
Natural health products management of applications policy

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Foreword

Guidance documents provide assistance to industry on how to comply with governing statutes and regulations. They also provide guidance to Health Canada staff on how mandates and objectives should be met fairly, consistently and effectively.

Guidance documents are administrative, not legal, instruments. This means that flexibility can be applied. However, to be acceptable, alternate approaches to the principles and practices described in this document must be supported by adequate justification. They 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 always, Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, to help us adequately assess the safety, efficacy and/or quality of a natural health product. We are committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read along with the relevant sections of the regulations and other applicable guidance documents.

Document Change Log

Date	Location	Nature and reason for change
December 15, 2025	Full document	Made changes to reflect the current state of application management, process improvements and editorial revisions.

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Overview

Purpose

This document outlines the:

- responsibilities and expectations of applicants throughout the product licence application (PLA) and post-licensing processes in accordance with the [Natural Health Products Regulations](#) (NHPR)
- processes applied by the Natural and Non-prescription Health Products Directorate (NNHPD) to the lifecycle of applications – from pre-submission to post-licensing

Scope

This document applies to all classes of NHP applications, including new applications and changes made after a product has been licensed (amendments and notifications).

It is designed to help applicants and licence holders navigate the application and post-licensing process and should be used alongside the relevant guidance documents linked throughout this document.

Exclusions

This document does not apply to:

- site licence applications for NHPs
- clinical trial applications for NHPs
- applications for foods, other health products including drugs (prescription and non-prescription), medical devices, biologic and genetic therapies, and veterinary drugs.

Site licensing

To manufacture, label, package, and/or import an NHP, a site licence is required. For details on the site licensing process, refer to the [Site Licensing Guidance Document](#).

Pre-submission process

Determining whether a product is an NHP

As the applicant, you must confirm that your product meets the definition of an NHP as outlined in [section 1\(1\)](#) of the NHPR **before** you submit a product licence application (PLA).

To be classified as an NHP, a product must meet both the **substance** and **function** criteria.

Substance criteria

The product must contain, or be considered as, one or more of the following:

- medicinal ingredients (MIs) listed in [Schedule 1](#) to the NHPR
- a homeopathic medicine
- a traditional medicine

Function criteria

The product must be represented for use in one or more of the following ways:

- diagnosing, treating, mitigating, or preventing a disease, disorder or abnormal physical state or its symptoms in humans
- restoring or correcting organic functions in humans
- modifying organic functions in humans

Understanding what is meant by “representation”

Health Canada interprets “representation” (explicit or implied) to include:

- indications of use or health claims
- any wording, image, symbol, or implication on product labels
- package inserts or advertisements (including websites)

- placement and location of sale

Product format

Product format can be a factor in the determination of whether a product is an NHP.

Example: conventional food formats such as prepackaged, ready-to-consume beverage products, bars, cereals, etc., versus dosage formats such as tablets or capsules

It is your responsibility, as the applicant, to determine the appropriate regulatory framework for your product.

Refer to [Appendix I](#) for resources to help determine whether your product falls under the NHPR.

If your product meets the definition of an NHP, you must obtain a product licence, that is Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) before it can legally be sold in Canada.

Proceeding with a product licence application

After reviewing all relevant resources, you may submit a PLA to NNHPD if you believe your product is an NHP and it meets the eligibility criteria.

NNHPD:

- does not issue classification decisions before receiving a submission
- makes regulatory classification decisions during the formal submission process
- will only respond to pre-submission inquiries that seek clarification on its guidance documents

Application types

NNHPD categorizes NHP licence applications by application type:

- traditional

- general (non-traditional)
- homeopathic (non-compendial)
- compendial

Refer to the [glossary](#) for definitions of each application type.

Application classes

NNHPD groups applications into 3 classes based on how NNHPD monographs are used.

An NNHPD monograph is a written summary describing specific elements of an ingredient or a combination of ingredients.

NNHPD has developed a [Compendium of Monographs](#), which you can use to support the safety, efficacy, and/or quality of an NHP as part of your PLA.

Class I applications

Class I (compendial) applications must fully comply with all parameters outlined in an individual NNHPD monograph. The application must match the monograph exactly, without any modifications. You may reference only one NNHPD monograph per Class I application.

Monograph requirements

- **Single-ingredient monographs:** The application must match all parameters of the monograph exactly
- **Multi-ingredient monographs:** Each ingredient must meet the safety and quality parameters of the monograph. At least one ingredient must also meet the efficacy parameters, unless otherwise specified in the monograph.

Class II applications

Class II applications may include general (non-traditional) or traditional, and fall into the following categories:

- Applications supported entirely by 2 or more NNHPD monographs, with no deviations, except in specific cases:

- there is no increased risk (for example: additive effects, over-medication, altered bioavailability and/or pharmacological activity) that cannot be mitigated by changes to the recommended conditions of use within the parameters of the monographs (for example: dosage, risk information, duration of use).
- there is no reduction in efficacy (for example: conflicting therapeutic effects).
- there are no incompatible recommended conditions of use (for example: contradictory claims, durations, and/or risk information).
- Applications supported entirely by an **individual** or by an acceptable **combination** of NNHPD monographs with minor deviations to one or more monograph statements, provided the changes maintain the original intent of the monograph (for example: using “statements to the effect of”)
- Applications supported entirely by a combination of NNHPD monographs that include fruits and vegetables listed in the [Canadian Nutrient File](#) (CNF), prepared in a manner suitable for human consumption. These must:
 - exclude source materials listed as “refuse”, that is, inedible parts
 - include a daily dose of up to 10 g of crude material or its crude equivalent for non-standardized extracts.
 - ensure the ingredient quantity aligns with typical consumption levels as per the CNF Database.

Homeopathic product applications with specific claims are not accepted under Class II.

Refer to the [Monograph combination guide](#) for more details.

Class III applications

Class III applications may include:

- general (non-traditional)
- traditional
- homeopathic (non-compendial)

Class III applications fall outside the scope of Class I and II and require a full assessment of the product's safety, efficacy, and/or quality.

Class III applications include, but are not limited to, the following scenarios:

- applications for products with an ingredient, claim, or condition of use not supported by an NNHPD monograph
- applications for products with modified formulations (for example: liposomal, phytosomal, etc.) intended to improve the bioavailability and/or absorption of its medicinal ingredients
- applications referencing a [Master File](#) or previously submitted evidence to support safety and/or efficacy
- applications that partially reference monograph information but exceed the parameters outlined in the monograph (for example: dosage forms or routes of administration not specified in the monograph)
- applications for homeopathic products with specific claims. Refer to the [Evidence for Homeopathic Medicines Guidance](#)
- applications supported entirely by NNHPD monographs but involving ingredient combinations that may require additional safety and/or efficacy assessment. These include combinations with lower certainty or increased risk, such as:
 - stimulant laxatives combined with diuretics
 - weight management ingredients/claims combined with diuretics
 - products with combined hormonal effects

Refer to the [Monograph combination guide](#) for further guidance.

Position on “statements to the effect of”

The use of “statements to the effect of” is not permitted in Class I applications. However, such statements remain acceptable in Class II and III applications. Any application that includes statements deviating from the exact wording provided in monographs must be submitted as a Class II or III application.

Before submitting a product licence application

This section outlines key information and instructions that must be reviewed and followed before submitting a PLA to NNHPD.

Failure to follow one or more of these requirements may jeopardize the application and could result in its refusal.

Refer to [Appendix II](#) for key guidance and supporting documents.

Pre-submission meeting

A pre-submission meeting gives you an opportunity to discuss the evidence required to support a Class III application. These meetings aim to:

- help NNHPD staff become familiar with the proposed application before it is submitted, and provide a forum to discuss supporting evidence to facilitate the review process
- establish which studies or scientific data you intend to use to support the safety and/or efficacy of the NHP, and assess the adequacy and appropriateness of proposed controls
- allow you to discuss application details with NNHPD and receive feedback on potential concerns based on current regulatory requirements and experience
- help NNHPD manage resources and expertise in accordance with the anticipated application workload

Pre-submission meetings do **not** involve a full assessment of the evidence and do **not** result in a regulatory decision. NNHPD's pre-submission feedback is informal and non-binding.

A pre-submission meeting is recommended for NHPs for which there is uncertainty (for example: limited or no history of authorizations under the given conditions of use), such as:

- MIs not previously licensed
- unfamiliar or unlicensed combinations of MIs

- recommended conditions of use that have not yet been assessed or licensed
- a dosage form that has not been assessed or has not been licensed for a particular MI

Meeting minutes for pre-submission meetings

You are responsible for taking minutes during a pre-submission meeting. You are expected to submit these minutes to NNHPD within 14 calendar days of the meeting for review and confirmation.

The meeting minutes do not constitute a regulatory decision, nor do they guarantee a favourable outcome. A regulatory decision can only be made upon receipt and assessment of a complete application.

How to request a pre-submission meeting

To request a pre-submission meeting, contact the NNHPD Client Support Unit at nnhpd-dpsnso@hc-sc.gc.ca.

You must submit your request at least 30 calendar days before the proposed meeting date. The request should include the following information:

- purpose of the meeting
- brief description of the product (for example: indicate if it is a combination product such as an NHP with a medical device)
- specific questions you wish to discuss
- international status of the product (for example: whether it has been authorized in another jurisdiction)
- 3 proposed meeting dates

Meeting prioritization and format

NNHPD prioritizes meeting requests that:

- impact the filing of an application (see [eligibility criteria for product licence applications](#))

- relate to an existing licence

If NNHPD determines that your questions can be addressed more efficiently in writing, a written response will be sent to you, along with the rationale. If the response does not sufficiently address your concerns, you may request a meeting.

NNHPD will make every effort to schedule the meeting on one of the proposed dates, depending on the availability of subject matter experts. However, due to file complexity or competing priorities, alternative dates may be proposed.

All pre-submission meetings are held virtually via video or phone conference. Meetings are not recorded.

Pre-submission meeting information package

You must submit a pre-submission meeting information package to NNHPD at least 14 calendar days before the scheduled meeting date. The package must include the following:

- cover letter
- agenda for the meeting
- list of participants, including their titles and roles
- list of specific issues or questions you wish to discuss
- summary of the product being presented
- detailed list of:
 - MIs and their quantities
 - non-medicinal ingredients (NMIs), including their purposes and quantities
 - recommended conditions of use, including the health claim(s) for which authorization is sought
- overview of the product's market history, including its regulatory status in foreign jurisdictions (if applicable)
- summary of safety and efficacy data supporting the NHP

Failure to submit the information package on time will result in the meeting being rescheduled.

