



# Natural Health Products Management of Applications Policy

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Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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## Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy, or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable Guidance documents.

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# Executive Summary

The Natural and Non-prescription Health Products Directorate (NNHPD) has updated the Management of Product Licence Applications for Natural Health Products (NHP) now referred to as the Natural Health Products Management of Applications Policy (NHP MAP).

NNHPD last updated the NHP MAP in 2014. The revisions to this document include changes to how applications for natural health products (new, or amendments and notifications for existing products) are processed, assessed and issued a regulatory decision.

The updates to this document are intended to achieve better outcomes for the health and safety of Canadians by ensuring that authorized NHPs meet regulatory requirements, provide greater predictability in the processing of applications, outline timelines for the review of applications and issuance of a decision, and align the policy with current practices, tools and systems.

## 1. Purpose

The NHP MAP outlines the process applied by NNHPD to manage Product Licence Applications (PLA) for Natural Health Products (NHPs) submitted in accordance with the [Natural Health Products Regulations](#) (NHPR). The policy also outlines the responsibilities and expectations of NHP applicants throughout the application process.

## 2. Scope

This policy applies to all classes of NHP applications (Class I, II and III), including changes made following the licensing of a product licence (amendments and notifications) and to all application types (general - formally categorized as non-traditional applications, traditional and homeopathic). It is intended to aid the applicant in navigating the application process and should be used in conjunction with associated guidance documents linked throughout this document.

This policy does not apply to site licence or clinical trial applications for NHPs. It also does not apply to applications for other health products including, drugs, medical devices, biologic and genetic therapies, veterinary drugs and foods.

## 3. Class of Applications

An NNHPD monograph is a written description of particular elements on an identified ingredient or product. NNHPD has developed and published a [Compendium of Monographs](#) that allows applicants to support the safety, efficacy, and quality of an NHP as part of their PLA.

There are three classes of applications, which are differentiated by their use of NNHPD monographs.

Each class is described below.

### 3.1 Class I

Class I applications are those that must comply with all of the parameters of an individual NNHPD monograph (exactly as worded in the monograph). Applicants can only reference one NNHPD monograph per application in Class I. Modifications to any of the parameters of a monograph are not permitted (e.g. the use of “statements to the effect of” will not be accepted in Class I).

### 3.2 Class II

Class II applications are general and traditional applications supported entirely by a combination of 2 or more NNHPD monographs as well as the following scenarios:

- Applications supported entirely by an individual NNHPD monograph with a deviation to one or more monograph statements which maintains the intent of the monograph(s) statements (e.g. “statements to the effect of”);
- Applications supported entirely by a combination of NNHPD monographs with a deviation to one or more monograph statements which maintains the intent of the monograph(s) statements (e.g. “statements to the effect of”);
- Products supported entirely by a combination of NNHPD monographs with the addition of common fruits or vegetables listed in the Canadian Nutrient File, excluding source materials listed as "refuse", with a daily dose of up to 10 g (of crude material or quantity crude equivalent for non-standardized extracts).

Homeopathic applications with specific claims are not accepted in Class II.

### 3.3 Class III

Class III applications are comprised of general, traditional and homeopathic applications requiring full assessment (not captured above in Class I or II) and include, but are not limited to, the following scenarios:

- Products with a novel preparation and/or dosage delivery system presenting unique safety and/or efficacy profiles;
- Applications referencing a Master File to support safety, efficacy and/or quality (see section 4.5 for information on Master Files, including a definition).
- Products with ingredient combination issues (including those covered by a monograph) that may require safety assessment. These combinations include but not exclusive to the following lower certainty combinations and combination risk factors (e.g. stimulant laxatives combined with diuretics, weight management ingredients/claims in combination with diuretics, combination hormonal effect products, combination sedative ingredients). These combinations are reviewed on a case by case basis.
- Applications partially referencing monograph information but going beyond the parameters established in the relevant monograph(s). For example, a dosage form or route of administration not indicated on the monograph(s) that requires further assessment.
- Homeopathic applications with specific claims.

Please refer to section 4.1 for guidance and supporting documents regarding the safety, efficacy and quality requirements for Class III applications.

## 4. Pre-submission Information (before submitting an application)

The following section identifies important information to review and instructions to follow prior to submitting a PLA to NNHPD.

### 4.1 Guidance and Supporting Documents

NNHPD has developed tools and guidance to assist the applicant in preparing their NHP applications, to facilitate more efficient processing, and to reduce the number of application deficiencies.

Regulations:

All NHPs sold in Canada are subject to the Natural Health Products Regulations (NHPR).

- [Natural Health Products Regulations](#)

General guidance:

This document provides details on general application requirements.

- [Product Licensing Guidance Document](#)

Safety and efficacy:

The following documents outline the approach to assessing safety and efficacy evidence for NHPs, including standards for health claims, the use of risk information and considerations for combinations of NHPs.

- [Pathway for Licencing Natural Health Products Making Modern Health Claims](#) (e.g. general application types),
- [Pathway for Licencing Natural Health Products Making Traditional Health Claims](#),
- [Evidence for Homeopathic Medicines](#)

Quality:

These documents provide details on the requirements for ensuring high quality NHPs and good manufacturing practices.

- [Quality of Natural Health Products Guide](#)
- [Good Manufacturing Practices Guidance Document](#)
- [Finished Product Specifications](#)

Labelling:

This document provides details on the proper labelling and packaging requirements when selling NHPs.

- [Labelling Guidance Document](#)

The Compendium of Monographs:

- [Compendium of Monographs](#)
- [Compendium of Monographs guidance document](#)

For a full list of NNHPD's available policies and guidance documents, consult the [Guidance Documents](#) website.

## 4.2 Submitting a Large Volume of Applications

Applicants are requested to notify NNHPD when they intend to submit a large volume of applications over a short period of time (e.g., more than 20 applications a week), in order to develop a submission plan with NNHPD for processing and assessing applications within service standards. This applies to applications of all three classes (including amendments and notifications). If the applicant does not advise NNHPD of a large incoming volume of applications, these applications will not be held to the service standards outlined in this document.

## 4.3 Requesting a Pre-submission Meeting

The purpose of a pre-submission meeting is to discuss the evidence required in support of a Class III PLA or to clarify the type of applications required. Such meetings will:

- familiarize assessment staff with the proposed application prior to its arrival and provide a forum to discuss the evidence in order to facilitate its assessment;
- establish which studies or scientific evidence the applicant is relying on to support the safety and/or efficacy of the NHP and discuss the adequacy and appropriateness of controls;
- provide an opportunity for the applicant to discuss details of the application with NNHPD and obtain feedback regarding any areas of concern based on current experience and regulatory requirements; and
- provide NNHPD an opportunity to re-align resources, if necessary, to accommodate the arrival of the application.

Pre-submission meetings do not entail a full assessment by NNHPD of the evidence presented and, as such, the outcome does not constitute a regulatory decision by NNHPD, nor will a regulatory decision be issued.

### 4.3.1 Pre-submission Meeting Request

A pre-submission meeting request must be submitted to the NNHPD Client Service Unit ([hc.nnhpd-dpsnso.sc@canada.ca](mailto:hc.nnhpd-dpsnso.sc@canada.ca)) no less than one month prior to the proposed meeting date and should include the following information:

- the purpose of the meeting;
- a brief description of the NHP to be discussed at the meeting;
- three proposed dates for the meeting; and
- preference for a meeting by teleconference or in person at the NNHPD workplace.
- The subject of the e-mail must clearly state “pre-submission meeting request”, otherwise, there could be delays in processing the request.

### 4.3.2 Pre-submission Package

Applicants will be requested to submit a pre-submission meeting information package at least two weeks in advance of the meeting. The package should contain the following information:

- a cover letter;
- an agenda for the meeting;
- a list of participants and their titles/roles;
- a list of specific issues the applicant would like to discuss or have addressed;
- a brief summary of the NHP for which the meeting is being requested;
- a list of proposed ingredient quantities and their recommended conditions of use for the NHP;

- an overview of the market history of the product, including the foreign regulatory status of the product, if applicable;
- an identification of the claim for which authorization is sought; and
- a brief summary of the safety and efficacy data relating to the NHP.

Failure to provide the information package on time will result in the pre-submission meeting being re-scheduled.

#### 4.3.3 Pre-submission Meeting

It is the responsibility of the applicant to take minutes at a pre-submission meeting. These minutes are to be provided to NNHPD within two weeks of the meeting for review and concurrence.

### 4.4 Product Classification Request

Applicants who are unsure if their product is an NHP should refer to the following regulations, guidance, and tools:

- [Food and Drug Act](#);
- [Natural Health Product Regulations \(NHPR\)](#);
- [Guidance Document: Classification of Products at the Cosmetic-Drug Interface](#);
- [Guidelines for the Non-prescription and Cosmetic Industry Regarding Non-therapeutic Advertising and Labelling Claims](#);
- [Guidance Document: Classification of products at the food-natural health product interface: products in food formats](#);
- [Classification of Products at the \(Medical\) Device-Drug Interface](#);
- [Natural Health Product Ingredient Database](#), which provides information on whether a medicinal ingredient is subject to the NHPR or [Food and Drugs Regulations](#).

