Management of product licence applications for natural health products

1. Purpose

The purpose of this policy is to outline the way the Natural Health Products Directorate (NHPD) manages product licence applications (PLAs) for natural health products (NHPs) submitted in accordance with the Natural Health Products Regulations (NHPR). The policy also outlines the responsibilities and expectations for NHP applicants before and throughout the application review process.

2. Scope

This policy applies to all NHP application types, including Compendial, Non-traditional, Traditional, Homeopathic, Homeopathy Monograph, Therapeutic Products Directorate (TPD) Category IV Monographs / Labelling Standards (containing NHP ingredients), and Post Licensing Changes. It describes the new three-class review system and associated application timelines for all NHP application types.

All applications will be examined for completeness and suitability for review. In addition, subsequent solicited or unsolicited information will be subject to a screening process. All information and data submitted in support of a PLA will be retained by Health Canada.

3. Before filing PLAs

3.1 Ingredients

The applicant must ensure that the medicinal ingredients contained in the product are NHP ingredients in accordance with schedules 1 and 2 of the NHPR. All medicinal and non-medicinal ingredients found in the product must be found within the Natural Health Products Ingredients Database (NHPID) and listed with their appropriate role. Please note that some ingredients within the NHPID have associated limits or restrictions and these must also be adhered to when filing. In addition, the NHPID lists some ingredients which are not NHP ingredients and those are clearly indicated as not acceptable. An entry in the database does not imply that the ingredient has been reviewed for safety and additional information may be requested during review.

If ingredients are not listed in the NHPID, applicants are responsible for submitting a request to the NHPD to add these ingredients to the database before the application is filed. The application can only be filed once the ingredients are deemed acceptable and added to the NHPID.

Applicants must also ensure that the dosage form, route of administration and non-medicinal ingredient purposes for the product are recognized by the NHPD and therefore found within the NHPID. Applicants are reminded to consult any associated monograph(s) available in the NHPID in order to support the ingredients in their PLAs. A listing of monographs is also available within the NHPID.
For more information on how to request the addition of ingredients or other information to the NHPID, please see the NHPID issue form.

3.2 Trading partner agreement

If applicants wish to correspond with and submit application packages to the NHPD electronically, they must do so via the NHPD’s chosen secure communication service: epost Connect™. Applicants must first enrol as a Trading Partner with the NHPD. For instructions on enrolment, please refer to the: Guidance document on how to interact with the NHPD electronically.

4. Filing of PLAs

4.1 Submitting a PLA form

Please note that it is the intent of the NHPD that the electronic PLA (ePLA) form will be the only form accepted in the future. The NHPD cannot commit to the service standards outlined in this document for applications received in any other format. Applicants are strongly encouraged to use the NHP Online eSubmission Builder (eSB) to create an electronic submission package file for full electronic processing by the NHPD. Applicants using other application formats should expect a substantial increase in processing time; however, all complete applications will be assessed within 180 calendar days following the screening period.

The ePLA form provides several benefits to both applicants and the NHPD; some of which include:

- reduces the possibility of the application being rejected/refused due to embedded rules and checks for specific regulatory requirements;
- eliminates duplication of manual entry of product information;
- reduces mail/courier costs;
- reduces paper use;
- ensures adherence to standard terminology for easier processing; and
- reduces processing time and enables faster market entry for NHPs.

Applicants must notify the NHPD prior to submitting a large volume of applications at one time in order for the NHPD to work with the applicant to develop a plan for processing and assessing applications within the performance standards.

4.1.1 Filing of ePLAs by secure email

The NHPD strongly encourages applicants to file PLAs, Post Licensing Changes, and Information Request Notice (IRN) responses electronically via the NHPD’s secure email service: epost Connect™. In order to use epost Connect™, applicants must be enrolled as a Trading Partner. For more information on how to enrol as a Trading Partner, please see section 3.2.
4.1.2 **Filing of ePLAs on CD or DVD**

Although applicants are strongly encouraged to enrol as Trading Partners and submit applications via epoSt Connect™, as mentioned in section 4.1.1, it is also possible to submit the ePLA form and supporting documents by mail or courier. In this scenario, applicants are encouraged to submit a CD or DVD containing the ePLA form and all supporting documents.