Master File

The manufacturer of an ingredient or raw material, known as the NHP Master File (NHP-MF) holder, may submit proprietary information directly to NNHPD without sharing it with the product licence applicant.

The NHP-MF holder (Senior Official) may issue a [letter of access](#) that allows one or more applicants to cross-reference the confidential file.

The NHP-MF is a confidential document and may only be accessed by Health Canada officials.

Submitting a Master File

The NHP-MF holder may submit unpublished evidence (for example: proprietary data not publicly available) to NNHPD to support product assessment.

Required information for NHP-MF submission:

- ingredient or product name
- company name and address
- Senior Official's information
- contact person's information
- Designated Party Authorization

Note:

- An NHP-MF is not an application for a product licence. It is supporting evidence for a PLA
- Only one electronic copy of the NHP-MF should be submitted
- NNHPD does not accept paper copies of NHP-MFs
- Do not submit a PLA form with an NHP-MF

Secure submission

NNHPD recommends submitting NHP-MFs via Connect (formerly known as ePost Connect), due to security limitations with regular email.

Refer to the section on [submitting an application](#) for details on using Connect.

Processing a Master File

Upon receipt of an NHP-MF, NNHPD will:

- assign an MF number
- send an acknowledgment letter to the NHP-MF holder

Although there is no service standard for processing NHP-MFs, NNHPD aims to assign an MF number within 30 calendar days of receipt.

Note:

- NNHPD only assesses an NHP-MF when it is referenced in a PLA
- NNHPD only reviews the information relevant to the PLA

During the product assessment process, the NHP-MF holder may receive an [Information Request Notice](#) (IRN) if clarification or additional information is needed.

NNHPD communicates the final regulatory decision on a PLA (that is, whether it issues a product licence or refuses the application) only to the PLA applicant.

Referencing a Master File

To protect the proprietary nature of the files and to confirm access, you, as the applicant, must include a letter of access from the NHP-MF holder as part of your PLA to reference information contained in an NHP-MF.

This letter must:

- be on the official company letterhead of the NHP-MF holder
- be dated and signed by the Senior Official of the NHP-MF holder company

- grant reference directly to the applicant (not to a manufacturer or consultant)
- must be no older than 3 years
- include:
 - name and address of the company being granted access
 - name of the product referencing the NHP-MF
 - assigned MF number

Example: Company A authorizes Company B to reference MF number: XXXXX MFXXX (NHP-MF Name)

Option to provide a general authorization

The NHP-MF holder may also authorize a company to reference some or all of their NHP-MFs. In these cases, a single general letter of access may be used, and individual letters for each application are not required.

Consequences of a missing authorization

If you do not provide a valid letter of access, NNHPD cannot assess the NHP-MF in conjunction with the PLA that references it. This may lead to the refusal of the application referencing the NHP-MF due to insufficient information to support the product's safety, efficacy and/or quality.

Modifying the Natural Health Products Ingredients Database

You must confirm that all proposed ingredients and sub-ingredients, including each ingredient's purpose, if applicable, are listed in the [Natural Health Products Ingredients Database](#) (NHPID) with the correct conditions of use before submitting a PLA.

Note:

- If an ingredient or its purpose is not listed in the NHPID, the PLA form cannot be completed, and the application will be refused, if submitted incomplete.
- Notes in the application or cover letter about missing ingredients and sub-ingredients are not accepted.

If you wish to include an ingredient, sub-ingredient, or ingredient purpose that is not listed in the NHPID, you must submit a formal modification request.

Refer to [Appendix II](#) for more information on the NHPID.

Evidence requirements

Requests to modify the NHPID must be supported by credible, verifiable, and objective information aligned with applicable regulations, definitions, guidance, and policies.

Acceptable sources include:

- pharmacopoeias
- peer-reviewed journal articles
- books by reputable, established authors
- foreign government or regulatory authority documents, evaluations, and websites

Submission process

To request a modification to the NHPID, you must:

1. Complete the [NHPID Request Form](#)
2. Provide sufficient supporting evidence for:
 - MI identity and function
 - NMI purpose
 - any other requested modification

Typographic corrections do not require supporting evidence.

You are responsible for ensuring that all necessary evidence is provided, which may go beyond what's expected in the form.

Additional information

NNHPD may request further details to ensure ingredients are appropriately displayed in the NHPID and aligned with the [Natural Health Products Online System Standard Terminology Guide](#).

This helps improve submission quality and ensures consistency in:

- PLA forms
- amendment and notification forms (ANFs)
- product labels (in accordance with the NHPR)

You are encouraged to prioritize requests associated with products intended for sale or manufacture in Canada within 12 months of licensing.

Processing timeline

Requests are generally processed in the order received, but may be prioritized based on:

- complexity
- volume of requests
- urgency related to an upcoming submission

All modifications must be completed before submitting a new application or an amendment.

Updates

- Changes made to the NHPID are listed in the "[What's New in the NHPID](#)" section after each update cycle.
- The NHPID is updated monthly, typically on the last Friday of each month.
- NNHPD will only contact requesters if clarification is needed or if the submitted information is insufficient.
- NNHPD does not notify applicants individually when an ingredient has been added to the NHPID.

New Company Registration

A **new applicant** must register their company with NNHPD before submitting their first PLA. This step is essential to:

- enabling access to the web-based PLA form
- ensuring traceability of applications

NNHPD will issue a unique 5-digit company code upon registration. You must include this code in all future applications to ensure proper processing.

How to register

You must complete the [New Company Registration Form](#) to register a company and obtain a company code.

Note:

- This requirement applies only to new companies
- Companies that have previously submitted a PLA have already been issued a company code and do **not** need to register again

Locating an existing company code

If you already have a company code, you can find it on NNHPD correspondence documents, such as:

- issuance letters
- IRNs
- notices of refusal

Preparing your submission

The following sections outline the requirements and procedures for submitting a PLA to NNHPD. Refer to [Appendix III](#) for more information on application requirements.

Eligibility criteria for product licence applications

New applications

You do not require a product licence if you do not intend to sell or manufacture your product in Canada.

NNHPD accepts PLAs for NHPs that will benefit Canadians. NNHPD will accept Class I, II, and III applications that meet the following criteria:

- The product is intended to be sold or manufactured in Canada within 12 months of receiving authorization.

Amendments & Notifications

NNHPD prioritizes amendments and notifications that meet the below criteria.

Changes to an authorized NHP that is:

- already sold in Canada; or
- will be sold or manufactured in Canada within 12 months of the licence being amended, regardless of the nature of the change(s).

Manufacturing in Canada

You are required to provide site information for products that will be manufactured in Canada as per [section 22](#) of the NHPR:

- Section 22 of the NHPR requires that site information be provided for the manufacturer, packager, labeler and importer (as applicable) prior to the sale of a product. Each site must be licensed – refer to the [Site Licensing Guidance Document](#).
- new applications must include site information in the PLA if available at the time of filing.
 - Otherwise, you must provide it prior to the sale or manufacture of your licensed product.

- amendments for marketed products must include all site information in the Amendment Notification Form if it has not already been provided to NNHPD

Additional considerations:

- If the product is authorized and currently sold in Canada, its market status should be listed as “**Active**” in the [Licensed Natural Health Products Database](#).
- Amendments prompted by a risk to the health and safety of Canadians will be prioritized. The [Amendment and Notification Form](#) includes a section to indicate whether the change is in response to a notice issued by NNHPD’s Risk Management Division.

Attestation requirements for submission

You must respond to attestation questions in the relevant form to confirm eligibility.

PLA form

You only need to obtain a product licence if you intend to sell or manufacture your product in Canada. The PLA form includes 2 questions in the Sales Intentions section to this effect:

- will this product be sold in Canada within 12 months of receiving authorization?
- will this product be manufactured in Canada within 12 months of receiving authorization?

Proceed as follows:

- If you intend to sell the product in Canada within 12 months of receiving authorization, answer “Yes” to the first question. Otherwise, answer “No”.
- If you intend to manufacture the product in Canada within 12 months of receiving authorization, answer “Yes” to the second question. Otherwise, answer “No”.
 - The application system will only finalize the form if you answered “Yes” to at least one of these questions.
- If your intentions change, you may complete and submit the application once you expect to sell and/or manufacture the product in Canada within the required timeframe.

Applicants must answer all questions on the PLA form honestly and provide accurate information to Health Canada, as required under [section 7\(c\)](#) of the NHPR.

Amendment and Notification Form (ANF)

The ANF includes the following attestation questions:

- is this product currently being sold in Canada?
- will this product be sold in Canada within 12 months of receiving a revised authorization?
- will this product be manufactured in Canada within 12 months of receiving a revised authorization?

To ensure Health Canada directs its resources toward products that benefit Canadians, we encourage you to [discontinue](#) your product licence if you have not sold or do not plan to sell or manufacture your product in Canada. If you discontinue the licence, you will not need to submit any amendments or notifications for that product licence.

The ANF does not prevent you from submitting amendments or notifications for products that you do not sell or manufacture (or intend to sell or manufacture) in Canada. However, if you choose to do so, we will not prioritize your application.

Applicant responsibilities

By selecting “Yes” to the attestation questions in either the PLA or ANF, you confirm your intent to notify NNHPD once the product becomes available for sale in Canada. The issuance letter reminds you of your obligation to:

- notify NNHPD when the product is being sold in Canada
- provide valid site information prior to commencing sale, as required under [section 22](#) of the NHPR

If you have already submitted site information for products intended for sale or manufacture in Canada, you do not need to resubmit it, unless the site information changes.

Language of submission

Applications may be submitted in either of Canada’s official languages (English or French).

The language you select at the time of submission for the product information presented

on the PLA form should be used consistently throughout the entire submission process and, preferably, for any post-licensing applications. NNHPD will issue correspondence, including a regulatory decision in the language of the application.

Application classification and cover letter requirements

To facilitate processing and assessment of the PLA, and to ensure appropriate resource allocation, you must clearly identify the application class (Class I, II, or III) in both the PLA form and the cover letter (if required). You must base this classification on the definitions provided in the [Application Types and Classes section](#).

