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Overview:

Reference:

The NHPD Mission:

- To ensure that all Canadians have ready access to natural health products that are safe, effective, and of high quality, while respecting freedom of choice and philosophical and cultural diversity.

The Natural Health Product (NHP) regulations:

- Outline requirements for manufacturing, packaging, labelling, importing, distributing and storing Natural Health Products (NHPs).
- Provide a framework for site and product licencing, good manufacturing practices (GMPs), clinical trials, and labelling requirements.
- Provide a 2-year transition period for **site licencing** (January 1, 2004—December 31, 2005) for manufacturers, packagers, labellers and importers of NHPs conducting activities in Canada before January 1, 2004.
- Provide a 6-year transition period for **product licencing** (January 1, 2004—December 31, 2009) for NHPs with drug identification numbers (DINs) issued under the *Food and Drug Regulations*.

NHPs are defined by function and substance

- **FUNCTION:** Those substances that are manufactured, sold or represented for use in:
 - Diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; restoring or correcting organic functions in humans; or modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.
- **SUBSTANCE:** Refer to Overview of the Natural Health Products Regulations for specific medicinal ingredients that natural health products may contain (Schedule 1) and those substances that are not permitted in a natural health product (Schedule 2).
- Health Canada's intent is to cover products that consumers select and use themselves without consulting a health care provider or obtaining a prescription. Accordingly, with the exception of homeopathic medicines, products with prescription ingredients are not NHPs.

For current NHPs, the *Food and Drug Regulations* apply until a NHP site licence and/or product licence is obtained

New products must comply with the NHP regulations immediately and are subject to the full licence application process prior to sale in Canada

All NHPs must comply with the *NHP Regulations* by January 1, 2010

See "Overview of the Natural Health Products Regulations Guidance Document" at:

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/regula-regle_over-apercu_e.html

Who Does This Apply To:

Reference:

- Importers
- Fabricators
- Packagers/Labelers
- Distributors
- Wholesalers
- Storage Facilities

What's New:

- Implementation dates for NHPs with DINs and Transitional products (Priority 4, 5, and 6 Product Categories) have been extended (see page 5 of this Quick Note for more information).
- New document: A Summary of NHP/DRUG Classification of TPD Category IV Labelling Standards Ingredients (February 1, 2006).
- New and revised Product and Single Medicinal Ingredient Monographs available on NHPD website.
- In April 2007, the NHPD published a notice clarifying the product licensing application process (i.e. the process for obtaining a NPN) for those natural health products (NHPs) currently holding Drug Identification Numbers (DIN). Applicants intending to submit a Transitional DIN Product Licence Application are encouraged to carefully follow the instructions outlined in this notice.
- As of September 1, 2007, the NHPD will require only a completed QAR with the first application, in the fourth year, in the tenth year and every three years thereafter. For renewal applications between these dates, a completed *Summary of Net Changes Form* along with copies of recent samples of records (logs) will be considered sufficient evidence of compliance with good manufacturing practices (GMP).
- The NHPD has recently revised its guidelines and procedures for applicants wishing to reclassify a product licence application into the Compendial or Non-compendial stream that has already been submitted for review.

Access the list of Single Ingredient and Product monographs at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/index_e.html

Refer to the Strategy for the Licensing of NHPs with DINs at http://www.hc-sc.gc.ca/dhp-mps/prodnatur/bulletins/din_tr ans_din_e.html

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Key Points:

Reference:

Site Licence Application (SLA)

- Site licences are required for the following activities:
 - Domestic Fabricators
 - Domestic Packagers
 - Domestic Labellers
 - Importers.
- Site licences are not required for the following activities, however, the expectation is that these facilities will follow NHP Good Manufacturing Practices (GMPs):
 - Domestic Distributors
 - Domestic Storage Facilities.
- Foreign sites are not required to be licensed, but a Quality Assurance Report (QAR) for the site is required to be submitted with the importer's SLA.
 - Alternatives to a QAR include: Corporate Audit Reports, Consultant Audit Reports, Drug Establishment Licence support documentation, FDA-483 with Corrective Actions (or Establishment Inspection Report), WHO Inspection Reports, quality Manuals for ISO 9001:2000 or licences from an acceptable regulatory authority in a designated country, or associational countries recognized by the HPFBI (i.e., Australia, Switzerland, Sweden, France and the UK).
- Importers serve as legal representation in Canada for foreign NPN (Natural Product Number) or DIN-HM (homeopathic medicines) number holders.
- The SLA can be obtained for each building or location, or multiple buildings or locations.
- Timelines:
 - All current fabricators, packagers, labellers, and importers of Natural Health Products (NHPs) without Establishment Licences (ELs) are required to follow and comply with the NHP GMPs as of January 1, 2004; they must have a site licence as of January 1, 2006.
 - NHP fabricators, packagers, labellers, importers, etc. who intend to commence any of the activities for an NHP after January 1, 2004, must comply with the regulations before beginning activities.
 - Sites with ELs must be compliant with the site licence and NHP GMP requirements as of January 1, 2006; until such date, these sites shall conduct activities in accordance with the Food and Drug Regulations. These sites may apply for a site licence during the 2-year transition.

