Natural health products good manufacturing practices pre-inspection package:

Checklist for labellers

Regulatory Operations and Enforcement

Health Canada Santé Canada

Canada

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Trousse de préinspection des bonnes pratiques de fabrication des produits de santé naturels : Liste de vérification pour les étiqueteurs

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Regulatory Operations and Enforcement

Premises (section 45)

- ☐ A detailed floor plan showing non-production, quarantine and labelling areas
- ☐ Standard operating procedures (SOPs) and associated records for:
  - ☐ prevention of contamination and cross-contamination of natural health products (NHPs)
  - ☐ storage condition of finished products
  - ☐ pest control
  - ☐ facility inspection and maintenance
  - ☐ janitorial duty schedule and cleaning completion
  - ☐ restricting access to storage areas for labels and printed materials

Equipment (section 46)

- ☐ Preventive maintenance schedule or program for equipment, which includes identification of equipment and instructions on how to maintain it
- ☐ Equipment usage, cleaning and maintenance logs
- ☐ Calibration program and records for equipment that requires it, including proof of the calibration standard or referenced being used
- ☐ SOPs for the operation of equipment

Personnel (section 47)

- ☐ SOPs for the appropriate education, training or work experience for all personnel
- ☐ List of qualified quality assurance person (QAP) designate(s)
- ☐ Records of completed training relating to assigned duties and responsibilities (for example good manufacturing practices (GMP) training) of personnel
- ☐ Employee training schedule or attendance records that demonstrate initial and on-going relevant training
- ☐ Job descriptions that outline roles and responsibilities of positions

- ☐ Résumé or curriculum vitae that shows the person meets their job description

Sanitation program (section 48)

- ☐ SOPs and associated records for a sanitation program that includes information on cleaning of premises, labelling and storage areas and equipment, such as:
  - ☐ storage and protection of equipment after cleaning
  - ☐ procedures for destroying and disposing of waste materials and debris
  - ☐ cleaning and sanitizing agents to be used
  - ☐ cleaning frequencies
  - ☐ facility cleaning schedule
  - ☐ cleaning completion
- ☐ SOPs and associated records for a health and hygiene program that includes:
  - ☐ personnel hygiene training
  - ☐ guidance related to personal hygiene

Operations (section 49)

- ☐ SOPs and associated records for:
  - ☐ transporting, receiving, handling, storing and distributing labelling materials or finished products
  - ☐ labelling NHPs
  - ☐ label control and reconciliation
  - ☐ sampling records for labelling components
  - ☐ product disposition, return and disposal
  - ☐ product complaints and resulting action
- ☐ Master labels
- ☐ Quality agreements with contractors (for example, manufacturers, packagers, labellers, importers, warehouses, wholesalers, quality assurance consultants) and suppliers

- ☐ List of all contract manufacturers, packagers and labellers used domestically and in foreign countries, as applicable

Operations (section 50)

- ☐ SOPs and associated records for recalling a NHP and recall reporting
- ☐ Each lot of finished product has distinct identification for traceability (for example, lot number)
- ☐ Distribution records for all products
- ☐ Signed quality agreement outlining recall responsibilities

Quality assurance (section 51)

- ☐ Organizational chart showing independence of QAP's function
- ☐ Identification of the QAP and delegate (where applicable)
- ☐ QAP's and delegate's (where applicable) résumé, including education
- ☐ QAP's training record demonstrating ongoing and relevant training
- ☐ SOPs and associated records for:
  - ☐ QAP job description that outlines roles and responsibilities, required training, experience and technical knowledge
  - ☐ approval of labelling materials and finished products
  - ☐ releasing labelling materials
  - ☐ investigation and resolution/corrective actions for complaints, deviations and returned, rejected and expired products
  - ☐ disposition, distribution and disposal of products
  - ☐ review and approval of methods, procedures and systems used to label NHPs

Records (section 55) and record maintenance (section 58)

- □ List of all NHPs labelled at the site
- □ A copy of the sanitation program in use at the site
- □ Records demonstrating that each lot or batch of the NHP was labelled in accordance with the requirements of Part 3 of the regulations
- □ Labelling order
- □ Relevant records are maintained for a period of 1 year following the expiry date of the NHP to which that record relates
- □ Records containing sufficient information to enable a recall, which includes product distribution records
- □ Relevant SOPs for the maintenance of records by labellers, including the following:
  - □ change control
  - □ record control and retention
  - □ control of electronic records
  - □ use of electronic signatures
  - □ good documentation practices
  - □ document translation
  - □ review and approval of GMP documents
  - □ SOP creation and maintenance
- □ When an electronic document management system is in place:
  - □ information that supports the suitability and reliability of the system
  - □ documentation that outlines the development and maintenance of the system
- □ When electronic signatures are in use:
  - □ documentation detailing the development and maintenance of the electronic signature identification system
  - □ they must be tested and evaluated for security, validity and reliability