A cover letter is **required** in the following situations:

- relevant company updates
- additional context relevant to the submission
- multiple PLA forms submitted (for kit applications)
- rationale for not fully attesting to a monograph or for omitting monograph statements
- verified form limitations confirmed through correspondence with NNHPD (for example: inability to select the correct class)

Cover letters are also useful for clarifying application details, particularly when technical limitations of the web-based forms or templates prevent accurate data entry. You may use the cover letter to:

- explain discrepancies
- provide context for unusual product features
- highlight supporting documents that may not be clearly linked in the submission

The cover letter may also include the [Summary Report](#) (if applicable).

We recommend that you include an overview of the submission contents (a table of contents).

Misuse of the cover letter, such as introducing new information not reflected in the PLA form or attempting to bypass regulatory requirements, may result in the refusal of your application.

Submission format

NNHPD does not accept scanned or PDF copies of the online PLA form. If you submit these formats, NNHPD will refuse the application. If you include scanned or PDF versions along with the online PLA form, NNHPD will disregard them during screening and review.

Refer to [Appendix III](#) for a detailed overview of application requirements by type and class.

Application forms

You must use 1 of 2 application forms, depending on the type of submission:

- new applications must be submitted using the web-based [PLA form](#).
- post-licensing changes (amendments and notifications) for licensed NHPs must be submitted using the [ANF](#).

You must use the most recent version of the PLA form or ANF. NNHPD does not accept submissions using outdated versions and will refuse them. In rare cases where you cannot use the forms, you should contact the Client Support Unit (nnhpd-dpsnso@hc-sc.gc.ca) for specific guidance.

When naming the PLA file, you must use the file name generated by the PLA form.

Single application for multiple products

You may submit a single PLA in the following scenarios:

- **multiple flavours, fragrances, or colours:** if the only differences between products are the non-medicinal ingredients responsible for flavour, colour, or fragrance, they may be included in one application. All other product details (for example dosage form, claims, medicinal ingredients) must be identical.
- **multiple net amounts:** for example, a product sold in bottles of 90 or 180 capsules requires only one application.

While the application may represent multiple products, only one NPN will be issued.

Technical issues

For technical issues with the PLA or ANF form, contact the NHP Online Solution Team at nhp.initiative-psn@hc-sc.gc.ca as soon as possible.

If the issue remains unresolved at the time of submission:

- include a summary of the issue and the guidance provided by the NHP Online Solution Team in the cover letter.
- attach the relevant email correspondence to the application.

Animal Tissue Form requirements

When required, you must complete an [Animal Tissue Form](#) (ATF). An ATF may be necessary for the following types of ingredients:

- MIs
- NMIs
- ingredients used in processing (for example: not present in the final product)

A separate ATF must be provided for each:

- individual ingredient (medicinal, non-medicinal, or processing-related)
- type of process
- type of animal (for example: mammal, bird, or crustacean)

When an ATF is required, the ATF section within the PLA form must also be completed.

Letter of access

You may reference supporting information from another company's application(s) and/or licensed NHP using a letter of access. This letter authorizes NNHPD to access the specified information and must be:

- on official company letterhead of the company being referenced

- dated and signed by the Senior Official or an approved company contact of the referenced application (not a third-party contact)
- addressed directly to the applicant or product licence holder (not to a third-party consultant)
- no older than three years

The letter must clearly state the:

- name of the company granting reference
- name of the company receiving reference
- product name and submission number of the referenced application
- NPN or Drug Identification Number–Homeopathic Medicine (DIN-HM), if applicable.

Example: Company A authorizes Company B to access and reference Submission No. XXXXX and NPN/DIN-HM XXXXX (Product Name).

The application will be considered incomplete and will be refused if a valid letter of access is not provided.

Designated Party Authorization forms

You must submit a [Designated Party Authorization form](#) (DPA) when the party submitting the application is a designated party acting on behalf of the Senior Official of the applicant company or product licence holder according to [section 5\(b\)](#) of the NHPR.

This authorization allows the contact person(s) to act on behalf of the applicant company or product licence holder for functions such as:

- submitting applications (for example: NPN applications, NHP-MFs, amendments, notifications)
- receiving and responding to Information Request Notices (IRNs)
- receiving and responding to regulatory notices (for example: safety concerns)
- submitting a request to withdraw the application or discontinue the product on behalf of the applicant or licensee

You must submit a DPA form once for each contact within a given company. You do not need to include the form with every application, as long as the authorization clearly allows the designated party to act on behalf of the Senior Official for multiple applications.

Acceptable signature formats are:

- hand-signed
- electronically signed
- docu-signed

Submitting a DPA form does not exempt you (or the product licence holder) from the responsibility to:

- maintain relevant records related to the PLA; and,
- ensure that the sale of your product complies with all applicable sections of the NHPR (once licensed), including record retention

To revoke a DPA, NNHPD requires a letter be sent via Connect in the new NHP applications conversation. The letter must be on company letterhead and signed by the Senior Official clearly indicating the end date of the DPA.

Label text

All PLAs must include corresponding label text that complies with the requirements outlined in sections 87-94 of the NHPR.

This requirement can be fulfilled in one of two ways:

- using the label text generator within the PLA form; or
- submitting the label separately in Word or PDF format

Graphical mock-ups are generally not required, unless specifically requested by NNHPD.

Monograph attestation requirements by application class

To meet all safety, efficacy, and/or quality requirements, you must either:

- attest to one or more NNHPD monographs from the [Compendium of Monographs](#), (using the PLA form); and/or
- provide supporting evidence as outlined in [Appendix II](#)

Refer to [Appendix V](#) for more information on attesting to NNHPD monographs.

Class I applications

- You must fully attest to all parameters of a single monograph
- The PLA form will automatically validate most submitted information against the selected monograph
- If any validated parameter does not meet the monograph requirements, the form will display an error message, preventing finalization of the application

Class II applications

- You must select all applicable monographs on the PLA form to which you attest
- Upon receipt, NNHPD will verify the application against the selected monographs
- Deviations from monograph parameters will be assessed as outlined in the section on [application types and classes](#)
- [Appendix V](#) outlines specific cases where conditions of use may be omitted when combining monographs

Class III applications

- You must select all relevant monographs on the PLA form, if applicable
- Any non-compliant parameters must be clearly identified in the Summary Report or cover letter
- For each parameter not covered by a monograph, you must provide:
 - supporting evidence; or
 - a scientific rationale, as outlined in [Appendix II](#).

Examples include (but are not limited to):

- omission of required conditions of use for an ingredient not covered by more stringent statements for other ingredients:
 - you cannot attest to safety, instead you must provide a justification for not attesting and provide evidence to support the omission.
- claims not supported by a monograph, but the ingredient and the dose of the ingredient is supported:
 - you can attest to safety, but not efficacy, and must provide supporting efficacy evidence for the non-monographed claim.

Products containing nanomaterial ingredients must be submitted as a Class III application, unless nanomaterial ingredients specification details are included in monographs. Any manufacturing process that may affect the safety or efficacy of ingredients, such as those involving novel technologies (for example: nanotechnology), must be supported by appropriate evidence under the Class III application stream. For information on nanomaterials, refer to the [Policy Statement on Health Canada's Working Definition for Nanomaterial](#).

Summary report for class III applications

NNHPD strongly encourages you to include a summary report in all Class III applications, especially for complex submissions such as those involving multiple extrapolations. Including a summary report helps guide and streamline the assessment process and may reduce review timelines.

In general, the summary report should:

- demonstrate how each piece of submitted information supports the recommended conditions of use for the NHP
- reflect the totality of available evidence relevant to the product
- provide context for any apparent gaps or uncertainties related to the product's safety, efficacy, and/or quality

For products with multiple MIs and/or multiple claims, it is helpful to clearly link each piece of evidence to the specific ingredient(s) or claim(s).

Where applicable, the report should explain how the evidence:

- relates to the ingredient's form (for example: source material) or preparation (for example: extraction method)
- supports the product's recommended conditions of use (for example: dosage information)

The summary report may be submitted as a separate document or incorporated into the cover letter.

Additional resources

For more detailed guidance on summary reports, refer to:

- [Appendix IV](#) – Example of a summary report
- [Pathway for Licensing Natural Health Products Making Modern Health Claims](#)
- [Evidence for Homeopathic Medicines](#)
- [Pathway for Licensing Natural Health Products Used as Traditional Medicines](#)

Finished product specifications and attestation requirements

When you submit a Class I application, you attest that your product meets the specifications outlined in both the relevant [NNHPD monograph](#) and the [Quality of Natural Health Products Guide](#).

It is your responsibility to ensure you are familiar with all applicable regulatory requirements when providing this attestation.

You do not need to submit finished product specifications (FPS) with Class I PLAs or Class I amendment applications; however, FPS must:

- be established in accordance with the requirements described in the [Quality of Natural Health Products Guide](#)
- remain in compliance with the requirements described in the [Quality of Natural Health Products Guide](#); and
- be provided to Health Canada upon request

For Class II and Class III applications, FPS are required as part of the submission. Refer to [Appendix VIII](#) for more information.

Kit applications

A kit is defined as a package that includes either multiple NHPs, or a combination of one or more NHPs with foods, non-prescription drugs, cosmetics, or medical devices. The kit is intended to deliver a combined benefit, such as unified branding or overarching health claims.

NNHPD requires that the MIs and NMIs for each component (that is, each product within the kit) be listed separately for kit applications. You meet this requirement by submitting individual PLA forms (one PLA form for each component of the kit).

Each PLA form must:

- include the same recommended conditions of use across all components
- indicate that the application is for a kit by checking the “This application is for a kit” box on the PLA form

Additionally, you must:

- specify the number of PLA forms included in the kit in the cover letter

Site information

In accordance with [section 22 of the NHPR](#), you must provide site information for each manufacturer, packager, labeller, importer, distributor, and/or storage facility prior to the sale of the NHP.

Where available, the following details must be included in the PLA form under Part 3 – Site Information:

- company name
- address
- site licence number (for Canadian sites)

An NHP cannot be sold in Canada until:

- an NPN or DIN-HM is issued, **and**
- complete site information has been provided to NNHPD.

If site information is not included in the PLA, it must be submitted to NNHPD via a notification using the ANF.

For questions regarding the site licensing process, contact Health Canada's Regulatory Operations and Enforcement Branch at: hpcd.nhp.sl-dcps.psn.le@hc-sc.gc.ca

Submitting your application

Once you submit an application, NNHPD does not accept unsolicited changes or additional information, except for updates to contact information.