Applications submitted by mail or courier may be sent to:

- Health Canada
- Health Products and Food Branch
- Natural Health Products Directorate
- Bureau of Licensing and Services Systems
- Submission Management Division
- 2nd floor, Qualicum, Tower A
- 2936 Baseline Rd, AL 3302B
- Ottawa, Ontario K1A 0K9
- (Couriers: K2H 1B3)

4.1.3 **Filing of ePLAs in paper format**

If applicants cannot submit applications and supporting documents through epoSt Connect™, nor on CD or DVD, the ePLA form and supporting documents can be printed and submitted by mail or courier. When completed, the ePLA form will generate a bar-code which can be scanned by the NHPD to extract the data electronically. The capture of this data requires an extra step by NHPD staff, which delays the processing of the application. Therefore, applicants are encouraged to submit applications as described in sections 4.1.1 and 4.1.2.

Applications submitted by mail or courier can be sent to the address indicated in section 4.1.2.

4.2 **Additional information to submit with a PLA form**

4.2.1 **Attestation to NHPD monographs**

The NHPD has developed monographs as a tool to support the safety and efficacy of many commonly used NHPs. For a list of published NHPD single ingredient and product monographs, see the NHPID (as referenced in section 3.1).

Applications containing one or more ingredient(s) supported by NHPD monograph(s) for safety, efficacy and/or quality are required to submit a **Monograph Attestation**. The attestation reminds applicants of their obligation to meet all monograph parameters. The attestation can be found on the ePLA form or as a **standalone form** available on the Health Canada website. Class-specific instructions are outlined in sections 5.1 and 5.2.
Instructions on how to attest to NHPD monographs are outlined in Appendix II.

The NHPD will conduct random and risk-based post-licensing audits of monograph-based applications, focusing on errors, inconsistencies, and deviations from the monograph(s). This will ensure that the parameters against which applicants have attested are met. Further, the NHPD will take appropriate actions to address any applicant who repeatedly submits erroneous attestations.

It is important to note that NHPD monographs are revised periodically. Refer to Section 5.3.2 for information on how to receive notification of revisions to NHPD monographs. Product licence holders are expected to align products affected by monograph revisions with the current monographs, as applicable. This can be accomplished by submitting a post-licensing change. Refer to Section 6.1 for information on post-licensing changes.

5. Processing and assessment of PLAs

For PLAs and amendments, the ePLA form or cover letter must indicate whether the product is Class I, Class II, or Class III. If a product identified as Class II is shifted to Class III, the applicant will be notified.

In addition, the NHPD requests that applicants use Class I, II, or III when naming their ePLA file – e.g. “Class I ePLA – brand name”.

5.1 Class I

Class I is comprised of products that comply with all parameters of an individual NHPD monograph. Please note that applicants cannot reference more than one NHPD monograph under Class I. Applicants submitting products complying with all parameters of an individual NHPD monograph must select “Compendial” or “Homeopathy Monograph” as the application type and complete the Monograph Attestation embedded in the ePLA form.

Class I applications will be examined for completeness. Complete applications complying with all Class I requirements and submitted using the ePLA form will receive a Product Licence (PL) within ten (10) business days.

Applications that are deficient with respect to administrative content will result in the issuance of a Rejection Notice - Administrative Deficiency. Additionally, the NHPD reserves the right to issue an Application Refusal Letter for applications that do not comply with all Class I requirements. If the applicant wishes to re-submit the application at a future time, it will be processed as a new application.

5.2 Class II and Class III

Applications requiring Class II or III assessment include “Traditional”, “Non-traditional”, “Homeopathic” and “TPD Category IV Monographs / Labelling
Standards”. Applicants should select the appropriate application type on the ePLA form.

