale, and

(ii) has the training, experience and technical knowledge relating to the activity conducted and the requirements of this Guideline; and

(*b*) investigate and record every complaint received in respect of the quality of the LRVHP and, if necessary, take corrective action.

(2) Every LRVHP shall be manufactured, packaged and labelled using only material that, prior to its use in the activity, has been approved for that use by a quality assurance person.

(3) Every LRVHP shall be manufactured, packaged, labelled and stored using methods and procedures that, prior to their implementation, have been approved by a quality assurance person.

(4) Every lot or batch of a LRVHP shall be approved by a quality assurance person before it is made available for sale.

(5) Every LRVHP that is sold and subsequently returned to its manufacturer, packager, labeller, importer or distributor, as the case may be, shall be approved by a quality assurance person before that LRVHP may be made available for resale.

Stability

9. Every manufacturer and every importer shall determine the period of time that, after being packaged for sale, the LRVHP will continue to comply with its specifications when

(*a*) it is stored under its recommended storage conditions; or

(*b*) if it does not have recommended storage conditions, it is stored at room temperature.

Records

Manufacturers

10. Every manufacturer who sells a LRVHP shall maintain the following records at the site at which the LRVHP is manufactured:

(*a*) the master production document for the LRVHP;

(*b*) a list of all ingredients contained in each lot or batch of the LRVHP;

(*c*) records of any testing conducted in respect of a lot or batch of raw material used in the manufacture of the LRVHP;

(*d*) records of any testing conducted in respect of a lot or batch of the LRVHP;

(*e*) a copy of the specifications for each LRVHP that is being manufactured at the site;

(*f*) records demonstrating that each lot or batch of the LRVHP was manufactured in accordance with the requirements of this Guideline;

(*g*) a record of each determination made by the manufacturer in accordance with section 9 and the information that supports that determination;

(*h*) records containing sufficient information to enable the recall of every lot or batch of the LRVHP that has been made available for sale;

(*i*) a list of all LRVHPs that are being manufactured at the site; and

(*j*) a copy of the sanitation program in use at the site.

Packagers

11. Every packager who sells a LRVHP shall maintain the following records at the site at which the LRVHP is packaged:

(*a*) records of any testing conducted in respect of the material used to package the LRVHP;

(*b*) records demonstrating that each lot or batch of the LRVHP was packaged in accordance with the requirements of this Guideline;

(*c*) records containing sufficient information to enable the recall of every lot or batch of the LRVHP that has been made available for sale;

(*d*) a list of all LRVHPs that are being packaged at the site; and

(*e*) a copy of the sanitation program in use at the site.

Labellers

12. Every labeller who sells a LRVHP shall maintain the following records at the site at which the LRVHP is labelled:

(*a*) records demonstrating that each lot or batch of the LRVHP was labelled in accordance with the requirements of this Guideline;

(*b*) records containing sufficient information to enable the recall of every lot or batch of the LRVHP that has been made available for sale;

(*c*) a list of all LRVHPs that are being labelled at the site; and

(*d*) a copy of the sanitation program in use at the site.

Importers

13. Every importer who sells a LRVHP shall maintain the following records:

(*a*) the master production document for the LRVHP;

(*b*) a list of all ingredients contained in each lot or batch of the LRVHP;

(*c*) records of any testing conducted in respect of a lot or batch of the LRVHP;

(*d*) a copy of the specifications for the LRVHP;

(*e*) a record of each determination made by the importer in accordance with section 9 and the information that supports that determination;

(*f*) records containing sufficient information to enable the recall of every lot or batch of the LRVHP that has been made available for sale; and

(*g*) a copy of the sanitation program in use by the importer.

Distributors

14. Every distributor shall maintain the following records at the site at which the LRVHP is stored:

(*a*) records containing sufficient information to enable the recall of every lot or batch of the LRVHP that has been made available for sale;

(*b*) a list of all LRVHPs that are being stored at the site; and

(*c*) a copy of the sanitation program in use at the site.

Record Maintenance

15. Every person required under this Guideline to maintain a record that relates to a lot or batch of a LRVHP shall maintain that record for a period of one year following the expiry date of the LRVHP to which that record relates.

Lot or Batch Samples

16. (1) Subject to subsection (3), if Health Canada has reasonable grounds to believe that a lot or batch of a LRVHP made available for sale may result in injury to the health of a purchaser or consumer, Health Canada may require the manufacturer, importer or distributor to provide a sample of that lot or batch.

(2) The sample shall be of sufficient quantity to enable a determination of whether the lot or batch of the LRVHP complies with the specifications for that LRVHP.

(3) Health Canada shall not require a sample of a lot or batch referred to in subsection (1) to be provided if more than one year has elapsed since the expiry date of that LRVHP.

Recall Reporting

17. Every manufacturer, importer or distributor who commences a recall of a LRVHP shall provide Health Canada with the following information in respect of that LRVHP within three days after the day on which the recall is commenced

(*a*) the proper name and the common name of each medicinal ingredient that it contains;

(*b*) each brand name under which it is sold;

(*c*) its product number;

(*d*) the number of each lot or batch recalled;

(*e*) the name and address of each manufacturer, importer and distributor of the LRVHP;

(*f*) the reasons for commencing the recall;

(*g*) the quantity manufactured or imported into Canada;

(*h*) the quantity that was distributed in Canada;

(*i*) the quantity remaining in the possession of each manufacturer, importer and distributor of the LRVHP; and

(*j*) a description of any other action that the manufacturer, importer or distributor, as the case may be, is taking in respect of the recall.

Product recalls are to be reported to the Health Products and Food Branch Inspectorate. The recall policy is available at the following URL:

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol_0016_tc-tm-eng.php

"**distributor**" means a person who sells a LRVHP to another person for the purpose of further sale by that other person. (*distributeur*)

"**expiry date**" means the earlier of (*a*) the date, expressed at minimum as a year and month, up to and including which a LRVHP maintains its purity and physical characteristics and its medicinal ingredients maintain their quantity per dosage unit and their potency, and (*b*) the date, expressed at minimum as a year and month, after which the manufacturer recommends that the LRVHP should not be used. (*date limite d'utilisation*)

"**importer**" means a person who imports a LRVHP into Canada for the purpose of sale. (*importateur*)

"**lot number**" means any combination of letters, figures, or both, by which a LRVHP can be traced in manufacture and identified in distribution. (*numéro de lot*)

"**manufacturer**" means a person who fabricates or processes a 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. (fabricant)