If you wish to make changes to a submitted PLA, you must [withdraw the original application](#) and submit a new one with the revised information.

Electronic submission requirements

NNHPD only accepts applications submitted electronically. The current method for electronic submission is via Canada Post's secure email service, Connect.

To use Connect, you must be enrolled as a Trading Partner. For details, refer to the guidance on [Electronically contacting the Natural and Non-prescription Health Products Directorate](#).

In rare cases where the PLA or ANF forms cannot be used, contact the Client Support Unit (nnhpd-dpsnso@hc-sc.gc.ca) who will provide additional guidance.

Submission instructions

All NHP applications must be submitted to the following Connect account:
nhpsn.epostel.applications

NNHPD uses this account to initiate company-specific conversation threads. All new applications, amendments, and notifications must be submitted to this account.

Applications will **not** be processed if they are submitted:

- to any other Connect account, including the correspondence account (nhpsn.epostel.correspond)
- via any other electronic means (e.g., email, CD, or DVD)
- on paper
- in duplicate

High volume submission notification

You are expected to notify NNHPD in advance if you plan to submit a large volume of applications over a short period of time (for example: more than 20 applications per week). This applies to all application classes, including amendments and notifications.

Early notification allows NNHPD to work with you to develop a submission plan that supports timely processing and assessment in alignment with service standards.

If NNHPD is not informed of a high-volume submission in advance, you should expect delays, and the applications may not be subject to (or meet) the service standards outlined in this document.

Application screening and assessment

This section outlines the stages involved in the screening and assessment of an application and provides guidance on when and how to communicate with NNHPD throughout the application process.

All applications submitted to NNHPD undergo an initial administrative screening to verify completeness and compliance with submission requirements.

- If administrative requirements are met:
 - new applications and amendments (for all classes) proceed to regulatory screening
 - notifications are processed

Following regulatory screening:

- Class I and II applications and amendments are issued a regulatory decision
- Class III applications and amendments that pass regulatory screening proceed to assessment

If additional information is required during regulatory screening or assessment, NNHPD may issue an [IRN](#).

Administrative screening

NNHPD verifies all applications submitted through Connect for administrative completeness.

Administrative deficiencies leading to refusal

A notice of refusal (administrative deficiency) will be issued if the application contains one or more of the following deficiencies:

- damaged or corrupted files
- incorrect application class listed on the PLA form (without a rationale provided in the cover letter)
- missing monograph attestation, if applicable
- incorrect or mismatched company name and/or code
- use of an incorrect or incomplete application form(s)
- PLA or ANF form not finalized prior to submission
- unexplained discrepancies due to technical issues (not addressed in the cover letter)

- missing or incomplete contact information or DPA form (unless authorization is clearly granted for multiple applications)
- mismatch between the Senior Official listed on the PLA form and NNHPD records, with no notification of change
- inappropriate use of the cover letter, such as addressing issues that are not form limitations, may lead to refusal.
- submission in an unacceptable format (for example: USB drive, password-protected files, paper, scanned copy)
- duplicate tracking number on the PLA or ANF form (for example: reusing the same form for multiple applications)

NNHPD will not issue an IRN for the above noted deficiencies.

If the classification of the product is unclear, NNHPD may issue an IRN to request clarification. If the product clearly falls outside the scope of the NHPR (for example: prescription drugs, products that puncture the dermis), an IRN will not be issued.

Acknowledgement of applications

Class II and III applications and amendments that meet all administrative requirements will receive an Acknowledgement Letter via Connect. This letter includes the:

- submission number
- date of receipt of the application

Regulatory screening

All new applications and amendments are screened against the regulatory requirements of the NHPR, as well as processes and expectations explained in this document, and in other applicable guidance documents.

In addition, applications are reviewed for relevant submission requirements and, where applicable, against all parameters of the selected NNHPD monograph(s).

NNHPD will verify any parameters not automatically validated by the PLA form. This may include:

- brand name(s)
- NMI
- free text fields

Regulatory deficiencies leading to refusal

A notice of refusal will be issued if the application contains one or more of the following regulatory deficiencies:

- product does not meet the definition of an NHP
- brand name does not conform to [section 9](#) of the [Food and Drugs Act](#), in a manner that is:
 - false, misleading or deceptive; or
 - is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety
- incomplete or inaccurate information in the application package
- missing application requirements, such as:
 - [FPS](#) (except for Class I);
 - [label text](#);
 - supporting evidence for safety and/or efficacy;
 - letters of access;
 - Animal Tissue Form; and/or
 - attestation(s)
- failure to meet monograph parameters to which the applicant attested

Other deficiencies

During regulatory screening, NNHPD may issue an [IRN](#) to address minor deficiencies.

Failure to respond to IRNs

A notice of refusal will also be issued if the:

- applicant fails to submit requested information in response to an [IRN](#) within the specified timeline
- response to an IRN is incomplete or deficient (for example: one or more deficiencies remain unresolved)

Assessment (Class III applications)

After NNHPD completes regulatory screening of a new Class III application or amendment application, it proceeds to assessment. During this stage, NNHPD evaluates the submission against the relevant safety, efficacy, and/or quality requirements.

Assessment deficiencies leading to refusal

A notice of refusal may be issued during the assessment stage for any of the following reasons:

- failure to respond to an IRN within the specified timeline
- submission of an incomplete or deficient IRN response, where one or more deficiencies remain unresolved
- submission of false, misleading, or inaccurate information (as per the [NHPR](#))
- insufficient evidence to support the safety and/or efficacy of the NHP under the recommended conditions of use (see [section 5\(g\)](#) of the NHPR)
- product is likely to result in injury to the health of a consumer

Information Request Notice

NNHPD may issue an IRN to obtain additional information from you to address non-administrative deficiencies or information omissions, in accordance with [section 15](#) of the NHPR.

- The response timeline for an IRN ranges from 5 to 15 calendar days, depending on the complexity of the information requested.

- IRNs may be issued during both the regulatory screening and assessment stages for deficiencies across all application classes.

This may include, in rare cases, a request for a Risk Management Plan (RMP) when:

- the available information on the product's use in the Canadian context or a comparable regulatory framework is limited or not robust.

If you fail to provide the requested information or if the evidence remains insufficient, NNHPD may issue a notice of refusal.

Comprehensive IRNs

To improve efficiency and clarity, NNHPD aims to issue one comprehensive IRN per stage (regulatory screening and/or assessment).

- You must respond to each item listed in the IRN.
- NNHPD will not reissue IRNs for deficiencies that were previously identified but not adequately addressed.
- NNHPD will not request the same information twice if the initial response is incomplete or insufficient.
- NNHPD will not accept unsolicited changes (for example: changes made to the application outside of those addressed in the IRN)
- A second IRN may be issued only if:
 - a new issue arises during screening or assessment, **or**
 - minor adjustments are needed to finalize the review.

Not all non-administrative deficiencies will result in an IRN. Applications with critical deficiencies will lead directly to a notice of refusal.

Responding to an IRN

You must monitor your Connect account for new messages from NNHPD. If you fail to respond to submission-related requests within the required timeframe, NNHPD may issue a notice of refusal.

As outlined above, NNHPD communicates with applicants exclusively through Connect. Responses to IRNs must be submitted:

- electronically, through the submission-specific Connection conversation thread; **and**
- within the specified time period indicated in the IRN

Request for an extension to an IRN response

If you require additional time to respond to an IRN, contact your assigned NNHPD Submission Coordinator via the submission-specific Connect conversation thread.

Approach to extension requests

Short extensions may be considered on a case-by-case basis. The request must include a:

- clear reason for the extension
- proposed alternative response date

NNHPD will review the request and provide a response within two business days of receipt.

It is your responsibility to ensure you (or your designated party) are available to respond to IRNs in a timely manner. NNHPD reserves the right to deny extension requests. If denied, you will be notified in writing via the submission-specific Connect thread, along with the reason for refusal.

Service standards

NNHPD has established service standards for various application types. Refer to the table in [Appendix VI](#) for a detailed overview of the applicable service standards.

Class III applications that require joint assessment with other Health Canada directorates (for example with the Medical Devices Directorate) are not subject to the 210-calendar day service standard. For such products, NNHPD encourages you to request a [pre-submission meeting](#) to help facilitate the review process.

Amendment applications are subject to the same service standards as new product applications.

Notifications do not require NNHPD approval prior to implementation. As a result, NNHPD has not established a service standard for processing these.

Product licence holders should consult NNHPD prior to submitting new PLAs, amendments, or notifications, when addressing compliance issues in collaboration with Health Canada's ROEB.

Unresolved compliance issues may prevent NNHPD from issuing or amending a product licence.

In response to a public health emergency or urgent need, NNHPD may prioritize certain submissions. In such cases, NNHPD will communicate any changes in prioritization to stakeholders.

Communicating with NNHPD

You may need to contact NNHPD during or after the submission of an application.

Contact the NNHPD Client Support Unit at nnhpd-dpsnso@hc-sc.gc.ca for questions related to:

- policies
- guidance documents
- submission procedures
- tools

Status update requests

NNHPD understands that you may wish to know the status of your application. Note, however, that NNHPD considers status update requests to be a lower-priority. A response will only be provided if an issue is identified with the application (for example if we have no record of having received the application).

If the application is still within the applicable service standard, NNHPD will not respond to the status request.

Required information for status update requests

All status update requests must include the:

- submission number (if available)
- name of the applicant company
- primary brand name
- application type
- date of submission

If the status update request is complex, the NNHPD Client Support Unit will assign a subject matter expert to review and respond.

Withdrawal of an application

At any point during the application process, a Senior Official or Designated Party may withdraw their application by completing the [NHP Application Withdrawal Request Form](#).

All withdrawal requests will be processed and acknowledged in writing, and the application status will be recorded internally as “Withdrawn by applicant.”

Withdrawal of an application is without prejudice to re-submission; applicants may submit a new application at any time.

Pre-licence company transfer or merger/acquisition

When a company transfers ownership or merges with another company, you, as the applicant, must inform NNHPD as this will impact the associated regulatory responsibilities.

If a transfer request pertains to an application that has already been submitted to NNHPD, but has not yet received a regulatory decision, you must submit the request as an unsolicited information update.

