

Quick NOTES

Natural Health Products Quality Systems: Setup

MARCH 2010



OVERVIEW

Once you have ascertained that your product is a Natural Health Product¹ (NHP), you must determine whether it is viable to bring the product to the Canadian market. To bring an NHP to market in Canada requires a commitment to the regulatory process and considerable time and money. In addition, you must have the following:

- Viable sales volume to justify regulatory and compliance investment
- Finalized and documented product formulation and drafted and/or reviewed product labels
- Understanding of the legal need to invest in the regulatory process
- Knowledge of Natural Health Product Directorate (NHPD) key enforcement issues
- Understanding of the legal limits of the personal use clause for importation of drugs or NHPs

WHO DOES THIS APPLY TO

Anyone who is considering importing, packaging, manufacturing or distributing NHPs in Canada.

KEY POINTS

1. VIABLE SALES VOLUME

- To be economically viable; both to meet the regulatory requirements and market a new product in Canada, it is necessary to have actual or projected annual sales to justify the expense of compliance for the product you want to bring to market.

¹ Health Canada defines a natural health product (NHP) as "a substance set out in Schedule 1 of the Natural Health Products Regulations or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine that is manufactured, sold or represented for use in:

- Diagnosing, treating, mitigating or preventing 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.

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2. FINALIZED AND DOCUMENTED PRODUCT FORMULATION AND DRAFT LABELS

- Health Canada NHPD requires that each NHP has documented product formulation and appropriate labelling.
- Quality & Compliance Services Inc./NHP Compliance can review the product formulation and labelling for each of your existing products, whether classified as a drug product or NHP, to determine what type of Product Licence Application (PLA) to submit. We have extensive experience completing applications for clients.
- Formulation changes are expensive and require amendments or resubmission of PLA.
- We understand that product formulas are proprietary and may contain unique ingredients. We routinely sign Confidentiality and Disclosure Agreements prior to starting the work.
- Once the NHP product type is determined, we can work with you to prepare the PLA for the product. Product types include the following:
 - Traditional
 - Non-traditional
 - Compendial
 - Monograph-based Non-traditional
 - Transitional

3. UNDERSTANDING THE LEGAL NEED TO INVEST IN THE REGULATORY PROCESS: TIME AND COST OF BRINGING AN NHP TO MARKET

- The time and cost required to bring an NHP through the regulatory process and to ensure ongoing compliance is specific to each category or type of product.
- Call Graham Mills at 1-877-877-5152, ext. 210, to facilitate a Confidentiality and Disclosure Agreement (if required) and to request an estimate.

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- The activities required may include the following:

<i>Activity</i>	<i>Time Required</i>	<i>Upfront Cost</i>
Product Evaluation	TBD	TBD
Product Licence Application (PLA) for NPN	TBD	TBD
Site Licence Application (SLA)	TBD	TBD
Quality Control System Setup™	TBD	TBD
Ongoing Product Disposition	TBD	TBD
Ongoing Quality Control Maintenance	TBD	TBD

4. KNOWLEDGE OF NHPD KEY ENFORCEMENT ISSUES

- Importers of NHPs must be aware that the Canadian Border Services agency confirms that product is destined for a location which is listed on the importer's site licence and that submission numbers for products which do not have Natural Health Product Numbers (NPN) are listed on shipping documents.
- Health Canada NHPD now expects a PLA for products marketed in Canada. You need an NPN.
- The NHPD currently requires Site Licences for NHP manufacturers, packagers, labellers and importers.
- There are separate GMPs for drug products and natural health products. Active GMP compliance enforcement is expected to begin in the fall of 2011. Sites with a site licence must comply with the NHP GMPs.
- Importers must also appoint a Quality Assurance (QA) person in Canada to disposition product and ensure compliance.
- Quality & Compliance Services Inc./NHP Compliance regularly performs these activities for many NHP importers.

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5. UNDERSTANDING OF THE LEGAL LIMITS OF THE PERSONAL USE CLAUSE

- Personal importation of drugs and natural health products is permitted in Canada by an individual via mail or courier for his or her own use, or for a person under that individual's care or guardianship, and not for further sale.
- Excluded products include: narcotics, controlled drugs, controlled substances, Class A precursors and prescription (Schedule F) drugs.
- The sale needs to be considered between a person in Canada and a company located outside of Canada.
- A 90-day supply of the product is allowed for use by one person, based on the directions for use or reasonable.
- The foreign supplier is under no obligation to fulfill personal use orders.

HOW CAN QUALITY & COMPLIANCE SERVICES/NHP COMPLIANCE HELP YOU?

- Perform Product Evaluations to determine your product's appropriate category (e.g., drug, NHP, cosmetic, etc.).
- Determine submission requirements (confirming type of PLA required).
- Prepare and submit:
 - Site Licence Applications (SLA) and associated documents for Canadian, U.S, and foreign manufacturing facilities, including QA report
 - PLAs and associated documents
 - Non-traditional
 - Compendial
 - Transitional (DIN to NPN, i.e., drug to NHP)
 - Amendments, notifications, and renewals
- Address NHPD queries, such as:
 - Information Request Notifications

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- Processing Deficiency Notifications
- Respond to any queries related to NHPs, whether the questions come from a client or the NHPD
 - Act as your qualified Quality Assurance (QA) personnel.

FAQ

1. If I operate a warehouse that stores NHPs, do I need a site licence?

No, but the manufacturer or importer where goods are stored needs to ensure that they practice GMP.

2. If I am a manufacturer of NHPs in the U.S., what do I need to do to market my product in Canada?

You will need a product licence and a Canadian importer with a site licence. Each manufacturing, packaging, and labelling site requires a QAR or equivalent. See our flowchart, Importing a Natural Health Product or Drug into Canada for more information.

3. What is a Compendial Application?

A product licence application that meets all the monograph requirements in NHPD's Compendium of Monographs for that product.

4. How do I support the shelf life of my product at launch?

Stability data from accelerated studies, real time studies or from similar product formulations may be used.

5. If I am a manufacturer of NHPs, do I need to test my product?

Yes. The manufacturer must perform finished product testing on each batch of the product produced.

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6. If I am an importer of an NHP, do I need to test my product?

Yes. You must fully test against specifications, the first lot of product received for each product and each supplier. In addition, you must ID test every lot on every shipment and complete confirmatory testing against specifications on at least one lot per dosage form per supplier per year. Testing can be conducted by a U.S. qualified laboratory or any qualified laboratory around the world.

Quality & Compliance Services Inc./NHP Compliance have advised and consulted on NHPs for many clients. Our GMP associates are uniquely qualified to consult on NHPs; we were assisting clients with the transition from DIN to NHP before initial guidances were posted on the NHPD website.

Contact Quality & Compliance Services Inc.
with your questions about Natural Health Products.
Phone Graham Mills toll-free at 1-877-877-5152,
extension 210, or email him at gmills@qualityandcompliance.com.

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