Applicants should refer to the Pathway for Licensing NHPs Making Modern Health Claims, Pathway for Licensing NHPs Used as Traditional Medicines and Evidence for Homeopathic Medicines guidance documents for information on how to support the safety and efficacy of their products.

“Traditional” and “Non-Traditional” applications supported entirely by a combination of NHPD monographs as well as “Homeopathic with Non-Specific Claim” and “TPD Category IV Monographs / Labelling Standards” will be classified as Class II\(^1\) products. Class II products can also include:

- any fruits or vegetables listed in the Canadian Nutrient File, excluding source materials listed as “refuse”, up to a daily dose of 10 g (of crude material or quantity crude equivalent for non-standardized extracts)
- products self-identified to be identical\(^2\) to licensed products (proprietary information cannot be referenced unless authorized by a Letter of Access)
- Traditional Chinese Medicine (TCM) products identical to a pharmacopoeia formulation with attestation to the TCM Ingredients (TCMI) monograph for safety (with a specific TCM remedy claim identical to the pharmacopoeia)

Please note that applicants cannot select “Compendial” as the application type for a combination of NHPD monographs.

“Traditional”, “Non-Traditional” and “Homeopathic with a Specific Claim” applications requiring full assessment will be classified as a Class III product. Class III may include, but is not limited to the following products:

- innovative products with partially or completely novel safety and efficacy profiles
- applications partially referencing monograph information but still requiring some assessment
- applications containing a mixture of monograph ingredients and additional supporting evidence, for example a dosage form or route of administration not indicated on the monograph(s) that requires further assessment

Class II and III applications containing one or more ingredient(s) supported by NHPD monograph(s) for safety, efficacy and/or quality must complete the standalone Monograph Attestation Form. For Class II applications supported entirely by a combination of NHPD monographs, select the box which indicates that the PLA solely contains information that is supported by NHPD monographs. Alternatively, select the box which indicates that the PLA contains a combination of ingredients supported by the monograph attestation and those not supported by NHPD monographs (for which safety

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\(^1\) The NHPD reserves the right to request further safety information and shift lower certainty combination products to Class III review.

\(^2\) Identical means that the formulation and conditions of use, in their entirety, are an exact match [route of administration, dosage form, medicinal ingredients, non-medicinal ingredients, source materials, quantities, duration of use, risk information, etc.]. Note: Not all of this information is contained in the LNHPD.
and efficacy evidence has been provided), and clearly complete the table on page 2 of the Attestation Form indicating to which ingredient(s) the attestation applies for safety, efficacy and/or quality.

5.2.1 Screening

All Class II and III applications will be examined for administrative completeness. Applications meeting all administrative requirements will be sent an Application Acknowledgement Letter. Applications that are deficient with respect to administrative content will result in the issuance of a Rejection Notice - Administrative Deficiency.

Applications meeting all administrative requirements will be further screened against minimum application requirements as outlined in the NHPD’s Product Licensing Guidance Document. In addition, these applications will be subject to screening for safety and efficacy evidence.

If deficiencies are identified during the screening process, the NHPD will issue the applicant an Information Request Notice (IRN).

Complete Class II applications submitted using the ePLA form and complying with all Class II requirements will receive a Product Licence within thirty (30) calendar days of receipt. Alternatively, applications proceeding to Class III review will be sent for full assessment after the thirty (30) calendar day screening period is complete.

If major deficiencies are identified during the screening process of these applications, an Application Refusal Letter will be issued to the applicant. If the applicant wishes to re-submit the application at a future time, it will be processed as a new application.

5.2.2 Full assessment

Upon successful completion of the screening process, applications classified as a Class III will be accepted into the assessment queue and reviewed for the safety and efficacy requirements outlined in the NHPR and in the aforementioned guidance documents. Once all requirements are met, a Product Licence will be issued within one hundred and eighty (180) calendar days from the end of the screening period.