If following a review of all relevant regulations, guidance and tools, an applicant is unsure if a product is an NHP, the applicant is encouraged to submit a product classification request to [hc.ingredient.support.sc@canada.ca](mailto:hc.ingredient.support.sc@canada.ca) prior to submitting a PLA. A product classification request should include the following information for each product:

- name of the product, route of administration, and subpopulation(s);
- complete lists of medicinal and non-medicinal ingredients, with their quantity per dosage unit or concentration;
- the recommended use(s) or purpose(s) associated with the product;
- any other relevant conditions of use (if available), such as duration of use, directions of use, and risk information;
- Dosage form or product format (e.g. beverage, powder, bar, cream, capsule, etc.);
- The product label (if available) or proposed label text;
- Information on the product placement of sale (if available); and
- Product website (if available)

Any advice provided will not constitute a regulatory decision. A regulatory decision is only made following the receipt and review of an application as per the NHPR.

### 4.5 Master File

A Natural Health Product Master File (NHP-MF) enables the manufacturer of a medicinal ingredient or raw material (the NHP-MF holder) to provide proprietary information directly to NNHPD without

disclosing the information to the Product Licence applicant. The NHP-MF can be cross-referenced by one or more applicants by providing a Master File Letter of Access from the Master File holder (Senior Official) as described below. An NHP-MF is a confidential document; only authorized officials of Health Canada may access the file. Refer to the [Master File Procedures](#) guidance document for more information.

#### 4.5.1 Submitting a Master File

The NHP-MF holder may submit any evidence required for product assessment to NNHPD that is not published, (e.g., proprietary information not available to the public).

The following information is required when submitting an NHP-MF:

- Ingredient/product name;
- Company name and address;
- Senior Official information; and
- Contact person information;
- Designated Party Authorization (DPA) form for any contact person(s) submitting/signing/receiving correspondence on behalf of the NHP-MF holder, as described in section 5.1.3.

NHP-MFs do not need to be filed using a specific form though a PLA form should not be submitted with an NHP-MF application. NHP-MF is evidence for an application and is not an application itself. A single copy of the MF should be submitted electronically. NNHPD will not accept MFs in hard-copy (e.g. on paper). Given the current security profile associated with NNHPD's e-mail accounts, NNHPD cannot assure that the NHP-MF submitted via regular e-mail will be safeguarded. As such, NNHPD advises the applicant to submit an NHP-MF application as per section 5.2.1 via epost Connect™.

#### 4.5.2 Processing a Master File

When an NHP-MF is received, it will be assigned an MF number and an acknowledgment letter will be sent to the NHP-MF holder. NNHPD aims to assign an MF number within 30 calendar days from the date of receipt. An NHP-MF is not independently assessed or approved; rather the assessment of an NHP-MF is triggered by the assessment of a PLA referencing the NHP-MF. Only information relevant to the PLA is assessed.

#### 4.5.3 Referencing a Master File

To reference information in an NHP-MF, a Letter of Access from the NHP-MF holder is required to be submitted as part of PLA and must meet the following parameters:

- Be on official company letterhead of the company holding the NHP-MF, dated and signed by the NHP-MF holder company's Senior Official or other designated company official;
- Provide access directly to the applicant company (e.g., the letter cannot be addressed to the manufacturer or consulting company);
- Include the name and address of the company the NHP-MF holder is granting access to, the name of the product referencing the NHP-MF, and the assigned Health Canada MF number (e.g., NHP-MF holder Company A authorizes Company B to access and make reference to MF number: XXXXX MFXXX (NHP-MF Name)).

The NHP-MF holder can also provide authorization to a company for some of or all their NHP-MFs. In this case, an individual Letter of Access would not be needed for each application making reference to the NHP-MF.

In the absence of a valid Letter of Access, the NHP-MF cannot be assessed in conjunction with the application referencing it. This could result in the refusal of the application referencing the NHP-MF as there may be insufficient information to support the safety, efficacy and/or quality of the product.

## 4.6 The Natural Health Products Ingredients Database

The [Natural Health Products Ingredients Database](#) (NHPID) is a repository of medicinal ingredients and non-medicinal ingredients for use in natural health products (NHPs), and is a key component of the [Natural Health Products Online Solution](#). The [Compendium of Monographs](#) is also made available through the NHPID and each ingredient entry listed in the NHPID refers to all associated monographs. The NHPID also includes information related to ingredients that are not allowed or are restricted for use in NHPs. The NHPID uses standard terminology as described in the [Natural Health Products Online System Standard Terminology Guide](#).

### 4.6.1 NHPID Modification Process

NNHPD updates the NHPID on a bi-weekly basis. If applicants wish to include ingredients in their product formulation that are not listed in the NHPID, they must submit a request to add the ingredients to the NHPID. Ingredients must be present in the NHPID to be selected on the PLA form prior to submitting an application.

To request NHPID modifications, applicants must complete an [NHPID Issue Form](#) and send it to [hc.ingredient.support.sc@canada.ca](mailto:hc.ingredient.support.sc@canada.ca). Requests must be accompanied by at least one piece of supporting evidence (unless a typographic correction). The NHPID Issue Form includes a non-exhaustive list of references that may be considered as a helpful starting point to find supporting evidence.

Requests for NHPID modifications are processed within 30 calendar days from the receipt of the request. The time required for reviewing a request may however vary depending on the quality and/or the complexity of the request, as well as on the volume of requests.

## 4.7 New Company Registration

NNHPD requires that all new applicants register their companies before submitting their first product licence application. This is a new requirement that is key for applicants to have access to the web based form and facilitate traceability of applications. Upon registration, NNHPD will provide new applicants with a unique 5 digit company code to be used on all subsequent applications submitted to NNHPD. This unique 5 digit company code is required on all forms to ensure they can be processed effectively once received.

To register your company and obtain a company code, please submit a request via the NNHPD Client Service Unit ([hc.nnhpd-dpsnso.sc@canada.ca](mailto:hc.nnhpd-dpsnso.sc@canada.ca)) and indicate "New Company Registration" in the subject line. In the body of the email, include your company contact information such as company name, address, and company contacts such as senior official and application contacts.

Note that this only applies for new companies. Companies that have previously submitted a PLA for an NHP have already been issued a company code and are not required to preregister. Applicants who already have a company code can locate their number on NNHPD correspondence documents including issuance letters, Information Request Notices (IRNs), Notices of Refusal etc.

## 5. Submitting an Application

### 5.1 Application Requirements

To facilitate the assessment of the product and to appropriately assign resources, NNHPD requests that applicants identify the class under which they are applying in the cover letter of their application according to the definitions in section 3 of this document. If a Class is not identified correctly in the cover letter, the application will be refused.

The following table outlines the various application requirements by class and application type.

Table 5.1

Requirements	Application type							Notification
	Class I		Class II or III			Class III		
	Compendial	Amendment	General	Traditional	Amendment	Homeopathic	Amendment	
Natural Health Product Licence Application form	✓	Not applicable	✓	✓	Not applicable	✓	Not applicable	Not applicable
Amendment and Notification Form	Not applicable	✓	Not applicable	Not applicable	✓	Not applicable	✓	✓
Label text	✓	If applicable to the proposed changes	✓	✓	If applicable to the proposed changes	✓	If applicable to the proposed changes	If applicable to the proposed changes
Summary Report (Evidence, Safety and/or Quality)	Not applicable	If applicable	Recommended	Recommended	Recommended	Recommended	Recommended	Not applicable
Evidence	See section 5.1.1.4	See section 5.1.1.4	✓	✓	✓	✓	✓	Not applicable
Animal Tissue Form (if applicable)	✓	✓	✓	✓	✓	✓	✓	Not applicable
Finished Product Specifications	See section 5.1.1.6	If applicable to the proposed changes	✓	✓	If applicable to the proposed changes	✓	If applicable to the proposed changes	Not applicable

✓ - Required

All information and data submitted in support of a PLA for an NHP, will be retained by Health Canada in accordance with the retention requirements (keeping records on file) of the [Library and Archives of Canada Act](#)

### 5.1.1 Requirements

The following section provides an overview of each of the requirements from Table 5.1.

#### 5.1.1.1 Application Forms

One of two application forms will be required depending on the type of application. Applications for new products must be provided using the web-based [NHP PLA](#) form while amendments to existing products must be submitted using the [Amendment and Notification Form](#) (ANF).

