




Canadian Regulatory Requirements for Natural Health Products: An Industry Perspective

Paul Gustafson
Vice-President of Quality





Canadian Natural Health Products Regulations

Key Elements

- Product Licencing
- Adverse Reaction Reporting
- Site Licencing
- Good Manufacturing Practices
- Clinical Trials
- Labelling/Packaging Requirements





What is a Natural Health Product

- Plant Material, alga, bacterium, fungus or non-human animal material (and extracts or isolates)
- Specified Vitamins
- Amino Acids
- Essential Fatty Acids
- Synthetic Duplicates of the Above
- Minerals
- Probiotics





Product Licencing

- Product Licence Application Form
- Label Text
- Safety
- Efficacy
- Quality





Product Licencing Application Types

- Compendial
- Traditional Claim
- Non-Traditional
- Homeopathic
- Labelling Standard
- Transitional DIN





Adverse Reaction Reporting

- 15 day reporting window for serious adverse reactions in Canada
- 15 day reporting window for any reports of serious unexpected adverse reaction inside or outside of Canada
- Annual summary of adverse reactions





Adverse Reaction Reporting

“..Noxious and unintended response to a natural health product..”


Serious Adverse Reactions Include

- In-patient hospitalization
- Prolongation of existing hospitalization
- Congenital malformation
- Persistent or significant disability or incapacity
- Life threatening
- Results in death



Licensable Activities

- Manufacture
- Package/Label
- Import

	Year of Renewal								
Renewal Cycle	0	1	2	3	5	7	9	12	15
									
GMP Evidence Required	QAR	SNC	SNC	QAR	SNC	SNC	QAR	QAR	QAR





Site Licencing Evidence Requirements

- Quality Assurance Report
- Certificate of Compliance (CoC) issued by a Recognized Regulatory Authority,
- Inspection report issued by a Recognized Regulatory Authority,
- Inspection report from a Qualified Authority
- Corporate Audits
- Other Audits: ISO, WHO, USP



Extract from the Quality Assurance Report

Stability [Section 52]

(23) An on-going stability program is in place at the site.

Yes No

If yes, describe

If no, provide a rationale (e.g. Not applicable because...)

Standard Operating Procedures

Relevant standard operating procedures are established.

Yes No

List all standard operating procedures (SOPs) (titles and numbers) for this section.

Deviations and corrective actions

Identify and describe any noted GMP deviation(s) and the rationale for the deviation, where applicable. Detail the corrective action(s) taken and/or to be taken.

Supporting documentation

***Attach* a minimum of one photocopy of a completed record(s)/log(s) as outlined in the SOP(s) listed above (see instructions for more details).
Attach supporting documentation such as action plans with timelines for each corrective action identified above.**

List of attachments:



Regulatory Requirement for Stability

52. Every manufacturer and every importer shall determine the period of time that, after being packaged for sale, the natural health product 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.





Good Manufacturing Practices

- Specifications
- Facility
- Equipment
- Personnel
- Sanitation
- Operations





Good Manufacturing Practices

- Quality Assurance
- Stability
- Records
- Sterile Natural Health Products
- Retained Samples
- Recall Reporting



Clinical Trials

- Expectations Similar to Drugs
- Prohibitions unless authorized
- Good Clinical Practice's
- Labelling Requirements
- Record Requirements
- Reaction Reporting





Product Labelling and Packaging

- Regulations that include specific labelling requirements for sale in Canada.
- Security Packaging Requirements
- Pressurized Container Requirements
- Child Resistant Packaging Requirements





Compliance and Enforcement Policy and Transitional Phases

- Product Licencing-Policy Based Enforcement in Effect
- Site Licencing – Jan 1, 2006 Transition
- GMP –Jan 1, 2006 Transition
- Clinical Trials – No Transition Period



Risk Based Approach

“NHPs identified as posing an unacceptable risk to the health of Canadians will be removed from sale.”



Product Category Priorities

“Health Canada focuses compliance efforts against NHPs in that category which have not been issued submission numbers.”





Compliance and Enforcement Policy Priority Listing

- New Drugs
- Extracts
- Animal Materials
- Plant Materials
- Vitamins/Minerals
- Homeopathics





Challenges to Product Licencing


- Submission review time frames
- Requirements to demonstrate safety and efficacy
- Absence of harmonization with international quality requirements



Challenges to Site Licencing

- Evidence of Compliance for Foreign Sites
- Site Licence Renewal Frequencies
 - Annual renewal if held for 3 years or less
 - Renewal every two years if held for 3 years but less than 9.
 - Renewal every three years if held for 9 years or more





Concerns Raised by Industry during the Regulatory Review Process

- NHP/Food Interface
- Security packaging
- Overregulation of ingredient disclosure, reporting of adverse effects, and testing specifications
- Transitional DIN review
- Risk proportion product licensing
- Small package labelling
- Quality assurance person's education requirements
- Veterinary NHPs
- Frequency of site licence renewals