Significant deficiencies or information omissions that preclude the ongoing review may be transmitted to the applicant in an Application Refusal Letter. However, in most instances, the NHPD will provide the opportunity for the applicant to address deficiencies or information omissions through an IRN. For the purpose of implementing and maintaining an efficient assessment process, the NHPD will aim to issue one comprehensive IRN. In certain situations, a second IRN may be issued. Once a response is deemed complete, the review process will resume. The NHPD reserves the right to request clarification on the information submitted.

If the IRN response is deemed deficient or if the applicant does not satisfy all Class III
requirements, an Application Refusal Letter may be issued. If the applicant wishes to re-submit the application at a future time, it will be processed as a new application.

5.3 Communication

Applicants wishing to contact the NHPD to receive advice regarding policies, guidance, procedures, tools, initiatives, or regulatory notices or decisions issued by the NHPD are encouraged to send an email at any point during the review process.

5.3.1 Requests for information

The NHPD may communicate with applicants by telephone, email (including epost Connect™) or fax at any point upon application receipt. The NHPD will issue requests for information in the form of an IRN with a maximum specified response time based on the complexity of the information requested. The NHPD reserves the right to request clarification of the information submitted and/or issue an Application Refusal Letter if the applicant does not provide a complete response in the allocated timeframe.

5.3.2 Really Simple Syndication (RSS) feed

The NHPD has added a Really Simple Syndication (RSS) feed to the Health Canada website to inform stakeholders of the latest web-related activities and postings; including updates regarding workshops, new documents (e.g. monographs), new initiatives or other information deemed relevant for NHP applicants. Once stakeholders have signed up for NHPD’s RSS feed, they will be alerted via RSS reader of new postings.

5.4 Unsolicited information

At any time during the assessment process, applicants are encouraged to submit information to supplement or correct information on the regulatory status of the product in other countries, problem reports impacting the safety or efficacy of the product submitted to other regulatory agencies, and/or safety information enhancing the safe use of the NHP, including updated safety-related labelling. The submission of such information does not constitute significant changes to the PLA under assessment.

Changes to non-medicinal ingredients and brand name(s) are acceptable at any stage provided the changes do not affect the safety, efficacy and/or quality of the product. For example, any non-medicinal ingredients being added must be present in the NHPID and adhere to any limits or restrictions.

To ensure the new information is forwarded efficiently to the appropriate review team, applicants are requested to clearly identify the relevant application by referencing the Submission Number in a cover letter. Applicants may send this information by email.

5.4.1 Unacceptable application or formulation changes during review
Notwithstanding section 5.4.2, changes to the application which would result in a re-review by the NHPD are not permitted. These changes include product reformulation, the addition of medicinal ingredients, the addition of claims, changes to dosing, changes to route of administration and/or changes to dosage form.

5.4.2 Exceptions

At any time, applicants may remove proposed claims. Additionally, applicants are always encouraged to align their product with NHPD monographs. Applicants can therefore revise proposed claims, ingredient quantities, dosing information or risk information to align with NHPD monographs and submit the standalone Attestation Form as per section 4.2.1.

Other revisions related to monographed information may be acceptable, but the applicant is advised to confirm via email before proceeding, in order to ensure acceptability.

5.5 Decision issuance

A Product Licence will be issued to applications satisfying all Class I, II or III requirements and thus meeting all requirements outlined in the NHPR and in the aforementioned guidance documents.

A Rejection Notice - Administrative Deficiency will be issued to all applications that have administrative content deficiencies.

A Refusal Letter will be issued in the following circumstances:

- failure to meet the requirements of the NHPR or any provisions of the Food and Drugs Act, after a comprehensive assessment; or
- failure to submit the requested information in response to an IRN within the timelines specified above, or submission of an incomplete or deficient response to an IRN.

The Refusal Letter will contain the specific reasons or deficiencies that resulted in the decision to refuse issuance or amendment of a Product Licence. All decisions to refuse an application are without prejudice to re-filing. If an applicant wishes to resubmit an application at a future time, it will be processed as a new application. Information and data submitted to support the original application will not be returned to the applicant. Such data may be cross-referenced only if re-filing of the new application occurs within six (6) months of the date of the Refusal Letter.