The most recent version of the PLA form and ANF must always be used. Applications using an older version of a form will not be accepted and will result in an automatic refusal of the application. In rare instances where the forms cannot be used, applicants will be advised to contact the NNHPD Client Service Unit ([hc.nnhpd-dpsnso.sc@canada.ca](mailto:hc.nnhpd-dpsnso.sc@canada.ca)) for additional guidance.

For kit applications, NNHPD requires that the medicinal and non-medicinal ingredients for each component of the kit to be separated. This can be achieved by submitting separate PLAs - one for each component. The recommended conditions of use must be the same in each PLA. Please ensure to indicate that this application is a kit and has # of forms as part of the application in your covering letter.

NNHPD requests that applicants use the following format when naming their PLA file: "PLA\_TrackNo\_BName\_Date\_Time.html". The applicant is asked to indicate the class in the name as well.

#### 5.1.1.2 Label Text

All product licence applications must include a corresponding label text that meets the requirements outlined in section 93-94 of the NHPR. This requirement can be met by using the label text generator within the PLA form, or by submitting a mock up separate from the PLA form.

#### 5.1.1.3 Summary Report

Summary reports are recommended to assist in the assessment process and reduce the time for completion, particularly for more complex submissions (e.g., where a number of extrapolations are being made). In general, the summary report should capture how each piece of information submitted addresses some or all aspects of the recommended conditions of use for the NHP. Where included, these summary reports serve to reflect the totality of available information relevant to the NHP and provide context that speaks to what may otherwise appear as gaps/uncertainties in the information concerning the safety, efficacy, and/or quality of the product.

#### 5.1.1.4 Evidence

In order to meet all safety and efficacy requirements and prescribed quality requirements, applicants must attest to one or more of the NNHPD Monograph(s) from the [Compendium of Monographs](#) and/or provide evidence as stated in guidance outlined in Section 4.1.

##### 5.1.1.4.1 Attesting to NNHPD monographs

By attesting to a monograph, the applicant is confirming that the application meets all of the monograph parameters to which the applicant has attested. Applications will be verified against the monograph and deviations from monograph parameters for a Class I application will result in the automatic refusal of the application. Using the PLA form, applicants are able to attest to safety, efficacy and/or quality, by identifying the monograph(s) relevant to their product.

Applications attesting to meeting quality requirements must attest for the finished product, in its entirety, and must meet the quality specifications outlined in the NNHPD monograph(s) and in the [Quality of Natural Health Products Guide](#).

The following table demonstrates the applicable attestation(s) (safety, efficacy and/or quality) for different scenarios:

Scenario	Applicable Attestation		
	Safety	Efficacy	Quality
All monograph parameters are met	✓	✓	✓
All monograph parameters are met, with the exception of minimum daily dose and/or recommended use/purpose (claim)	✓	Not applicable	✓
All monograph parameters are met, with the exception of minimum daily dose, claim and specifications	✓	Not applicable	Not applicable
All monograph parameters are met, with the exception of specifications	✓	✓	Not applicable
All monograph parameters are met, with the exception of maximum daily dose and/or risk information	Not applicable	✓	✓
Parameters of the Quality for Natural Health Products Guide are met	Not applicable	Not applicable	✓

If applicants are not attesting to full monograph parameters in Class II or III applications, they must ensure that evidence or a rationale for not attesting to the monograph has been provided (refer to section 4.1 for a list of guidance and supporting documents on evidence and rationale requirements).

Examples include (but are not limited to):

- The required conditions of use are omitted for a product. Applicants cannot attest to safety; instead they must indicate the reason for not attesting and provide evidence or a rationale to support the omission as part of the application package.
- The claim is not supported by a monograph, but the ingredient dose is supported. Applicants can attest to safety but not efficacy and they must ensure evidence is provided to support the efficacy of the non-monographed claim.
- A “statement to the effect of” monograph statement is used for the product.
- The safety and efficacy conditions are supported by a monograph, but not quality. Applicants can attest to safety and efficacy, but not quality and must provide Finished Product Specifications (FPS) with a rationale for deviating from the quality specifications outlined in the NNHPD monograph and [Quality of Natural Health Products Guide](#).

For more information on attestation to NNHPD monographs please refer to Appendix I.

#### 5.1.1.5 Animal Tissue Form

When required, an [Animal Tissue Form](#) (ATF) must be completed.

An ATF may be required for the following types of ingredients:

1. medicinal ingredient;
2. non-medicinal ingredient; or
3. an ingredient used in processing (e.g. not present in the final product).

A separate ATF should be provided for:

1. each ingredient (e.g. medicinal, non-medicinal, or an ingredient used in processing);
2. each type of process; and
3. each type of animal (e.g. mammal, bird or crustacean).

#### 5.1.1.6 *Finished Product Specifications*

By submitting a compendial (Class I) application, applicants attest to the specifications in the [Quality of Natural Health Products Guide](#) and relevant monograph. It is the applicant's responsibility to be aware of the regulatory requirements for their product when providing the attestation. Finished Product Specifications (FPS), although not required to be provided in Class I applications, must be provided to NNHPD upon request.

#### 5.1.2 *Letter of Access*

Applicants may reference supporting information in another company's application(s) with a Letter of Access. The Letter of Access authorizes NNHPD to access the indicated information in the application. The Letter of Access must meet the following parameters:

- Be on official company letterhead of the company being referenced, dated and signed by the Senior Official of the referenced application;
- Provide access directly to the applicant or licensee (e.g., the Letter of Access cannot be addressed to the manufacturer or consulting company); and
- Include the name of the company that is being granted access to use the referenced application, the name of the product and the submission number of the application being referenced (e.g., Company A authorizes Company B to access and make reference to Submission No. XXXXX and/or Natural Product Number (NPN)/Drug Identification Number-Homeopathic (DIN-HM) XXXXX (Product Name).

In the absence of a valid Letter of Access, the referencing application may be incomplete resulting in a request for more information/evidence or a refusal of the application.

#### 5.1.3 *Designated Party Authorization forms*

A Designated Party Authorization ([DPA form](#)) is required when the party signing the application is a designated party acting on behalf of the Senior Official of the applicant or licensee according to paragraph 5(b) of the NHPR. This authorization allows the contact person(s) to act on behalf of the applicant or licensee for functions such as:

- submitting applications, signing for applications;
- receiving/responding to Information Request Notices (IRNs);
- receiving/responding to regulatory notices (e.g. safety concerns); or
- submitting withdrawal or discontinuation requests for a product on behalf of the applicant or licensee.

A DPA is required to be submitted once for each contact of a given company; it does not need to be sent with every application provided that authorization is clearly granted for the designated party to act on behalf of the Senior Official for more than one application.

The DPA form is located on the [Product Licensing Forms and Templates](#) website.

#### 5.1.4 Site Information

Applicants must provide the site information for each manufacturer, packager, labeller and importer prior to the sale of the NHP according to section 22 of the NHPR. Where available, the applicant must list the company name and address, and site licence number for Canadian sites, under Part 3 – Site Information of the PLA form for each manufacturer, packager, labeller, importer, distributor and/or storage facility for the NHP.

An NHP cannot be made available for sale in Canada until a Natural Product Number (NPN) is issued and the above information has been provided in full to NNHPD. If this information is not provided on the PLA, the applicant must provide the information to NNHPD via a notification using the ANF.

## 5.2 Methods of Submitting an Application

NNHPD will only accept applications submitted electronically. The electronic application should include the original electronically generated application form format, from the web-based NHP PLA form (i.e. .html), which can be integrated into the NNHPD system. The current electronic submission method is via Canada Post's secure email service, epost Connect™. Applications submitted in hard-copy (i.e., on paper), will not be accepted. NNHPD will not accept scanned copies of the PLA form. Other formats may be considered under exceptional circumstances (e.g. CD/DVD).

Applicants should submit an application only once. Duplicate applications will be refused.

### 5.2.1 Submitting applications by secure email

The web PLA form must be submitted in HTML format. NNHPD accepts completed submission packages via epost Connect™. In order to use epost Connect™, applicants must be enrolled as a Trading Partner. Please refer to the [Guidance Document on How to Interact with the Natural and Non-prescription Health Products Directorate electronically](#).

An application should be submitted to the following:

- **nhpsn.epostel.applications**  
NNHPD uses this account to start company-specific conversation threads. New applications or amendments and notifications must be submitted under this account.

Applications submitted to the nhpsn.epostel.correspond account will not be processed.

## 6. Processing and Assessment of Applications

The following section outlines the stages involved in processing and assessing an application, as well as when and how to communicate with NNHPD throughout the application process.

### 6.1 Processing Applications

All applications (new submissions, amendments and notifications) submitted to NNHPD will be screened for administrative requirements. If the administrative requirements are met, notifications are processed and new applications or amendments (for all classes) proceed to regulatory screening. Following regulatory screening, Class I and II applications and amendments will be issued a regulatory decision. Class III applications and amendments that have successfully completed the regulatory process will

proceed to assessment. If additional information is required at the regulatory screening or assessment stage, an Information Request Notice (IRN) may be issued (see section 6.1.4).