The following documents must be submitted via Connect:

- a signed and dated letter from the Senior Official of each company, on company letterhead, confirming the transfer

- the 2 letters must clearly identify the applications being transferred, including the submission numbers and primary brand names
- if a submission number has not yet been issued, the letters must include the primary brand names, tracking numbers, and submission date via Connect
- an updated PLA form reflecting the new applicant and contact information
- DPA form(s), if applicable

Regulatory decision

Once NNHPD has completed the processing of a PLA, one of the following regulatory decisions will be issued:

- issuance of a product licence, or
- notice of refusal to issue a licence

Issuance of a product licence

NNHPD will issue a product licence for applications that meet the regulatory requirements of the NHPR. The licence includes the NPN or DIN-HM assigned to the product.

Once NNHPD issues a product licence, the product licence status appears as 'Active' in the LNHPD approximately 48 hours later. However, the product remains listed as 'Not Marketed' until the licence holder submits a [Market Notification](#) to inform NNHPD that the product is available for sale in Canada.

It is your responsibility, as the product licence holder, to submit a Market Notification to update the status of your product(s) from “Not Marketed” to “Marketed.” Details on this process are provided in the [Market Notification section](#).

Information about licensed products is available through the [LNHPD](#).

Notice of refusal

A notice of refusal will be issued for applications that do not meet the requirements of the NHPR and the [administrative expectations and processes set out in this document](#).

You can contest a notice of refusal through the reconsideration process.

Request for reconsideration

In accordance with [section 9](#) of the NHPR, you may request a reconsideration of a notice of refusal within 30 calendar days of its issuance.

Upon review, a request for reconsideration may result in one of the following outcomes:

Decision upheld: The original refusal is maintained. A letter outlining the reasons for the decision will be sent to the applicant.

Decision partially amended: If only some of the objections are resolved, the application remains refused. The file will not return to review. You may submit a new application that addresses the remaining issues.

Decision amended: If the original refusal is overturned, NNHPD will issue or amend the product licence, provided the requirements of [section 7](#) of the NHPR are met.

For more information, refer to the [Guidance document: Reconsideration of Decisions Issued for Human Drug and Natural Health Product Submissions](#).

Re-submitting an application

You may re-submit [withdrawn](#) applications or those for which a notice of refusal was issued.

In all cases, you must complete a new PLA and reference the submission number of the original application.

The re-submitted application will be assessed under the regulations, policies, procedures, guidance documents, and service standards that are in effect at the time of submission.

Safety and Efficacy Assessment Report

If NNHPD issues a notice of refusal, you may request a copy of the Safety and Efficacy Assessment Report (SEAR) by contacting the NNHPD Client Support Unit at nnhpd-dpsnso@hc-sc.gc.ca. You must:

- make the request in writing
- include the submission number of the application

NNHPD will strive to provide the SEAR via Connect within 20 calendar days of receiving the request. This applies only to Class III applications, where safety and/or efficacy is assessed.

NNHPD does not provide a copy of the SEAR upon issuance of a product licence.

Record-keeping responsibilities

You are responsible for maintaining records of all information submitted to NNHPD. In cases where there is a change in licence holder or consulting company, the current licence holder must retain a copy of the PLA package.

Product licences are sent via Connect to the Senior Official and all company contacts listed in the application. Refer to your Connect account for submission records. You are expected to save all files received through Connect to your own secure system.

Any information or data submitted to support the application will not be returned to you.

NNHPD will not provide convenience copies of any submitted materials, including NHP-MFs. NNHPD has no regulatory obligation to provide copies of licences or documents submitted as part of an application.

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 of the [Library and Archives of Canada Act](#)

Post-licensing processes

Post-licensing processes refer to all actions that take place after a product has been issued a product licence. These include:

- [product licence correction requests](#)
- [post-licence changes](#)
- [monograph updates](#)
- [requests to discontinue a product licence](#)

- [post-licence audit](#)
- [post-licence IRN](#)

Product licence correction requests

In accordance with [section 14\(2\)](#) of the NHPR, you, as the licence holder, have 60 calendar days from the date of product licence issuance to notify NNHPD of any known inaccuracies on the licence.

Correction requests must be submitted via email to the NNHPD Client Support Unit at nnhpd-dpsnso@hc-sc.gc.ca, with the subject line referencing the submission number and/or NPN.

Requests should be limited to administrative errors on the product licence (for example: spelling mistakes or discrepancies between the submitted PLA and the issued licence).

This process is not intended for post-licensing changes that fall outside the scope of the original PLA. For such changes, refer to the [section on amendments and notifications](#) in this document.

The [LNHPD](#) will be updated within 15 calendar days to reflect the correction, and a revised product licence will be issued.

Post-licence changes

Amendment applications and notifications must be submitted via Connect using the [ANF](#). If you encounter system limitations that prevent you from using the ANF, contact the NHP Online solution team at nhp.initiative-psn@hc-sc.gc.ca for assistance. If you cannot resolve the issue after reaching out, clearly state the unresolved issue in your submission cover letter.

Adhering to this process is essential. If you do not follow these steps, NNHPD will not process your requested change.

There are three types of post-licence changes:

- [fundamental change](#)
- [amendment](#)

- [notification](#)

Licence holders with a product licence that is under a stop sale or suspension will not be able to submit an ANF.

Each type of change has distinct regulatory requirements. Refer to [Appendix VIII](#) for a detailed list of changes and their associated requirements.

Fundamental changes

The NHPR do not permit fundamental product changes following the issuance of a product licence. As defined in [section 13](#) of the NHPR, fundamental changes include a change to the:

- quantity of a medicinal ingredient per dosage unit, or the addition or substitution of a medicinal ingredient
- dosage form
- recommended route of administration

These changes require the submission of a new PLA. If approved by NNHPD, the product will be issued a new NPN or DIN-HM.

This requirement also applies to products that [attest to a monograph](#), even if the proposed changes remain within the monograph's limits.

If the original product will no longer be manufactured, you should request a [discontinuation](#) of the original product licence.

Amendments

Amendments refer to changes to a licensed NHP that may impact its safety, efficacy, or quality. An amendment application must include supporting evidence demonstrating that the product remains safe and effective.

As outlined in [section 11](#) of the NHPR, an amendment application is required for any of the following changes:

- 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.

Classification of amendments

NNHPD classifies, processes, and assesses amendment applications related to a product licence in a manner similar to new applications, following the same procedures and [service standards](#).

The classification of an amendment may differ from that of the original application, depending on the nature and scope of the proposed change.

Upon receipt of the amendment application, NNHPD will screen each amendment to assess whether the proposed changes align with the anticipated class as indicated on the cover letter. NNHPD may reclassify the amendment based on the nature of the product and the proposed changes:

- Class I and II: If the product and proposed changes are fully supported by NNHPD monographs, the amendment will be classified as Class I or II.
- Class III: If the changes require an assessment of safety and/or efficacy, the amendment will be classified as Class III.

Refer to [Appendix VII](#) for more information on amendment classifications.

Acknowledgement Letters

- Class I amendments do not receive an Acknowledgement Letter. A final regulatory decision will be issued in accordance with Class I performance standards.
- Class II and III amendments will receive an Acknowledgement Letter with the final classification of the amendment.

For products under previously issued licences with the statement “As authorized according to the NNHPD monograph to which the applicant attested”, an amended product licence will be issued listing all product information.

Amendments can only be implemented after NNHPD has approved the change(s) and the product licence is updated to reflect the changes.

Notifications

Notifications refer to changes to a licensed NHP that do not significantly impact its safety, efficacy, or quality.

You must notify NNHPD of such changes within 60 calendar days of the change, using the [ANF](#).

As outlined in [section 12](#) of the NHPR, a notification is required for the following changes:

- 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.

Unlike new applications and amendments, notifications do not have service standards.

If the volume of notifications exceeds NNHPD's processing capacity, priority will be given to company updates and updates needed to address a risk issue.

You are responsible for identifying such updates by answering "YES" to the following question in the ANF:

- Is this amendment/notification in response to a notice issued by the NNHPD Risk Management Division?

Once a notification is processed, NNHPD will issue a notification acknowledgement letter.

Note:

- A revised product licence will not be issued following a notification.
- The LNHPD will reflect the processed changes (except for NMI quantities, source material and site information) and will display the "Revised Date of Licensing".

Market status notification

The market status of a product is displayed in the LNHPD, indicating whether a product is "marketed" or "not marketed" (that is, whether it is currently available to Canadian consumers).

For submissions that have attested to the [eligibility criteria](#), you are required to:

- notify NNHPD when the product is being sold in Canada
- provide valid site information prior to commencing sale, as required under [section 22](#) of the NHPR

You are strongly encouraged to update NNHPD when the market status of your product changes. This helps support efficient and effective post-market surveillance and allows NNHPD to prioritize post-licence applications.

The Senior Official of the company or an authorized Designated Party must submit market status updates using the [NHP Market Notification Web form](#). If a Designated Party submits the update, NNHPD must have received a valid DPA form beforehand; otherwise, NNHPD will not process the request.

NNHPD processes the market status update request, notifies the product licence holder via email, and updates the market status in the LNHPD at the end of each month.

Maintaining company contact information

In accordance with [section 12](#) of the NHPR, you are responsible for notifying NNHPD of any changes to company and/or contact information within 60 calendar days of the change. This requirement applies throughout the entire product life cycle. Changes requiring notification include:

Company Information:

- change in company name
- change in company address

Contact Information:

- change in the Senior Official
- updates to email, phone number, or mailing address that do not affect a manufacturing, packaging, labelling, or importing site

These changes must be submitted as a company update notification using the ANF, and must be submitted by the Senior Official or Designated Party of the company.

Post-licence company transfer or merger or acquisition

When a company merges with, acquires another or transfers ownership and associated regulatory responsibilities of one or more licensed products and the associated regulatory responsibilities, you must notify NNHPD by submitting a notification.

In addition to the ANF, the following documents must be submitted via Connect:

- a signed and dated letter on company letterhead from the Senior Official or Designated Party of each company confirming the transfer
 - The 2 letters must clearly identify the product licences being transferred, including the NPN(s) or DIN-HM(s) and the primary brand names
- DPA form(s), if applicable

For mergers and/or acquisitions, in addition to the above, you must also provide the preferred outcome of the modifications that may need to occur in NNHPD's database. For example:

- deactivating company codes
- changing company name and contact information
- transferring active NPNs

These modifications will be dealt with on a case-by-case basis, depending on each company's unique merger/acquisition situation.