An applicant may request a reconsideration of the NHPD’s decision to refuse their application in accordance with the NHPD Reconsideration Process. Additional information on this process can be found in section 6.3.
5.6 Withdrawal

At any time during the review of their application, an applicant may withdraw the application by submitting their intent via email. All withdrawal letters will be acknowledged in writing. The status of the application will be recorded as “withdrawn by applicant”.

Withdrawal of an application is without prejudice to re-filing. If an applicant wishes to re-submit an application at a future time, the application will be processed as a new application. Information and data submitted to support the original application will not be returned to the applicant. Such data may be cross-referenced only if re-filing of the new application occurs within six (6) months of the date of withdrawal.

6. Post decision issuance activities

6.1 Post licensing change

Applicants submitting post licensing changes should select the “Post Licensing Change” option on the ePLA form and consult the requirements for each Class, outlined in section 5. Applicants submitting post licensing changes supported by one or more NHPD monographs are required to submit the standalone attestation form along with their revised PLA. Applicants submitting post licensing changes which are not supported by NHPD monographs are required to submit additional evidence to support the desired changes, as described in section 5.2.

Post licensing changes are not required for changes to products that have been issued a Product Licence with the statement(s) “as authorized in the NHPD monograph(s) to which the applicant attested” if the post licensing change is supported by the same monograph to which the applicant attested, and thus permitted within the terms of market authorization (i.e. Product Licence).

**Class I Amendment:** Applies to products that, after applying the proposed changes in the amendment package, are entirely supported by an individual NHPD monograph.

**Class II Amendment:** Applies to product changes that fall within the Class II definition in Section 5.2 and are identified as Class II in Table 1 below.

**Class III Amendment:** Applies to product changes that fall within the Class III definition in Section 5.2 and to product changes identified as Class III in Table 1 below.

<table>
<thead>
<tr>
<th>Table 1: Classification of amendments supported by NHPD monograph(s)</th>
<th>Amendment Class</th>
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Canada
<table>
<thead>
<tr>
<th>Requested change supported by NHPD monograph</th>
<th>Product is supported entirely by a combination of NHPD monographs</th>
<th>Product contains at least one ingredient not supported by an NHPD monograph</th>
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</thead>
<tbody>
<tr>
<td><strong>Medicinal ingredient</strong></td>
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<tr>
<td>Addition of a medicinal ingredient</td>
<td>Class II</td>
<td>Class III</td>
</tr>
<tr>
<td>Substitution of a medicinal ingredient</td>
<td>Class II</td>
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</tr>
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<td>Removal of a medicinal ingredient</td>
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<td>Class II</td>
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<tr>
<td><strong>Quantity per dosage unit</strong></td>
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<td>Change to a medicinal ingredient’s quantity per dosage unit</td>
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<td>Class III</td>
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<td><strong>Route of administration</strong></td>
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<td><strong>Recommended dose</strong></td>
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<td>Change to number of dosage units</td>
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<td>Class II</td>
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<td>Change to sub-population group</td>
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<td>Class II</td>
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<td>Removal of a recommended duration of use</td>
<td>Class II</td>
<td>Class III</td>
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<td><strong>Directions of Use</strong></td>
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<td>Class II</td>
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<td>Removal of directions of use</td>
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<tr>
<td><strong>Risk information</strong></td>
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<td>Deletion of risk information</td>
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<td>Class III</td>
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<tr>
<td>Modification of risk information</td>
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<td>Class III</td>
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<td><strong>Recommended use or purpose</strong></td>
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<td><strong>Potency of any medicinal ingredients</strong></td>
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<tr>
<td>Change to a potency</td>
<td>Class II</td>
<td>Class II</td>
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</table>

6.2 Reviewer’s report

Following the receipt of a Product Licence or a Refusal Letter as a result of Full Assessment, an applicant or licensee may request the reviewer’s reports by writing to the Submission Management Division Manager and referencing the Submission Number. The NHPD will strive to provide a copy of the requested reports to the applicant within fifteen (15) working days from receipt of the request.