Applicants are required to identify their application as Class I, II or III through the application form or in the cover letter.

### 6.1.1 Administrative verification

NNHPD verifies all applications for administrative completeness.

A Notice of Refusal - Administrative Deficiency will be issued for all applications that have one or more administrative deficiencies. Administrative deficiencies are the following:

- missing or incorrect (inconsistency between cover letter and application) application type;
- missing monograph attestation, if applicable;
- missing contact information or Designated Party Authorization (DPA) form;
- no record of change in Senior Official;
- incorrect or incomplete application form(s);
- application submitted in an unacceptable format (e.g. on USB drive, password protected, paper, scanned copy);
- application contains damaged/corrupted file(s);
- duplicate tracking number on the submitted PLA (when applicants reuse the form for different applications, the same number is generated which interferes with NNHPD systems).

Class II and III applications and amendments meeting all administrative requirements will be acknowledged (Application Acknowledgement Letter via ePost) before proceeding to the regulatory screening stage (see section 6.1.2). The acknowledgement will provide applicants with the submission number and date of receipt of the application.

### 6.1.2 Regulatory Screening

All PLAs will be screened against regulatory requirements, as outlined in the NHPR, this policy and NNHPD's applicable guidance documents. In addition, applications will be screened for minimum application requirements and, when applicable, against all parameters of the NNHPD monograph(s) as described below.

A Notice of Refusal will be issued, if any of the following significant deficiencies are identified during the screening process. These significant deficiencies are:

- incomplete or inaccurate information on the PLA form;
- failure to provide minimum application requirements, such as FPS, product label text, supporting evidence for safety and/or efficacy, letters of access, animal tissue form, and/or attestation(s);
- product does not meet the definition of an NHP;
- failure to meet the parameter(s) of an NNHPD monograph to which the product attested.

A Notice of Refusal will also be issued in the following circumstance:

- failure to submit the requested information in response to an IRN within the timelines specified in the notice, or submission of an incomplete or deficient response to an IRN.

### 6.1.3 Assessment

Upon successful completion of the screening process, Class III applications and amendments will be assessed for the safety and efficacy requirements.

A Notice of Refusal will be issued at the assessment stage in the following circumstances:

- failure to meet the requirements of the NHPR and the applicable provisions of the *Food and Drugs Act* due to one or more of the following:
  - failure to submit the requested information in response to deficiencies/information/document omissions that preclude the ongoing assessment;
  - failure to submit the requested information in response to an IRN within the timelines specified in the notice; and/or
  - submission of an incomplete or deficient response to an IRN.

#### 6.1.4 Information Request Notice

NNHPD will provide applicants the opportunity to address non-administrative deficiencies or information omissions through an Information Request Notice (IRN), as per section 15 of the NHPR, with a specified response time between 2 to 15 calendar days depending on the complexity of the information requested.

Class I applications may be issued an IRN for brand names or other non-significant deficiencies (Please refer to 6.1.2 for more information on significant deficiencies). Class II and III applications may be issued an IRN for non-significant deficiencies during the regulatory screening stage. Class III applications may be issued IRNs during the assessment stage which may include a request for a [Risk Management Plan \(RMP\)](#). Over the course of an assessment, applicants may be asked to adopt an RMP particularly where information concerning the use of the NHP within the Canadian context or a similar regulatory framework is not as robust.

For the purpose of improving the regulatory screening and efficiency of the assessment process, NNHPD will aim to issue one comprehensive IRN that includes all deficiencies identified with the application at each stage of screening and assessment as required. The response to NNHPD must address each of the items listed in the comprehensive IRN. NNHPD will not send IRNs for issues identified in a previous IRN that are not adequately addressed nor will NNHPD request information a second time if the applicant has not adequately responded. An additional IRN may be issued at the regulatory screening or assessment stage based on the complexities of a given application.

##### 6.1.4.1 Responses to an IRN

NNHPD uses the following account to initiate submission-specific conversation threads to issue notices specific to a Product Licence application.

- **nhpsn.epostel.correspond**  
Applicants must submit responses to Information Request Notices (IRNs) through these conversation threads. Note that once a decision has been issued for an application, these conversations are no longer be monitored and are removed from the system.

As mentioned above, NNHPD will communicate with applicants by epost Connect™. Responses to an IRN must be submitted electronically through the submission-specific epost Connect™ conversation within the specified time period.

If a response to an IRN is deemed deficient or if the applicant does not satisfy all requirements within the allotted timeframe, a Notice of Refusal will be issued.

##### 6.1.4.2 Request for an IRN response extension

Applicants should contact their Submission Coordinator listed on the IRN via the submission-specific epost Connect™ conversation thread or by phone to request an extension for responding to an IRN. The

request should detail the reason for the extension and a proposed alternative date of response. NNHPD will assess the request on a case-by-case basis and provide a response to the request within 2 business days of receipt. NNHPD will work with applicants to ensure extension requests are addressed.

It is the responsibility of applicants to be available (or have a designated party available) to respond to IRNs in a timely manner. NNHPD reserves the right not to grant an extension for an IRN, in which case the applicant will be notified and the reason provided.

### 6.1.5 Service standards

The following table outlines the service standards for each application type. These service standards apply to PLAs submitted in electronic format using NNHPD's most recent version of the PLA and ANF. Please refer to section 5.1.

Application Type		Type of Notice Issued	Assessment	Regulatory Decision Issued	Service Standards
CLASS I	Compendial	Notice of Refusal - No acknowledgement notice applies for this class	Not Applicable	Product Licence or Notice of Refusal	60 Calendar Days
	Class I Amendment				
CLASS II	General	Application Acknowledgement or Notice of Refusal	Not Applicable	Product Licence or Notice of Refusal	90 Calendar Days
	Traditional				
	Class II Amendment				
CLASS III	General		Application Acknowledgement or Notice of Refusal	180 Calendar Days	Product Licence or Notice of Refusal
	Traditional				
	Homeopathic				
	Class III Amendment				

Novel products that require joint assessment with other directorates (e.g. Medical Devices Bureau) are not subject to the service standards outlined above. NNHPD encourages a pre-submission meeting for such products.

Licence holders are encouraged to contact NNHPD prior to submitting new PLAs, amendments, or notifications while addressing compliance issues in collaboration with the Regulatory Operations and Enforcement Branch (ROEB) as unresolved compliance issues may result in an inability for NNHPD to issue or amend a product licence.

## 6.2 Exchange of Information

Applicants wishing to contact NNHPD to receive advice regarding policies, guidance, procedures, tools, or initiatives, are encouraged to send their enquiry to the NNHPD Client Service Unit ([hc.nnhpd-dpsnso.sc@canada.ca](mailto:hc.nnhpd-dpsnso.sc@canada.ca)).

### 6.2.1 Application status updates

NNHPD will review each e-mail received through the NNHPD Client Service Unit ([hc.nnhpd-dpsnso.sc@canada.ca](mailto:hc.nnhpd-dpsnso.sc@canada.ca)) and in cases of status requests, will verify that an application was received. A response will only be provided when an issue is identified with an application. For status requests on applications that are still within the applicable service standards, no reply will be sent. If the applicable service standard period has elapsed, e.g., it has been more than 60, 90, or 210 calendar days since the date of submission of a Class I, II or III application, respectively, and applicants have not received a regulatory decision, applicants may send a status update request to the NNHPD Client Service Unit ([hc.nnhpd-dpsnso.sc@canada.ca](mailto:hc.nnhpd-dpsnso.sc@canada.ca)).

All status update requests must include the following information:

- submission number (if available),
- name of the applicant company,
- brand name,
- application type,
- date of submission, and
- method of submission (e.g. epost Connect™), of the application.

### 6.2.2 Submitting unsolicited information

Once an application is submitted, NNHPD will not accept unsolicited information or changes to the original application, with the exception of providing updates to the contact information. Otherwise, applicants wishing to make changes to a PLA are required to withdraw their application and resubmit a new application with the revisions. See section 6.4 for information on how to withdraw an application.

### 6.2.3 Request for records

Applicants should maintain records of the information they submit to NNHPD. If there is a change in licence holder or consulting company, for example, the current licence holder must have a record of the complete Product Licence application package. NNHPD is not responsible for maintaining records for applicants, and will not provide copies of submission information to licence holders or application contacts. NNHPD has no regulatory obligation to provide copies of licences or other documents submitted as part of an application.

Information and data submitted to support the original application will not be returned to the applicant.

## 6.3 Decision Issuance

Once NNHPD has completed the processing of a PLA, this will result in one of two regulatory decisions: a licence or refusal.

### 6.3.1 Issuance of a licence

A Product Licence will be issued for applications satisfying regulatory requirements as outlined in the NHPR. The Product Licence will include the Natural Product Number (NPN) or Drug Identification Number-Homeopathic Medicine (DIN-HM) assigned to the product. Information on licensed products is available online on the [Licensed Natural Health Products Database \(LNHPD\)](#). The status of the licensed product on the LNHPD will appear as “Active”.