Typically, the surviving company must submit legal documentation, such as a certificate of amalgamation or purchase agreement, confirming that it has merged with or acquired the other company and has assumed all associated product licences and regulatory responsibilities.

In these cases, letters from both companies are not required if the documentation clearly shows corporate continuity.

Transferred NPNs or DIN-HMs will retain their current regulatory status (for example: active, stop sale, or suspended). If a compliance file is associated with the product licence, the new company assumes responsibility for resolving the non-compliance.

For example: If a product licence with a "suspended" status is transferred, the new company must demonstrate that the situation has been corrected or did not exist.

Determining that a company is no longer in operation

If a company does not respond to a post-licence IRN within the 15-day response period, NNHPD follows up with a reminder via email and phone. If the company does not respond, NNHPD may begin a process to determine whether the company is no longer in business.

This process includes:

- multiple attempts to contact the company using the most up-to-date information in NNHPD's database
- researching the company and product, including business registries
- contacting DPAs, site licence holders, and other listed contacts

If these efforts are unsuccessful, NNHPD may presume the company is no longer operational.

In such cases, a regulatory notice may be issued under [section 18–20](#) of the NHPR for all product licences held by the company. This is based on reasonable grounds that the company has contravened [section 12](#) of the NHPR by failing to maintain current records with Health Canada.

To ensure all possible avenues of contact are exhausted, notices are sent via email and postal mail using the most current address in NNHPD's database.

If a [section 18–20](#) notice is issued, it will outline the full regulatory pathway. The company may respond at any time within the 180-day timeframe, during which product licences will be:

- suspended 90 days after the notice is issued, pursuant to [section 20](#)
- cancelled after 180 days, pursuant to sections [20\(b\) and 21](#), if no sufficient response is received

You, as the licence holder, must submit a sufficient response to NNHPD as per the instructions in the notice. It must include updated contact information or a statement explaining that the situation leading to the intended or actual suspension did not exist.

You cannot sell a product if your licence is suspended or cancelled. A suspended product licence may be reinstated upon receipt of a sufficient response. A cancelled product licence cannot be reinstated.

Non-notifiable changes

Non-notifiable changes refer to revisions made to a licensed NHP that are not required to be submitted to NNHPD. They refer to changes that are not outlined in sections 7, 11, or 12 of the [NHPR](#) and generally do not impact the safety, efficacy, or quality of the product.

Examples of non-notifiable changes include:

- revisions to net package quantity (e.g., changing from 50 to 100 capsules per bottle), provided there is no safety concern
- label updates that do not require assessment or are not included in the PLA, such as marketing statements, formatting changes, or certain storage conditions
- revisions to manufacturing flow charts that do not affect the FPS

Refer to [Appendix VIII](#) for a detailed list of non-notifiable changes related to product quality.

NNHPD will not issue a notification acknowledgement letter for non-notifiable changes, even if they are submitted.

Monograph updates

NNHPD monographs contain pre-cleared information that applicants may use to support the safety, efficacy, and/or quality of an NHP.

These monographs are periodically revised or updated as needed to address risks to the health and safety of Canadians.

Impact on product labelling

When monograph revisions affect product labelling, you are expected, unless otherwise notified, to align your product labelling with the most recent version of the monograph according to the following timelines, whichever occurs first:

- within 3 years of publication;
- at next label run; or
- with the next post-licensing change (amendment or notification)

These revisions must be submitted to NNHPD through an amendment application, notification or, in some cases, a resubmission.

If NNHPD revises a monograph for safety reasons, it issues a post-licensing IRN that specifies the required timelines for label updates. These timelines may be shorter than the standard 3-year period. If the licence holder does not respond or submits an inadequate response, NNHPD may issue a [section 16](#) notice.

Impact on product quality

If you attested to an NNHPD monograph to support product quality (refer to [Attesting to NNHPD Monographs](#)), the FPS should be updated to reflect the latest quality-related changes in the monograph. Note that updates to safety or efficacy information may also impact the quality parameters and FPS of the product.

Product licence amendment requirements may apply when monographs are revised for quality, or for safety and/or efficacy changes that affect quality. While FPS are not required to be submitted for new Class I applications or Class I amendment applications, the specifications must comply with the [Quality of Natural Health Products Guide](#) and be provided to NNHPD upon request.

Suggesting revisions to a monograph

Suggestions for revisions to existing monographs, or proposals for new monograph topics, may be submitted to NNHPD via email at ingredient_support@hc-sc.gc.ca.

Submissions should include:

- the name of the monograph being proposed or revised
- a clear rationale for the suggestion
- supporting evidence for NNHPD's consideration

Discontinuing a product licence

You are encouraged to notify NNHPD if you no longer require an active product licence (NPN or DIN-HM). To request a discontinuation, the Senior Official of the company must submit the [NHP Discontinuation Request Form](#). Alternatively, a Designated Party (for whom a valid [DPA form](#) has been submitted) may make the request on behalf of the Senior Official.

Discontinuation requests submitted by undesignated company representatives will not be processed.

NNHPD will notify you via email once the request has been processed or if additional information is required. The licence status will be updated in the LNHPD to reflect “Discontinued” within 48 hours of receiving the notification.

Once a product licence is discontinued, you cannot reactivate it. To regain authorization to sell the product, you must submit a new application, which will be subject to any current regulations, policies, procedures, guidance documents, and service standards in effect at the time of submission.

You do not need to submit updates to contact information for a product licence listed as “Discontinued” in the LNHPD.

Post-licensing audit

NNHPD may conduct post-licensing audits on any application at any time. These audits are distinct from audits conducted by Health Canada’s ROEB.

If NNHPD identifies a discrepancy during an audit, it will notify the product licence holder and issue a post-licence IRN. The IRN asks you, as the licence holder, to correct the deficiency and bring the product into regulatory compliance.

Addressing post-licence issues

Prior to initiating regulatory action, NNHPD may provide licence holders with an opportunity to address post-licence concerns (such as safety or administrative issues) through the issuance of a post licence IRN.

The post-licence IRN outlines a response timeline, determined by NNHPD, which may vary based on factors such as:

- potential risk posed by the product
- complexity of the information requested
- urgency of the issue
- impacted sub-population

- Other relevant considerations

A post-licence IRN may request specific modifications to the product licence and/or labelling to address the identified concern. You may respond by submitting a post-licence amendment or notification using the [ANF](#).

Examples of post-licence concerns include:

- changes to an ingredient entry in the [NHPIID](#) that must be reflected in licensed products
- updates to a monograph affecting a licensed product
- new information or restrictions related to an ingredient or product that impact safety
- administrative errors during licensing
- complaints indicating a potential safety issue
- product updates resulting from safety assessments

Any application(s) submitted may be put on hold if there are outstanding post-licence non-compliance issues that have not been addressed.

The post-licence IRN is one of several tools used to manage post-licence issues. NNHPD may also issue regulatory notices under sections [16 to 20](#) of the NHPR if a safety concern or other alleged contravention of the NHPR or [Food and Drugs Act](#) is identified.

When NNHPD issues a regulatory notice requesting updates to product licence information, the product licence holder must respond using the ANF tool. The submission must be clearly marked as 'in response to a notice issued by the NNHPD Risk Management Division.' You must also submit the ANF and revised label (if applicable) according to the instructions provided in the post-licence IRN.

The assessment of post-licence issues and any resulting amendments required from the product licence holder are not subject to the service standards outlined in this document.

Appendix I – Product classification information and resources

Criteria of an NHP		Helpful Resources
<p>Substance</p>	<p>Contains a substance set out in Schedule 1 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.</p> <p>However, a natural health product does not include a substance set out in Schedule 2, any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.</p>	<ul style="list-style-type: none"> • Natural Health Products Ingredients Database (NHPID) provides information on whether a medicinal ingredient is subject to the <i>NHPR</i> or other regulations under the <i>Food and Drugs Act</i>.*
<p>Function</p>	<p>The product is manufactured, sold or represented for use in:</p> <p>(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;</p> <p>(b) restoring or correcting organic functions in humans; or</p> <p>(c) modifying organic</p>	<ul style="list-style-type: none"> • Pathway for Licensing Natural Health Products Making Modern Health Claims (Section 2.4 Types of Health Claims) • Pathway for Licensing Natural Health Products used as Traditional Medicines (Section 2.3 Health Claims) • Evidence for Homeopathic Medicines

Criteria of an NHP	Helpful Resources
<p>functions in humans.</p> <p>Note: Although a function/claim for a product may meet this definition, it must also be appropriate for use as a NHP (for example: for self-selection/monitoring conditions) Refer to Section 2(2) of the NHPR.</p>	

*If an ingredient is not contained in the NHPID, this does not mean that it is not acceptable in an NHP, but rather it has not yet been presented as an ingredient in an NHP. To have an ingredient included or modified in the NHPID, applicants should follow the guidance in the section on [NHPID modification](#).

While a product may meet both the substance and function criteria of the NHP definition, it may not be classified as an NHP in certain cases. This includes products that fall at the food-NHP interface or at the medical device-NHP interface.

You must determine the appropriate product classification by consulting relevant resources and examples that address these interface scenarios.

For more information, refer to the table below outlining key resources related to product classification at different interfaces.

Interface	Helpful resources
<p>Drug</p>	<ul style="list-style-type: none"> • The Prescription Drug List is a list of prescription drugs and classes of prescription drugs established by the Minister of Health under section 29.1 of the Food and Drugs Act. The Prescription Drug List does not include medicinal ingredients listed in the Schedules of the Controlled Drugs and Substances Act. • Guidance Document: Determining Prescription Status for Human and Veterinary Drugs

Interface	Helpful resources
Cosmetic	<ul style="list-style-type: none"> • The Guidelines for the Nonprescription and Cosmetic Industry Regarding Non-therapeutic Advertising and Labelling Claims lists claims that are considered therapeutic/health claims and others that are considered non-therapeutic claims • Guidance Document: Classification of Products at the Cosmetic-Drug Interface • Section 3 of the Industry guide for the labelling of cosmetics
Food	<ul style="list-style-type: none"> • Guidance Document: Classification of products at the food-natural health product interface: products in food formats • According to Section 9 (1) of the <i>Food and Drugs Act</i>, “No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.” – A health product must not be represented as a food. • Food-like dosage forms are not acceptable (e.g., bars, chewing gums, beverages).
Medical Device	<ul style="list-style-type: none"> • Classification of Health Products at the Device-Drug Interface • Drug/Medical Device Combination Products
Raw Material	<ul style="list-style-type: none"> • Natural Health Product Raw Material Policy • Natural Health Product Compounding Policy

Appendix II – Guidance and tools

Use the available guidance and tools to meet your responsibilities across all stages of the product lifecycle — including before, during, and after submitting your PLA. These resources are intended to:

1. support more efficient application processing;
2. help reduce common deficiencies in submissions; and
3. promote compliance with the NHPR

Regulations

- [Natural Health Products Regulations](#) (NHPR)
- [Supplementary Rules Respecting Nicotine Replacement Therapies Order](#)
 - Refer also to the [Guide to the Supplementary Rules Respecting Nicotine Replacement Therapies Order](#)

Natural Health Products Ingredients Database

The [NHPIID](#) is a repository of medicinal and non-medicinal ingredients used in NHPs that can be selected in the PLA form or the ANF. It is a key component of the [Natural Health Products Online System](#).