See "Site Licence Guidance Document" at:

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/sl-gd-drle_e.html

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Key Points: *(continued)*

Reference:

Site Licence Application (SLA) *(continued)*

- Amendments – addition of a new facility or building, change in operations (fabricate, package, label, import, non-sterile to sterile).
 - Changes must be authorized prior to implementation.
- Notifications – change in contact information (name, address, telephone number, fax number, e-mail address), or substantial changes to building, equipment, practice or procedure (as mentioned in the QAR).
 - Notification required within 60 days of the change.
- Renewals – scheduled approach. NHPD will distribute notifications 30 days prior to renewal dates.
 - Every year for years 1—3
 - Every two years for years 4—9
 - Every three years, thereafter.

Quality Assurance Report

- Template is available on the NHPD website.
 - Part 1 – Site Information
 - Part 2A – Places
 - Part 2B – People
 - Part 2C – Processes
 - Part 2D – Products
- QAR is required to cover all areas of GMPs.
- QAR or an acceptable alternative is required for each foreign buildings or locations at the same address
- QA persons must be qualified by pertinent education, training and experience.

Access the template for the QAR form at:

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/form_qar-raq_e.html

Access instructions for using the QAR form at:

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/forms_qar_instructions_e.html

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Key Points: *(continued)*

Reference:

Importers

- Importers are required to be licensed and the onus is on the importer to provide evidence that the imported products originated from sites that meet the Canadian GMPs or equivalent standards. Importers are required to have a QA person in Canada to release product and to ensure compliance.

Good Manufacturing Practices

- Divided into GMPs for NHP and Supplement for Homeopathic Medicines
- Places – Premises & Equipment
- People – Personnel & Quality Assurance
- Processes – Sanitation Program & Operations
- Products – Specifications, Stability, Samples, Records, Recall Reporting, Sterile Products

See “Good Manufacturing Practices” at:

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/gmp-bpf_e.html

Regulatory Inspections

- Regulatory inspections by HPFBI inspectors, commenced January 1, 2006, in accordance with the Compliance and Enforcement Policy, Version 2 (effective May 31, 2005).
 - Industry activities are monitored to ensure they are following established policies and procedures and complying with all appropriate regulations related to the type of health product they are marketing.
 - Monitoring activities vary by product and include inspections, market surveys and a product sampling program.
 - Products coming into the country should be destined to a site with a Site Licence as an importer or their distributor.

Key Points: *(continued)***Reference:****Product Licence Application (PLA)**

- Types: Compendial, Non-compendial (traditional and non-traditional), Homeopathic and Transitional (NHPs already holding a Drug Identification Number or DIN)
- General Requirements:
 - Completed PLA
 - Proposed label text
 - Animal Tissue Form
 - Quality Summary Report (depending on application type)
 - Evidence of Safety and Efficacy (depending on application type)
- No safety and efficacy required for DIN products in PLA as this has already been assessed by TPD. This applies as long as labelling has not been changed and non-medicinal ingredients are not medicinal under the regulations.

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Key Points: *(continued)*

Product Licence Application (PLA) *(continued)*

Transitional Phase (Product Category Priority Approach)

- 1 – NHP Substances in the TPD New Drug List
 - June 1, 2004
 - 2 – Extracts and Isolates (amino acids and essential fatty acids)
 - January 1, 2005
 - 3 – Algal, bacterial, fungal, probiotic and animal materials
 - June 1, 2005
 - 4 – Plant and plant materials
 - Previously June 1, 2006; now June 1, 2007
 - 5 – Vitamins and Minerals
 - Previously January 1, 2007; now January 1, 2008
 - 6 – Homeopathic Medicines
 - Previously June 1, 2007; now June 1, 2008
- Timing Summary:
 - New NHPs introduced after December 31, 2003 must comply with the product licensing requirements.
 - NHPs without DINs on market before December 31, 2003, transitional phase – must transition before the dates indicated above.
 - NHPs with DINs, currently marketed, target completion date – December 31, 2009.
 - Notifications – changes that do not affect safety and efficacy (name changes, brand changes).
 - Notify within 60 days of the implementation.
 - Fundamental Change – quantity of a medicinal ingredient, addition or substitution of a medicinal ingredient, dosage form, route of administration.
 - New product licence (PL) required.