### 6.3.2 Licence correction requests

As per section 14(2) of the NHPR, licensees have 60 calendar days following the issuance of a Product Licence to notify NNHPD of any information on the licence that the licensee knows to be incorrect. Correction requests should be submitted via the NNHPD Client Service Unit ([hc.nnhpd-dpsnso.sc@canada.ca](mailto:hc.nnhpd-dpsnso.sc@canada.ca)). All licence correction requests should have in the subject line the Submission No. XXXXX and/or Natural Product Number (NPN) XXXXX. Requests should be made only for administrative errors made on the Product Licence (e.g. spelling errors or other discrepancies between the submitted Product Licence Application form and the Product Licence). Licence corrections are not post licensing changes outside of what was reviewed in the PLA. These changes are considered post licensing changes (please refer to section 7.1 for more information). The NNHPD will be updated within 15 calendar days to reflect the correction and a revised licence will be issued.

### 6.3.3 Refusal to issue a licence

A Notice of Refusal will be issued for applications that do not satisfy the requirements of the NHPR. See section 6.1 for an overview of administrative verification, regulatory screening and assessment refusal reasons.

A reconsideration process is available to applicants seeking to contest a Notice of Refusal. If the applicant wishes to submit additional information on the product for which a Notice of Refusal was issued, a new application must be submitted. If an applicant wishes to re-submit an application that was refused, please refer to section 6.5.

#### 6.3.3.1 Request for reconsideration

As per section 9 and 10 of the NHPR, an applicant may request a reconsideration of a Notice of Refusal within 30 calendar days of issuance. Refer to the [Reconsideration Guide](#) for more information.

### 6.3.4 Safety and Efficacy Assessment Report

Following the receipt of a Product Licence or a Notice of Refusal, an applicant or licensee may request the Safety and Efficacy Assessment Report (SEAR) for their application by writing to NNHPD Client Service Unit ([hc.nnhpd-dpsnso.sc@canada.ca](mailto:hc.nnhpd-dpsnso.sc@canada.ca)) and referencing the Submission Number. NNHPD will strive to provide a copy of the requested SEAR via ePost Connect™ within 20 calendar days from the date of receipt. This is applicable to Class II and III applications only as Class I applications do not have a SEAR.

## 6.4 Withdrawal of an Application

At any time during the application process, an applicant may withdraw their application by submitting a request to the NNHPD Client Service Unit ([hc.nnhpd-dpsnso.sc@canada.ca](mailto:hc.nnhpd-dpsnso.sc@canada.ca)) or if the withdrawal is in response to an IRN, to the Submission Coordinator via epost Connect™ as outlined in section 6.1.4.2. All withdrawal requests will be acknowledged in writing within 15 calendar days. The status of the application will be recorded internally as "Withdrawn by applicant".

Withdrawal of an application is without prejudice to re-submitting. If an applicant wishes to re-submit a complete application at a future time, the application will be processed as a new application.

## 6.5 Re-submitting an Application

Applicants may re-submit previously withdrawn applications or applications for which a Notice of Refusal was issued. In all cases, a new and complete application is required and the applicant must reference the submission number of the previous application if the application was refused. The new application will be subject to any new regulations, policies, procedures and/or guidance documents in effect at the time of submission.

# 7. Post Licensing Activities

Post licensing activities include all activities that occur once a product is licensed, such as amendment and notification applications, requests to discontinue a Product Licence, post-licensing audit activity and NNHPD-initiated activities. Information on each of these activities is described below.

## 7.1 Post Licensing Changes

Amendment and notification applications must be submitted using the [Amendment and Notification Form \(ANF\)](#). There are three types of post-licence changes: a fundamental change, an amendment and a notification.

See Appendix II for a detailed list of changes and what the regulatory requirements are for each change.

### 7.1.1 Fundamental changes

The NHPR do not allow for product changes considered fundamental changes following the issuance of a Product Licence. The following changes are considered fundamental changes as defined in section 13 of the NHPR:

- change to the quantity of a medicinal ingredient per dosage unit, addition or substitution of a medicinal ingredient;
- change to the dosage form; or
- change to the route of administration.

These changes require a new application and upon approval by NNHPD, will receive a new NPN or DIN-HM. This also applies to products attesting to a monograph which are making any of the above changes while remaining within the limits of the monograph. Licence holders should request a discontinuation of the original licence as outlined in section 7.3, if the original product will no longer be manufactured.

### 7.1.2 Amendments

Amendments are changes to an NHP that may have an impact on the safety, efficacy and/or quality of the product. An amendment application must include evidence to demonstrate that the NHP remains safe and efficacious. The amendment can only be applied to a product once approval is obtained and the Product Licence is updated to reflect the changes. Once the amendment is approved, the applicant will be notified and sent the amended Product Licence via epost Connect™. Products previously issued licences with the terms “As authorized according to the NNHPD monograph to which the applicant attested” will receive an amended licence listing full product information.

An amendment is required for all licensed products that are making any of the following changes, as per section 11 of the NHPR:

- a. a change to its recommended dose;
- b. a change to its recommended duration of use;
- c. the deletion or modification of risk information shown on any of its labels, including the deletion or modification of a caution, warning, contra-indication or known adverse reaction associated with its use;
- d. a change of its recommended use or purpose;
- e. a change of the source material of any of its medicinal ingredients;
- f. changing any of its medicinal ingredients to or from being synthetically manufactured;
- g. a change to the potency of any of its medicinal ingredients;
- h. a change affecting its safety or efficacy that does not arise as a result of
  - i. a change to the quantity of a medicinal ingredient per dosage unit,
  - ii. the addition or substitution of a medicinal ingredient,
  - iii. a change to its dosage form, or
  - iv. a change to its recommended route of administration; or
- i. one or more of the following changes to its specifications, namely,
  - i. the removal of a test method set out in the specifications,
  - ii. the modification of a test method set out in the specifications in a manner that widens the purity tolerances of the natural health product or the quantity, identity or potency tolerances of any of its medicinal ingredients, or
  - iii. the modification of a test method set out in the specifications in a manner that renders it less precise, accurate, specific or sensitive.

#### 7.1.2.1 *Classes of amendments*

Amendment applications are classified, processed and assessed in a manner similar to new applications. Please refer to section 6 for more information. A post-licence audit may also be conducted if the original application was submitted using an attestation as outlined in section 7.4.

Amendments follow the same service standards as new applications as outlined in section 6.1.5.

#### 7.1.3 *Notifications*

Notifications are changes to an NHP that does not have a significant impact on the safety, efficacy and/or quality of the product. Licensees must notify NNHPD of the change within 60 calendar days after the day on which the change is made, using the [ANF](#).

A notification is required for all licensed products that are making any of the following changes, as per section 12 of the NHPR:

- a) a change to any of the information submitted under paragraph 5(a) or (b);
- b) a change to any of the information provided under section 22;
- c) the addition or substitution of a non-medicinal ingredient, the addition or substitution of which does not affect its safety or efficacy;
- d) its sale under a brand name other than one submitted under paragraph 5(e);
- e) a change of the common or proper name of any of its medicinal ingredients; and
- f) the addition of risk information to any of its labels, including the addition of a caution, warning, contra-indication or known adverse reaction associated with its use.

Notifications are not included in the three-class system. NNHPD will send a Notification Acknowledgement Letter.

### 7.1.3.1 Non-notifiable changes

A non-notifiable change is a change to a licensed product that is not required to be submitted to NNHPD. These are revisions that are not outlined in sections 7, 11 or 12 of the NHPR. Non-notifiable changes include revisions to the net package quantity (e.g. 50 to 100 capsules per bottle) that do not pose a safety concern, revisions to information on the label not indicated on the PLA or requiring assessment (e.g. marketing, formatting, certain storage conditions), or revisions to manufacturing flow charts which do not impact the Finished Product Specifications (FPS).

NNHPD will not send a Notification Acknowledgement Letter to the applicant if non-notifiable changes are submitted.

### 7.1.3.2 Maintaining company and contact information

As per section 12 of the NHPR, licensees are responsible for notifying NNHPD within 60 calendar days of changes to contact information, as required. This requirement applies across the full life-cycle of the product.

Changes to contact information include:

- The Senior Official has changed; and
- A change in contact information (email, phone, mailing address, etc.) occurs for the company not affecting a manufacturing, packaging, labelling, or importing site.

These changes must be submitted by the Senior Official or Designated party of the company and must be submitted to NNHPD as a Notification using the ANF.

#### 7.1.3.2.1 Company transfer or merger

When a company transfers ownership of one or more licensed product(s) and its associated regulatory responsibilities, the transfer must be submitted to NNHPD as a notification using the ANF. If the transfer is for an application that has already been submitted to NNHPD, but has not yet been issued a regulatory decision, the information listed below should be submitted as an unsolicited information update. Please refer to section 6.2.2 for more information on how to submit.