The NHPIID provides access to a range of pre-cleared information, including:

- Single ingredient monographs
- Product monographs
- Controlled vocabulary, which covers standardized terms for, but not limited to:
 - Dosage forms
 - NMI purposes

- Routes of administration
- Test methods
- Units of measurement

In addition, the NHPID may include information to help improve awareness and understanding of how to comply with regulatory requirements related to specific ingredients and their use in NHPs. The database also includes information on ingredients that are restricted or not permitted for use in NHPs.

The NHPID uses standardized terminology as outlined in the [Natural Health Products Online System Standard Terminology Guide](#).

Compendium of Monographs

NNHPD has developed and published a [Compendium of Monographs](#) to help you support the safety, efficacy, and/or quality of an NHP as part of your PLA. The compendium is accessible through the NHPID, and each ingredient entry links to all relevant monographs.

- [Compendium of Monographs](#)
 - Refer also to the [Compendium of Monographs guidance document](#)
- [Monograph combination guide](#)

Safety and efficacy

The following documents outline NNHPD's approach to assessing evidence related to safety and efficacy of NHPs. They provide standards and considerations related, but not limited, to:

- Health claims
- Risk information
- Combining specific ingredients in NHP formulations

These resources are essential for ensuring that your NHPs meet regulatory requirements and are supported by appropriate evidence.

- [Pathway for Licencing Natural Health Products Making Modern Health Claims](#)
- [Pathway for Licencing Natural Health Products Making Traditional Health Claims](#)
- [Schedule A and Section 3 to the Food and Drugs Act \[Health Canada, 2010\]](#)
- [Evidence for Homeopathic Medicines](#)
- [Monograph combination guide](#)

Quality

The following documents are designed to help you ensure that your NHP is produced to a high standard of quality. They also outline how you can demonstrate compliance with the NHPR, specifically regarding the quality requirements.

- [Quality of natural health products guide](#)
- [Finished Product Specifications](#)
- [Good manufacturing practices guide for natural health products \(GUI-0158\)](#)

Labelling

On March 26, 2025, Health Canada published a [Ministerial Order](#) in the *Canada Gazette, Part II* that provides a temporary exemption from the [new labelling requirements](#) for certain NHPs.

This exemption applies to NHPs that are licensed on or after June 21, 2025, provided they continue to meet the previous labelling requirements outlined in the NHPR.

Key details include:

- The Ministerial Order came into force on June 21, 2025, the same day the new labelling provisions took effect.
- The exemption allows newly licensed NHPs to be labelled under the former regulations, as long as they are not sold to manufacturers or distributors.
- The Ministerial Order will be repealed on June 21, 2028, aligning with the end of the transition period for other NHPs.

- As a result, all NHPs must comply with the new labelling requirements by June 22, 2028.

The [Guidance document: Labelling of Natural Health Products](#) provides detailed instructions to help you comply with the new labelling requirements for NHPs, as outlined in [Part 5](#) of the NHPR. It also includes information on security packaging requirements, which came into effect in 2022.

You are encouraged to consult the [Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products](#), which offers best practices for effective and compliant label design.

For reference, the previous, archived labelling guidance document can be found at: <https://publications.gc.ca/collections/Collection/H164-24-2006E.pdf>

You are also encouraged to consult the [Guidelines for Consumer Advertising of Health Products](#).

Post-licensing

[Compliance and enforcement policy for health products \(POL-0001\)](#)

Appendix III – Application requirements by application type and class

Requirements	Application Type							Notification
	Class I		Class II or III			Class III		
	Compendial	Amendment	General	Traditional	Amendment	Homeopathic(with specific claims)	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	Not applicable	If applicable				Recommended	Recommended	Not applicable

Requirements	Application Type							Notification
	Class I		Class II or III			Class III		
	Compendial	Amendment	General	Traditional	Amendment	Homeopathic(with specific claims)	Amendment	
Quality)			Recommended (Class III)	Recommended (Class III)	Recommended (Class III)		(if applicable)	
Evidence	See Monograph attestation requirements	See Monograph attestation requirements	Monograph attestation or other evidence, as applicable. See Monograph attestation requirements	Monograph attestation or other evidence, as applicable. See Monograph attestation requirements	Monograph attestation or other evidence, as applicable. See Monograph attestation requirements	Monograph attestation or other evidence, as applicable. See Monograph attestation requirements	Monograph attestation or other evidence, as applicable. See Monograph attestation requirements	Not applicable
Animal Tissue Form (if applicable)	✓	✓	✓	✓	✓	✓	✓	✓
Finished Product Specifications	See Finished product specifications	See Finished product specifications	✓	✓	If applicable to the proposed changes	✓	If applicable to the proposed changes	Not applicable

✓ Required

Appendix IV – Summary report for class III applications

To strengthen the Summary Report, you should consider addressing the questions in the table below for each piece of evidence.

Note: The table provided is intended as an example. Other formats are acceptable, provided they clearly convey the expected information.

Medicinal Ingredients (MI)	Recommended Daily Dose (include single dose if relevant)	Evidence (including description of the MI (source material); dose; supported claim(s) if any; duration and risk and any comments)	What does the evidence support?			
			Safety		Efficacy	
			Yes	No	Yes	No
MI#1 name	XX mg/day (extract information/potency if any)	Evidence #1				
		Evidence #2				
		<i>Insert as many lines as needed</i>				
MI#2 name	YY mg/day (extract information/potency if any)	Evidence #1				
		Evidence #2				
		<i>Insert as many lines as needed</i>				

Appendix V – Attesting to NNHPD monographs

The table below outlines the required attestation(s) regarding safety, efficacy, and/or quality based on different submission 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 purposes	✓	Not applicable	✓
All monograph parameters are met, with the exception of minimum daily dose, use(s)/purpose 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	✓	✓
No monograph parameters are met, with exception of the specifications	Not applicable	Not applicable	✓

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 in the monograph, where applicable, or as outlined in the Compendium of Monographs. Food-like dosage forms are not acceptable (e.g., bars, chewing gums, beverages).

Except when otherwise stated on a monograph, NNHPD monographs do not support modified formulations. Products formulated with the intent to alter the pharmacokinetics (i.e., absorption, distribution, metabolism or excretion) of one or all of its medicinal ingredients are not considered equivalent to products formulated and/or medicinal ingredients prepared with *conventional* dosage forms and/or methods. Examples include, but are not limited to:

- Enhanced absorption (for example: liposomal, phytosomal formulations)
- Modified release (for example: extended release, delayed release, time-release, sustained release)

Modified formulation

An NHP in a **modified formulation** (for example: liposomal, phytosomal) 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 modified release or any 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. The cover letter must declare the modified formulation/preparation if not otherwise indicated in the PLA webform and the finished product specifications (FPS) form should include any relevant parameters.

6. **Recommended use or purpose**

Claims have been identified for each monographed ingredient based on NNHPD's evaluation of the safety and efficacy data. As an applicant, you may choose one or more claims provided in the monograph.

You must ensure that any conditions surrounding the claim (such as dose, source material, etc.) are met.

7. **Dose**

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

- Subpopulation
 - At least one subpopulation listed in the monograph should be selected.
- 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. Refer to 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 in 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 in the PLA, as applicable.

9. **Risk information**

When the monograph includes risk information, it 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 applicant 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](#).

Some monographs, such as the Aromatherapy – Essential Oils monograph, include additional restrictions for NMIs beyond those listed in the NHPID.

Products containing or using an NMI beyond and/or outside of the restrictions outlined in the NHPID and/or monograph must be submitted with supporting evidence as Class III applications. For products containing NMIs which may contribute to the efficacy or to the total quantity of a medicinal ingredient (MI) or potency constituent, applicants should consider whether the NMIs may affect safety or efficacy of the product. The NNHPD may request clarification via IRN if a concern is identified that is not addressed by the applicant via cover letter or the inclusion of NMI quantities in the PLA.

If an NMI combined with an MI is expected to have an effect on safety of efficacy, the NMI should either be declared as medicinal (and application class determined accordingly) or the application should be submitted as Class III for further assessment.

11. **Storage conditions**

When the monograph includes storage conditions for the consumer, they must appear on the product label as per section 87 of the NHPR, in addition to any other storage conditions required for the product.

12. **Specifications**

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

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 (such as duration of use, risk information) 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
 - For example: the risk statement "Ask a health care practitioner prior to use if you are 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:
 - For example: "Ask a health care practitioner prior to use 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 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.
 - For example: "Ask a health care practitioner for use beyond 4 weeks" relates to the safety of the medicinal ingredient and is longer than "Ask a health care practitioner for use beyond 1 week."

Applications 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.

Appendix VI – Service standards

Application type and class		Type of notice issued at administrative screening	Regulatory decision issued	Service standard
Class I	Compendial	Notice of refusal - no acknowledgement notice applies for this class	Product Licence or Notice of refusal	60 Calendar Days
	Class I Amendment			

Application type and class		Type of notice issued at administrative screening	Regulatory decision issued	Service standard
Class II	General	Application Acknowledgement or Notice of refusal	Product Licence or Notice of refusal	90 Calendar Days
	Traditional			
	Class II Amendment			
Class III	General		Product Licence or Notice of refusal	210 Calendar Days
	Traditional			
	Homeopathic			
	Class III Amendment			

All service standards listed above include the administrative screening and regulatory screening/assessment stages.