Reference:

See an overview of the Product Licensing Requirements and Process at:

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/license-licence_guide_tc-tm_e.html

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Reference:

Refer to the "Labelling Guidance Document" at:

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/labelling-etiquetage_e.htmlKey Points: (continued)**Labelling and Packaging**

- Note: The labelling requirements for NHP should be used in conjunction with the *Consumer Chemicals and Containers Regulations* and the *Charter of the French Language*.
- Inner and Outer Label:
 - Principle Display Panel (PDP): Brand name, NPN#, DIN-HM#, dosage form, "sterile," net amount.
 - Any Panel: name and address of PL holder, name and address of importer, common name of each medicinal ingredient, proper name of each medicinal ingredient, quantity of each medicinal ingredient per dosage unit, potency of each medicinal ingredient, recommended use or purpose, route of administration, recommended dosage, recommended duration of use, risk information, recommended storage conditions, lot number, expiry, description of source material of each medicinal ingredient, the quantity of mercury contained in the product.
- Outer Label:
 - Qualitative list of Non-Medicinal Ingredients (NMI) – alphabetic OK.
 - Leaflets or tags attached to the NHP are also considered labels and must comply with the outer labelling requirements.
- Small Package requirements (see guidance document)
- Security packaging required for all NHPs except lozenges.
- Pressurized containers, as required by *Consumer Chemicals and Containers Regulations*.
- Cautionary Statements and Child-resistant packages, as per the Food and Drug Regulations.
- English and French required for:
 - Recommended conditions of use
 - Common name and proper name of an medicinal ingredient or NMI
 - Description of source material of each medicinal ingredient
 - Storage conditions
 - Reminder: The Charter of the French Language should be consulted for products which may enter Québec.
- Presentation of information clear and prominent, readily discernable to consumer.
- USP, BP, NF, etc. only if product conforms to the standard.
- Organic labelling is voluntary. (Certification must be supplied if claimed.)
- Irradiated products, inner and outer label "treated with irradiation, treated by irradiation or irradiated" are voluntary.
- Nutritional Information is not permitted on the label.

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Reference:

Refer to the Clinical Trials guidance document at:

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/clinical_trials-essais_nhp-psn_e.html

Clinical Trials

- Clinical trial guidance document effective June 10, 2005 is now posted.

FAQ:

1. Do I need to release each lot of imported product?

Yes, a Quality Assurance person is required to release product in Canada.

2. If there are updates to the product monographs included in a submitted Product Licence Application, do the changes have to be made?

Yes, applicants should note that any submissions in queue are required to be kept current with information in any new and/or revised monographs.

3. What sites are required to be listed on the Site Licence?

Canadian Importers must ensure that the foreign sites where imported products are originating from and the Canadian importation sites where they are being shipped to are listed on their site licences.

4. What Guidance Documents are currently available on the NHPD website?

Overview of the Natural Health Products Regulations (January 1, 2004)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/regula-regle_over-apercu_e.html

Transition Guidance Document for Natural Health Products (November 2003)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/transition_guide_doc_e.html

Good Manufacturing Practices Guidance Document (August 2006, Updated)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/gmp-bpf_e.html

Product Licensing Guidance Documents (December 2006, Updated)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/license-licence_guide_tc-tm_e.html

Site Licensing Guidance Documents (August 2006, Updated)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/sl-gd-drle_e.html

Product Licensing Forms and Templates

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index_e.html

These regulations and guidances are a work in progress. Be prepared for further changes.

FAQ: (continued)

Site Licensing Forms and Templates

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/index_e.html

Instructions for Completing the Quality Assurance Report form (July 2005)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/forms_qar_instructions_e.html

Labelling Guidance Document(August 2006. New)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/labelling-etiquetage_e.html

List of Acceptable Non-Medicinal Ingredients (NMI) (Feb 2004)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/nmi-immn_list1_e.html

Compendium of Monographs (October 2006)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/compendium_e.html

Evidence for Safety and Efficacy of Finished Natural Health Products
(December 2006. Updated)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/efe-paie_e.html

Evidence for Quality of Finished Natural Health Products (November 2003)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/eq-paq_e.html

Evidence for Homeopathic Medicines (May 2007. Updated)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/ehmg-nprh_e.html

Adverse Reaction Reporting – Product Licence Holders (January 15, 2004)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/arr-dri_e.html

Clinical Trials for NHPs (October 30, 2005)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/clini_trials-essais_nhp-psn_e.html

Application for International Trade Certificate for NHPs (July 14, 2006)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/int-certificat/doc/itc_cci-pol_e.html

A Summary of NHP/DRUG Classification of TPD Category IV Labelling Standards
Ingredients (April 2006)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/monograph/list_mono4_e.html

Consumer Advertising Guidelines for Marketed Health Products (October 2006. New)

http://www.hc-sc.gc.ca/dhp-mps/advert-publicit/pol/guide-ldir_consom_consum_e.html

Raw Material Policy (October 2006. New)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/pol/raw_policy-politique_premiere_e.html

Compounding Policy (October 2006. New)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/pol/policy_compound-politique_compose_e.html

Master File Procedures (August 2006. New)

http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/master_file_fichier_principal_e.html

Appropriate Dispute Resolution Process (Not yet available)

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Feel free to contact *Quality & Compliance Services Inc.* ® with your questions about NHPs

Phone Graham Mills toll-free at 1-877-877-5152 Extension 210 or email him at info@qualityandcompliance.com