In either instance, the following information is required:

- A letter from the Senior Official from each company on company letterhead confirming the transfer.
  - Both letters must identify which products licences are being transferred, including the NPNs/DIN-HMs and primary brand names.
- Designated Party Authorization (DPA) form(s), if applicable.

For a post-licence application transfer: an ANF with the new company information is required:

1. Select “Licence transfers” on the ANF home page
2. Identify the current licensee
3. Complete submitter information
4. Complete the new licensee information

For a pre-licence application transfer via an unsolicited information update: an updated PLA Form with the new applicant and contact information is required.

## 7.2 Monograph Updates

It is important to note that NNHPD monographs are revised periodically. Product Licence holders are expected to align products affected by monograph revisions with the most recent monographs within 3 years or the next label run or a post licensing change (amendment or notification), whichever comes first,

of the publication of the revised monograph, unless otherwise notified, by submitting an amendment. Note that if a monograph is changed for safety reasons, applicants will be advised of the timelines for requiring label changes; these timelines may be shorter than indicated above.

### 7.3 Discontinuing an NPN or DIN-HM

Licence holders are encouraged to notify NNHPD if they no longer require an active NPN or DIN-HM for a product. The licensee must request to discontinue the NPN or DIN-HM by notifying NNHPD. Only the Senior Official or contact, acting on behalf of the Senior Official, (formalized by way of a Designated Party Authorization (DPA) form) can request a discontinuation. Requests submitted by individuals other than the Senior Official or a recognized contact will not be processed. The request should be sent on company letter and be signed by the senior official (or designate) and include the following information:

- the NPN(s) or DIN-HM(s) to be discontinued
- the associated submission number(s)
- the associated brand name(s)

A discontinuation request must be submitted to the NNHPD Client Service Unit ([hc.nnhpd-dpsnso.sc@canada.ca](mailto:hc.nnhpd-dpsnso.sc@canada.ca)). NNHPD will notify licensees when the request has been processed (within 15 calendar days) and the status on the LNHPD will be updated to “Discontinued”.

NNHPD may also initiate an NPN or DIN-HM discontinuation. If NNHPD attempts to contact a company post-licensing (e.g. as outlined in section 7.4) and during this process, it is determined that the company is no longer operational or bankrupt, NNHPD will take action to discontinue the licence holder’s NPN(s) or DIN-HM(s). The status will be reflected on the LNHPD as “Discontinued”.

Please note that licences cannot be reactivated once they have been discontinued. Any revisions to the contact information for licence holders for discontinued products does not need to be provided to NNHPD.

### 7.4 Post Licensing Audit

NNHPD may conduct post-licensing audits for any application that provided an attestation (re: safety, efficacy and/or quality) at any time. The objective of an audit is to confirm the validity of the attestation. If there is a discrepancy noted during an audit, applicants will be notified.

### 7.5 Post Licensing NNHPD Initiated Activities

If an issue (e.g. safety or administrative) is identified for a licensed product, NNHPD may issue a request for additional information or clarification from the licence holder. The assessment of post-licence issues identified by Health Canada, for instance through its [Canada Vigilance Program](#) or compliance and enforcement activities conducted by the Regulatory Operations and Enforcement Branch (ROEB), and any resulting amendments required from the licence holder, are not subject to the service standards outlined in this document.

When a post-licence issue is identified, NNHPD may issue a Post-Licence Information Request Notice requiring specific changes/modifications to the product and/or its labelling in order to address the issue. Post-Licence Information Request Notices provide a timeline for a response that is determined by Health Canada, to account for the complexity of the request, the urgency of the situation, and other factors. The Notice also allows the licensee to address the issue by submitting a post-licence amendment or notification using the [ANF](#).

Examples of post-licence issues:

- changes made to an ingredient entry in the NHPID that must be reflected in affected licensed products;
- updates to a monograph affecting a licensed product;
- discovery of new information or restrictions specific to an ingredient or product that impacts the safety of a licensed product;
- the identification of administrative errors during licensing;
- complaints received regarding a licensed product that identify a potential safety issue; and
- product updates resulting from safety assessments.

A Post-Licence Information Request Notice is not the only tool used by Health Canada to address a post-licence issue. NNHPD may also issue regulatory notices as outlined in sections 16 to 20 of the NHPR, if there is a safety concern, or other alleged contravention of the NHPR or Food and Drugs Act for a licensed product. In the event that a licensee receives a regulatory notice from NNHPD and is requested to update the product information by submitting an amendment, applicants must use the ANF tool and identify the application as “in response to a notice issued by the NNHPD Risk Management Division”. The ANF must be submitted as outlined in section 5.2.

# Appendix I – Attestation to NNHPD monographs

## 1. Monograph Parameters

When attesting to a monograph, the PLA must match the monograph content exactly or fall within its parameters. The following parameters of a monograph must be met upon attestation:

1. Proper name

The proper name must be chosen from one of the options provided in the monograph.

2. Common name

The common name must be chosen from one of the options provided in the monograph.

3. Source material

The source material must be chosen from the options provided in the monograph. More than one source material is acceptable, provided that all source materials listed on the PLA form reflect the same dose and/or use or purpose on the referenced monograph.

4. Route of administration

The route of administration must be chosen from the options provided in the monograph. Please see the [NHPID Controlled Vocabulary](#) for a description of the routes of administration.

5. Dosage form

The dosage form must reflect the route of administration for the product and be chosen from the options provided on the monograph, where applicable, or as outlined in the Compendium of Monographs. Food-like dosage forms are not acceptable (e.g., bars, chewing gums, or beverages).

- Please note that an NHP in a modified formulation (e.g., liposomal, phytosomal, etc.) intended to improve the bioavailability and/or absorption of its medicinal ingredients is not considered equivalent to an NHP in a non-liposomal/phytosomal formulation or conventional dosage form. Therefore applicants cannot attest to a monograph for the safety and efficacy of an ingredient unless the monograph specifically states that such formulations are acceptable. Products with liposomal/phytosomal formulations or any other formulation with enhanced bioavailability must be submitted through the appropriate application type (e.g. “General” application type) with specific evidence to support the corresponding formulation/dosage form.

6. Recommended use or purpose

Claims have been identified for each monographed ingredient based on NNHPD's evaluation of the safety and efficacy data. Applicants may choose one or more claims provided in the monograph. Applicants must ensure that any conditions surrounding the claim (dose, source material, etc.) are met.

7. Dose

The single and/or daily dose(s) must fall within the range, or be equal to that, indicated in the monograph. The dose indicated on the monograph may be specific to:

- Subpopulation
  - All monographs are intended for adults, unless otherwise specified.
- Method of preparation
  - Must be chosen from the list of acceptable methods, if indicated. Furthermore, to make a traditional use claim, the method of preparation must be one that was traditionally

used. Please see the [Pathway for Licensing Natural Health Products Used as Traditional Medicines](#) guidance document for a list of traditional methods of preparation.

- Potency
  - When a monograph includes potency, it must be included in the PLA, unless otherwise specified.
  - The inclusion of a potency when not permitted by the monograph is not acceptable for attestation.
- Frequency
  - The frequency must be the same as or fall within the range of the frequency on the monograph, when specified. When the monograph specifies a divided dose, the frequency must be more than once daily. If no frequency is specified, the applicant may select an appropriate frequency.
- Directions of use
  - Where specified, all directions of use must be included in the PLA, as applicable.

#### 8. Duration of use

When the monograph includes a duration of use, it must be included on the PLA, as applicable.

#### 9. Risk information

All risk information contained in the monograph must be included in the PLA, as applicable.

#### 10. Non-medicinal ingredients

Only non-medicinal ingredients listed in the NHPID may be used with an appropriate excipient purpose. Any applicable restrictions indicated in the database must be met.

The presence of non-medicinal ingredients without conditions on the [Cosmetic Ingredient Hotlist: Prohibited and Restricted Ingredients](#) (the hotlist) indicates that there are potential safety issues with these ingredients. If the hotlist indicates that additional evidence is required for an ingredient or if an ingredient is listed with no specified conditions, it is not permitted in a Class I topical product. If the hotlist specifies certain conditions for an ingredient, or label requirements, it is the responsibility of the licence holder to ensure that the ingredient meets the conditions outlined.

Requirements for non-medicinal ingredients are outlined in the following documents: [Quality of Natural Health Products Guide](#), [Pathway for Licensing Natural Health Products Making Modern Health Claims](#), [Pathway for Licensing Natural Health Products Used as Traditional Medicines](#) and the [Evidence for Homeopathic Medicines](#).

#### 11. Storage conditions

When the monograph includes storage conditions, they must appear on the product label as per section 87 of the NHPR.