Appendix VII – Classification of amendment applications

This table clarifies application requirements and service standards. Use it to identify your amendment application class.

Classification of the original PLA	Amendment application screening factors	Classification of the amendment
Class I (or Compendial application type)	The product, taking into consideration the amendment changes, is in line with the Class I definition.	Class I
	The amendment changes are beyond the scope of the monograph attested to in the original application.	Class II or III (as per the Class definitions)
	Exception: If prior amendments for the product were classified as Class II or III, the amendment will be classified according to the most recent amendment.	Class II or III (as per the Class definitions)
Class II	The product, taking into consideration the amendment changes, is in line with the Class II definition.	Class II
	The product, taking into consideration the amendment changes, does not to meet the definition of Class II (for example, addition of a claim outside the monograph), or requires further review (for example for combination issues).	Class III

Classification of the original PLA	Amendment application screening factors	Classification of the amendment
Class III	Amendments will follow the Class III review timelines.*	Class III
Other: Quality-only amendment	Amendments making changes to the FPS only.	Class II**
Other: products authorized prior to the introduction of the Class system in 2014	Amendments will follow the Class III review timelines.*	Class III

* If the product, taking into consideration the proposed changes, does not require a comprehensive assessment of safety or efficacy, NNHPD will strive to amend the product licence in a shorter timeframe, subject to NNHPD's available resources and workload capacity.

** If the original PLA was Class I and the product still meets the criteria for Class I, then an amendment that only updates the Finished Product Specifications (FPS) is considered a Class I amendment as long as the new specifications continue to meet the requirements described in the Quality of Natural Health Products Guide. Refer also to the section on [Finished Product Specifications](#) for additional guidance for Class I FPS changes

Appendix VIII – Post-licence changes and associated regulatory requirements

Each type of post-licensing change has distinct regulatory requirements. The table below outlines the different types of changes and their associated regulatory requirements.

✓	Safety and/or efficacy evidence is required
▲	Safety and/or efficacy evidence may be required depending on the proposed change
□	Administrative evidence/documentation is required
*	Fundamental Change requiring a new application. Requirements for evidence and Finished Product Specifications must be submitted with the new application

Type of change	Regulatory requirement	Safety, efficacy, or administrative evidence	Finished Product Specifications
Recommended dose			
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	▲	–
Recommended duration of use			
Lengthening the recommended duration of use	Amendment	✓	–
Shortening the recommended duration of use	Amendment	▲	–
Risk information shown on any label			
Deletion of risk information	Amendment	✓	–

Type of change	Regulatory requirement	Safety, efficacy, or administrative evidence	Finished Product Specifications
Addition of risk information	Notification	▲	–
Modification of risk information	Amendment	▲	–
Recommended use or purpose			
Modification to the recommended use or purpose	Amendment	▲	–
Deletion of a recommended use or purpose	Amendment	–	–
Addition to the recommended use or purpose	Amendment	✓	–
Source material of any medicinal ingredients			
Change to the part or tissue used	Amendment	▲	–
Change to a source not listed on a monograph	Amendment	✓	–
Change of source within a monograph	Amendment	–	–

Type of change	Regulatory requirement	Safety, efficacy, or administrative evidence	Finished Product Specifications
Change from a source not listed within a monograph to a source listed within 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	✓	–

Changing any of medicinal ingredients to or from being synthetically manufactured

Change from being synthetically manufactured to a natural ingredient	Amendment	–	–
Change from a natural source to a synthetically source	Amendment	–	–

Potency of any medicinal ingredients

Type of change	Regulatory requirement	Safety, efficacy, or administrative evidence	Finished Product Specifications
Addition of a potency	Amendment	▲	✓
Deletion of a potency	Amendment	▲	✓
Change in the potency	Amendment	▲	✓
Change affecting safety and efficacy (other than those listed in paragraph 11(h))			
Change in manufacturing information	Amendment	–	▲
Change to the quantity of a medicinal ingredient per dosage unit			
Decrease in quantity	Fundamental Change	*	*
Increase in quantity	Fundamental Change	*	*
Addition or substitution of a medicinal ingredient			
Adding a medicinal ingredient	Fundamental Change	*	*
	Fundamental Change	*	*

Type of change	Regulatory requirement	Safety, efficacy, or administrative evidence	Finished Product Specifications
Removing a medicinal ingredient			
Substituting a medicinal ingredient for one not already found in the product	Fundamental Change	*	*
Dosage form			
Change in the dosage form	Fundamental Change	*	*
Recommended route of administration			
Any change in route of administration	Fundamental Change	*	–
Removal of a test method set out in the specifications			
Any removal of test methods in the specification	Amendment	–	✓
Changes to a test method set out in the specifications			
Modification of a test method in a manner that widens the purity	Amendment	–	✓

Type of change	Regulatory requirement	Safety, efficacy, or administrative evidence	Finished Product Specifications
tolerances of the product			
Modification of a test method in a manner that widens the quantity, identity or potency tolerances of any of its medicinal ingredients	Amendment	–	✓
Modification of a test method in a manner that renders it less precise, accurate, specific or sensitive	Amendment	–	✓
Change to information submitted under paragraphs 5 (a) and 5 (b)			
Change in the name of the product licence holder or applicant	Notification	–	–
Change in ownership of the product licence	Notification	<input type="checkbox"/>	–
Mergers between companies	Notification	<input type="checkbox"/>	–
Change of Senior Official	Notification	<input type="checkbox"/>	–

Type of change	Regulatory requirement	Safety, efficacy, or administrative evidence	Finished Product Specifications
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	–	–
Change of title, phone number, fax number, e-mail address or mailing address of the contact person for application	Notification	–	–
Information provided under section 22			
Addition of a manufacturer, packager, labeller, importer or distributor	Notification	–	–
Removal of a manufacturer, packager, labeller, importer or distributor	Non-notifiable change	–	–
Addition, removal, or substitution of a non-medicinal ingredient			

Type of change	Regulatory requirement	Safety, efficacy, or administrative evidence	Finished Product Specifications
Changing to a different ingredient in the NHPID	Notification	–	–
Removal of a non-medicinal ingredient	Notification	–	–
Sale under a brand name other than one submitted under paragraph 5 (e)			
The addition or modification of a brand name	Notification	–	–
Changing the brand name from one listed on the licence to another brand name listed on the licence	Non-notifiable change	–	–
Finished product specification changes (not affecting the safety and efficacy of the product)			
Addition of a test method	Non-notifiable change	–	–
Narrower limits	Non-notifiable change	–	–
Changing to a test method that is more precise, accurate, specific or sensitive (without decreasing the other three factors)	Non-notifiable change	–	–

Type of change	Regulatory requirement	Safety, efficacy, or administrative evidence	Finished Product Specifications
Changing the finished product physical description	Non-notifiable change	–	–
Change to product markings, involving a change in embossing, debossing, or engraving (except scorelines/break lines) (e.g., plain tablet to engraved, engraved to plain, change in engraving) or a change in imprinting (e.g., plain tablet/capsule to imprinted tablet/capsule)	Non-notifiable change	–	–
Change in scoring configuration	Non-notifiable change	–	–
Change in shape or dimensions of tablets, capsules, suppositories or pessaries as long as safety and efficacy are not impacted	Non-notifiable change	–	–
Pre-market quality information (changes not affecting the safety and/or efficacy of the product)			
Change in standard (e.g. USP grade, manufacturer's)	Non-notifiable change	–	–

Type of change	Regulatory requirement	Safety, efficacy, or administrative evidence	Finished Product Specifications
standard) declared for a medicinal ingredient			
Change to shelf-life for the finished product	Non-notifiable change	-	-
Finished product pharmacopeial standard change if amendment testing requirements are not triggered, and safety and efficacy are not affected	Non-notifiable change	-	-
Medicinal Ingredient Quality			
Changes in test methods, protocols and acceptance criteria on the raw material specification for a medicinal ingredient	Non-notifiable change	-	-
Change in the raw material specification for the medicinal ingredient to comply with an updated Schedule B pharmacopoeial	Non-notifiable change	-	-

Type of change	Regulatory requirement	Safety, efficacy, or administrative evidence	Finished Product Specifications
monograph or change to House Standard			
Change in the batch size for the medicinal ingredient or for a continuous process	Non-notifiable change	–	–
Change in the primary container closure system(s) for the storage and shipment of the medicinal ingredient	Non-notifiable change	–	–
Change in the re-test period (or shelf-life) for the medicinal ingredient	Non-notifiable change	–	–
Change in the labelled storage conditions for the medicinal ingredient, involving: addition/deletion of a cautionary statement or relaxation/tightening of a temperature criterion (e.g., from 15-25° C to 15-30°C)	Non-notifiable change	–	–
Stability Program			
Change to the post-approval stability protocol or stability commitment	Non-notifiable change	–	–

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 or product licence holder once a licence has been granted or amended). For PLAs, the licensee (product licence holder)/applicant is not necessarily the company that fabricates the product (e.g., may be the distributor of the product or the importer).

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

Discontinued

A discontinued NPN is a once valid authorization issued by Health Canada for a natural health product, that has since been officially withdrawn and relinquished by the product's licence holder. The date of discontinuation is when the manufacturer last sold its NHP for distribution, not when it is last sold at retail.

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.

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 (for example: 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 [Guidance document: Labelling of natural health products](#).

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.

Merger/Acquisition

A legal consolidation in which one company may absorb another and assume its assets, licences and liabilities.

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.

Non-traditional

Products that make modern health claims based on the sum total of knowledge, skills, and practices based on theories, beliefs, and experiences indigenous to a specific culture, used in the maintenance of health, as well as prevention, diagnosis, improvement, or treatment of physical and mental illness.

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.

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.

Product licence holder

See “Applicant”.

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).

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 (product licence holder)/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 follow the instructions provided in the IRN communication.

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 used 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.

Transfer

An authorized/acknowledged reassignment of active produce licences from one product licence holder to another.

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

MI – Medicinal ingredient

NHPID – Natural Health Products Ingredients Database

NHP-MF – Natural Health Product Master File

NHPR – Natural Health Products Regulations

NHP – Natural Health Products

NNHPD – Natural and Non-prescription Health Products Directorate

NPN – Natural Product Number

PLA – Product Licence Application

RMP – Risk Management Plan

ROEB – Regulatory Operations and Enforcement Branch

SEAR – Safety and Efficacy Assessment Report