#### 12. Specifications

Note that certain monographs include additional specifications relevant to that ingredient or product. This information must be considered when establishing product specifications.

## 2. Attesting to Multiple Monographs

When attesting to more than one NNHPD monograph in support of safety and/or efficacy of a Class II or III product, monograph conditions of use (duration of use, risk information, etc.) must be omitted in the following situations:

- Sub-population-specific risk information is not required if the product is not indicated for that sub-population
  - E.g. the risk statement "Consult a health care practitioner prior to use if pregnant or breastfeeding" is not required for a product indicated for an "adult male" sub-population.
- The risk information being omitted is considered less stringent and covered by the risk information required by another monograph attested to within the application:
  - E.g. "Consult a health care practitioner if you are pregnant or breastfeeding" is considered less stringent and covered by "Do not use if you are pregnant or breastfeeding".
- The duration of use being omitted relates to the efficacy of the claim and is shorter than the duration of use relating to efficacy required by another monograph attested to within the application:
  - E.g. "Use for a minimum of 3 months to see beneficial effects" relates to the efficacy of the claim and is shorter than "Use for a minimum of 6 months to see beneficial effects."
- The duration of use being omitted relates to the safety of the medicinal ingredient and is longer than the duration of use relating to safety required by another monograph attested to within the application.
  - E.g. "Consult a health care practitioner for use beyond 1 month" relates to the safety of the medicinal ingredient and is longer than "Consult a health care practitioner for use beyond 1 week."

Applicants omitting conditions of use in a Class II or III application within the situations described above must still attest to the monograph for all other monograph parameters that are met.

## 3. Monograph Revisions

Suggestions for revisions to currently published monographs and suggestions for ingredients that should be the subject of a monograph can be submitted to NNHPD via the [Natural Health Product Ingredients Database Issue Form](#). This form should include the name of the monograph to which amendments are being proposed along with the rationale and supporting evidence for consideration.

## 4. Position on "Statements to the effect of"

The use of "statements to the effect of" is not permitted in Class I applications. The use of "statements to the effect of" will continue to be permitted in Class II and III applications. When this policy becomes effective, at the time of final publication of this policy, applications that make use of statements that deviate from the exact wording provided in monographs must be submitted as a Class II or III application.

## Appendix II

### Post Licence Changes and Associated Regulatory Requirements

Type of Change	Regulatory Requirement	Safety & Efficacy Evidence	Finished Product Specifications
<b>Recommended dose</b>			
Change to amount of dosage unit	Amendment	√	–
Change to frequency	Amendment	√	–
Change to sub-population group	Amendment	√	–
Change to directions of use appearing on the label	Amendment	▲	–
<b>Recommended duration of use</b>			
Lengthening the recommended duration of use	Amendment	√	–
Shortening the recommended duration of use	Amendment	▲	–
<b>Risk information shown on any label</b>			
Deletion of risk information	Amendment	√	–
Addition of risk information	Notification	▲	–
Modification of risk information	Amendment	▲	–
<b>Recommended use or purpose</b>			
Modification to the recommended use or purpose	Amendment	▲	–
Deletion of part of the recommended use or purpose	Amendment	–	–
Addition to the recommended use or purpose	Amendment	√	–
<b>Source material of any medicinal ingredients</b>			
Change to the part or tissue used	Amendment	▲	–
Change to the source material from a monograph source to a source not listed on a monograph	Amendment	√	–
Change of source within a monograph	Amendment	–	–

Type of Change	Regulatory Requirement	Safety & Efficacy Evidence	Finished Product Specifications
<b>Source material of any medicinal ingredients (Continued)</b>			
Change from a source not listed on a monograph to a source listed on a monograph	Amendment	–	–
Change of source material to an animal-derived source	Amendment	–	–
Change to information submitted on the Animal Tissue Form	Amendment	–	–
Change to the salt or derivative used	Amendment	▲	–
Change to the strain used	Amendment	√	–
<b>Changing any of medicinal ingredients to or from being synthetically manufactured</b>			
Change from being synthetically manufactured to a natural ingredient	Amendment	–	–
Change from a natural source to a synthetically source	Amendment	–	–
<b>Potency of any medicinal ingredients</b>			
Addition of a potency	Amendment	▲	√
Deletion of a potency	Amendment	▲	√
Change in the potency	Amendment	▲	√
<b>Change affecting safety and efficacy (other than those listed in paragraph 11(h))</b>			
Change in manufacturing information	Amendment	–	▲
<b>Change to the quantity of a medicinal ingredient per dosage unit</b>			
Decrease in quantity	Fundamental Change	▲*	√*
Increase in quantity	Fundamental Change	▲*	√*

Type of Change	Regulatory Requirement	Safety & Efficacy Evidence	Finished Product Specifications
<b>Addition or substitution of a medicinal ingredient</b>			
Adding a medicinal ingredient	Fundamental Change	√*	√*
Removing a medicinal ingredient	Fundamental Change	▲*	√*
Substituting a medicinal ingredient for one not already found in the product	Fundamental Change	√*	√*
<b>Dosage form</b>			
Change in the dosage form	Fundamental Change	√*	√*
<b>Recommended route of administration</b>			
Any change in route of administration	Fundamental Change	√*	–
<b>Removal of a test method set out in the specifications</b>			
Any removal of test methods in the specification	Amendment	–	√
<b>Modification of a test method set out in the specifications</b>			
Any modification to test methods in the specification	Amendment	–	√
<b>Change to information submitted under paragraphs 5 (a) and 5 (b)</b>			
Change in the name of the Product Licence holder or applicant	Notification	–	–
Change in ownership of the Product Licence	Notification	–	–
Mergers between companies	Notification	–	–
Change of Senior Official	Notification	–	–
Change of title, phone number, fax number, e-mail address or mailing address of Senior Official	Notification	–	–
Change of contact person for the application	Notification	–	–

Type of Change	Regulatory Requirement	Safety & Efficacy Evidence	Finished Product Specifications
<b>Change to information submitted under paragraphs 5 (a) and 5 (b) (Continued)</b>			
Change of title, phone number, fax number, e-mail address or mailing address of the contact person for application	Notification	–	–
Change of company name for Regulatory Affairs Information in Canada	Notification	–	–
Change to contact information for Regulatory Affairs Information in Canada	Notification	–	–
<b>Information provided under section 22</b>			
Addition of a manufacturer, packager, labeller, importer or distributor	Notification	–	–
Removal of a manufacturer, packager, labeller, importer or distributor	No need to communicate with the NHPD	–	–
<b>Addition or substitution of a non-medicinal ingredient</b>			
Changing to a different ingredient in the NHPID	Notification	–	–
<b>Sale under a brand name other than one submitted under paragraph 5 (e)</b>			
The addition or modification of a brand name	Notification	–	–

√ - Required

▲ - May be required depending on the proposed change

\*Fundamental Changes require a new application. Requirements for evidence and Finished Product Specifications must be submitted with the new application.

## Glossary

### **Adverse reaction (or known adverse reaction)**

A noxious and unintended response to a natural health product that occurs at any dose used to test for the diagnosis, treatment or prevention of a disease or for modifying an organic function. Examples include flushing, nausea, diarrhea and constipation.

### **Applicant**

The company in whose name the NHP application is submitted and the Product Licence will be registered (the applicant will be referred to as the licensee once a licence has been granted or amended). For Product Licence Applications, the licensee/applicant is not necessarily the company that fabricates the product (e.g., may be the distributor of the product or the importer, etc.).

### **Brand name**

A name in English or French, whether or not it includes the name of a manufacturer, corporation, partnership or individual (a) that is used to distinguish the natural health product; and (b) under which a natural health product is sold or advertised. The brand name may or may not include a trade name.

### **Common name**

For any medicinal or non-medicinal ingredient contained in an NHP, the name by which it is commonly known and is designated in a scientific or technical reference.

### **Compendial**

An application type used on the PLA form for Class I products which meet all parameters of an individual NNHPD monograph.

### **Directions of use**

How the product should be taken. This may include time of administration, or administration with respect to food or drink.

### **Discontinuation**

An action taken by a licence holder or by NNHPD to remove the active status of a NPN or DIN-HM.

### **Dosage form**

The final physical form of the NHP which may be used by the consumer without requiring any further manufacturing.

### **Dose**

The amount of finished product in dosage form used for the recommended purpose, including any directions of use. The dose is represented as the amount of dosage units, the frequency of use, and directions for use, if any, by a sub-population group.

### **Duration of use**

The time frame in which an NHP can be consumed safely for its intended purpose.

### **Efficacy**

The extent to which a specific intervention, procedure, regimen or service produces a beneficial result under ideal conditions.

### **Extract**

A substance prepared by treating a plant or a plant material, an alga, a bacterium, a fungus, or non-human animal material with solvents or pressure to remove any constituents.

**Finished product**

A product that has undergone all stages of production, including packaging in its final container and labelling.

**Finished product specifications**

Quality standards for an NHP that contains the information described in section 44(2) of the NHPR which includes tests, references to analytical procedures and appropriate tolerance limits which are numerical limits, ranges or other criteria for the tests described. Specifications establish the criteria to which a finished product should conform in order to be considered acceptable for its intended use.

**Frequency**

How often the product is to be taken in a given time or time interval (e.g. 3 times daily).

**General Application**

An application type used on the PLA form for products formally categorized as non-traditional applications and for all products which cannot be classified into the Compendial (Class I), Traditional, and Homeopathic application types.

**Good manufacturing practices**

Measures to ensure an overall effective approach to product quality control and risk management. They apply to places, people, processes and products with respect to which activities are being conducted. Refer to Part 3 of the NHPR and the [Good Manufacturing Practices for Natural Health Products Guidance Document](#).

**Health claim**

See “Recommended use or purpose”.

**Homeopathic Application**

An application type used on the PLA form for products categorized as homeopathic medicines (See Homeopathic Medicine).

**Homeopathic medicine**

To be considered a homeopathic medicine, a product must meet two criteria. It must be:

(1) Manufactured from, or contain as medicinal ingredients, only substances referenced in a homeopathic monograph in one of the following homeopathic pharmacopoeias, as they are amended from time to time:

- Homeopathic Pharmacopeia of the United States (HPUS)
- Homöopathische Arzneibuch (HAB) or German Homeopathic Pharmacopoeia
- Pharmacopée française or French Pharmacopoeia (PhF)
- European Pharmacopoeia (Ph.Eur.)
- Encyclopedia of Homeopathic Pharmacopoeia (EHP)

(2) Prepared in accordance with the methods outlined in one of the homeopathic pharmacopoeias listed above, as they are amended from time to time.

**Importer**

A person who imports a natural health product into Canada, for the purpose of sale. This would include bulk natural health products.

**Ingredient**

A single substance that is a component part of any product formulation.

**Kit**

A kit is defined as a package containing more than one NHP OR a combination of one or more NHPs and one or more foods, cosmetics or medical devices that is intended to have a combined benefit, e.g. overarching claims or brand name.

**Label**

Includes any legend, word or mark attached to, included in, belonging to or accompanying an NHP. Products must be labelled in both official languages.

Refer to Part 5 of the NHPR and the [Labelling Guidance Document](#).

**Licensee**

See “applicant”.

**Manufacturer**

A person who fabricates or processes a natural health product for the purpose of sale, but does not include a pharmacist or other health care practitioner who, at the request of the patient, compounds a natural health product for the purpose of sale to that patient.

**Master File**

An NHP Master File may be submitted, when a company would like to submit confidential information on behalf of another company (e.g. supplier submitting confidential manufacturing information on behalf of a manufacturer).

**Medicinal ingredient**

Any substance set out in Schedule 1 of the NHPR that is intended to provide pharmacological activity or other direct effect in: (a) the diagnosis, treatment, mitigation, or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; or (b) restoring or correcting organic functions in humans; or (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

**Natural Health Product**

A substance set out in [Schedule 1](#) of the 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: (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; (b) restoring or correcting organic functions in humans; or (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in [Schedule 2](#) of the Regulations or any combination of substances that includes a substance set out in Schedule 2.

**NNHPD monograph**

A written description of particular elements on an identified ingredient or product. The [Compendium of Monographs](#) is comprised of single and product monographs to be used to support the safety and efficacy of the medicinal ingredient(s). Single ingredient monographs indicate only one medicinal ingredient, while product monographs indicate multiple ingredients or describe the conditions of use for a product category.

**Non-medicinal ingredient**

A non-medicinal ingredient is defined as any substance that is added to a product to confer suitable consistency or form to the medicinal ingredients (suitable as per dosage form and route of administration).

Non-medicinal ingredients:

- should not exhibit pharmacological effects;
- should not have any effect contradictory to the product's recommended purpose;
- should not exceed the minimum concentration required for the formulation;
- should not adversely affect the bioavailability, pharmacological activity, or safety of the medicinal ingredients; and
- should be safe.

### **NPN/DIN-HM**

A Natural Product Number (NPN) is an eight (8) digit numerical code assigned to each natural health product approved to be marketed under the NHPR. The Drug Identification Number for Homeopathic Medicines (DIN-HM) is an eight (8) digit numerical code assigned to each homeopathic medicine approved to be marketed under the NHPR.

### **Proper name**

In respect of an ingredient of an NHP, a proper name refers to one of the following:

- if the ingredient is a vitamin, the name for that vitamin set out in item 3 of Schedule 1;
- if the ingredient is a plant or a plant material, an alga, a bacterium, a fungus, a non-human animal material or a probiotic, the Latin nomenclature of its genus and, if any, its specific epithet; and
- if the ingredient is other than one described in paragraphs (a) or (b), the chemical name of the ingredient.

### **Quantity**

The amount of medicinal ingredient(s) per dosage unit.

### **Quantity crude equivalent**

The amount of crude dried or fresh material (amount of original material) from which the ingredient was extracted (per dosage unit).

### **Potency**

The amount per dosage unit of the standardized component that further characterizes the quantity of the ingredient. Potency may reflect the active constituent, a marker compound or the “activity” of the medicinal ingredient.

### **Recommended conditions of use**

As defined in section 1(1) of the NHPR, ‘conditions of use’ or ‘recommended conditions of use’ for a natural health product include:

- its recommended use or purpose;
- its dosage form;
- its recommended route of administration;
- its recommended dose;
- its recommended duration of use, if any; and
- its risk information, including any cautions, warnings, contraindications or known adverse reactions associated with its use.

### **Recommended use or purpose**

A statement that indicates the intended beneficial effect of an NHP when used according to the recommended dose, duration of use and route of administration listed on the label.

**Regulatory decision**

In the context of this document, a regulatory decision refers to the assessment of a Product Licence Application, including post-licensing applications, resulting in the issuance of a Product Licence or Notice of Refusal.

**Risk information**

Any cautions and warnings, adverse reactions and contraindications associated with the use of the NHP.

**Risk Management Plan (RMP)**

A document that describes a set of pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize risks related to drug products, and the assessment of the effectiveness of those interventions (adopted from the European Medicines Agency definition of a Risk Management System).

**Route of administration**

The method by which the NHP is to be delivered to the body. Routes of administration include, but are not limited to: oral, buccal, dental, nasal and topical.

**Safety**

The ability for a natural health product to produce a beneficial health outcome, outweighing the risk associated with using it, in humans, according to the recommended conditions of use.

**Senior Official**

The principal contact person for the licensee/applicant, to whom regulatory mail is sent. This is not the contact person for product application-specific questions, but the person who will represent the company.

**Site**

A place of or for an activity specified under the NHPR.

**Source material**

The substance from which the medicinal ingredient as defined in Schedule 1 of the NHPR was prepared or derived. There may be multiple sources for a medicinal ingredient.

**Specifications**

A description of an NHP that contains the information described in section 44(2) of the NHPR.

**Submission coordinator**

The Regulatory Project Officer assigned to coordinate a PLA through the assessment process. In order to contact the Submission Coordinator, applicants should send an email to [hc.nnhpd-dpsnso.sc@canada.ca](mailto:hc.nnhpd-dpsnso.sc@canada.ca).

**Submission number**

The six-digit processing number assigned to an individual application, including post-licensing applications. The submission number should be referenced in all correspondence and enquiries referring to the product application.

**Sub-population group**

The group to which the NHP is targeted (may be more than one) that may require different dosing from the standard. For example, most NHPs are for adults, but seniors or children may take them at different doses.

**Traditional application**

An application type use on the PLA form for products categorized as traditional medicines (See Traditional Medicine).

**Traditional medicine**

A medicine based on the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness. This definition is one modified from the World Health Organization Traditional Medicine Program, recognizing traditional medicines at their core as ancient medical practice that existed in human societies before the application of modern science to health and that have evolved to reflect different philosophical backgrounds and cultural origins.

**Withdrawal**

An action taken by the applicant to remove an application from the application review process.

## Acronyms

ANF – Amendments and Notification Form

ATF – Animal Tissue Form

DIN-HM – Drug Identification Number-Homeopathic Medicine

DPA – Designated Party Authorization

FPS – Finished Product Specifications

IRN – Information Request Notice

LNHPD – Licensed Natural Health Products Database

MAP – Management of Application Policy

NHPID – Natural Health Products Ingredients Database

NHP-MF – Natural Health Product Master File

NHPR – Natural Health Products Regulations

NHPs – Natural Health Products

NNHPD – Natural and Non-prescription Health Products Directorate

NPN – Natural Product Number

PLA – Product Licence Application

QCE – Quantity Crude Equivalent

RMP – Risk Management Plan

ROEB – Regulatory Operations and Enforcement Branch

SEAR – Safety and Efficacy Assessment Report