6.3 Request for reconsideration

The purpose of a request for reconsideration is to allow the NHPD and a PLA applicant to discuss issues related to a NHPD decision on an application. The parties may clarify and justify their positions using information available to the NHPD when the decision was made. The request for reconsideration must be based on the same information and material as the original decision. Information and material not submitted at the time of the initial decision will not be accepted.

The Reconsideration Process does not apply to the challenge of existing policies, guidelines or standards. The NHPD maintains other mechanisms to review and revise these documents which involve input from and consultation with a broad range of stakeholders. In addition, the Reconsideration Process does not apply to issues related to changes in requirements brought about from the evolution of regulatory policy that has resulted in other products reaching the market under less stringent or more favourable conditions. Requests for reconsideration involving these types of issues will be denied.

6.4 Re-filing an application

Applicants may re-file previously withdrawn applications or applications for which a Refusal Letter was issued. In all cases, a re-filed application is considered to be a new application and will be managed according to this policy. In addition, a re-filed application is subject to any new policies, procedures and/or guidance documents in effect at the time of re-filing.

6.4.1 Re-filing within six (6) months

If an application is re-filed within six (6) months of a Refusal Letter or Withdrawal Letter, the applicant should submit only the material requested in the outstanding IRN.
or listed in the Refusal Letter provided there is appropriate cross-referencing to the original material submitted. If the applicant chooses to cross-reference original material previously filed, certification that the original material pertaining to the NHP remains unchanged must be included with the re-filed application. Applicants must also clearly identify new and previously submitted information in the cover letter or table of contents accompanying the re-filed application.

6.4.2 Re-filing after six (6) months

If an application is re-filed after six (6) months of a Refusal Letter or Withdrawal Letter, the applicant must submit a completely new application, i.e. no cross-referencing to previously submitted material is allowed.

6.4.3 Re-filing of a rejected application

If an application has been rejected as described in section 5.1 and 5.2, the applicant must submit a completely new application, i.e. no cross-referencing to previously submitted material is allowed.

Service standards for the management of PLAs for NHPs

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<th>APPLICATION TYPE</th>
<th>SCREENING PROCESS</th>
<th>FULL ASSESSMENT</th>
<th>REGULATORY DECISION ISSUED</th>
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<td>TYPE OF NOTICE ISSUED</td>
<td>SCREENING</td>
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<td>Homeopathy Monograph</td>
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<td><strong>CLASS II</strong></td>
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<td>(30 Calendar Days)</td>
<td>Non-Traditional</td>
<td>Application Acknowledgement Letter or Rejection Letter</td>
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<td>TPD Category IV/ Labelling Standard</td>
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<td></td>
<td>Class II Post-Licensing Change</td>
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### Service Standards for PLAs

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<th>Class III (180 Calendar Days)</th>
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<th>Traditional</th>
<th>Homeopathic Medicines with Specific Claim</th>
<th>Class III Post-Licensing Change</th>
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<th>180 Calendar Days</th>
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These service standards apply to PLAs submitted using NHPD’s ePLA form. Applications submitted using a different format will be assessed within *180 calendar days* following the screening period. Please refer to Section 4 of this document for more information.

* 180 calendar days from successful completion of the screening process.
Appendix I

Pre-submission meeting

Applicants may wish to deliver a brief presentation to the NHPD prior to submitting a PLA. The purpose of pre-submission meetings is to discuss the presentation of evidence in support of the application. In addition, such meetings:

- familiarize assessment staff with the forthcoming application prior to its arrival, and provide a forum to discuss the evidence in the application to facilitate its assessment;
- have the potential to uncover any major unresolved problems or issues and manage disputes early in the application process;
- establish which studies the applicant is relying on to support the efficacy of the NHP and discuss the adequacy and appropriateness of controls;
- provide an opportunity for the applicant to discuss details of the application with the NHPD and obtain feedback regarding any areas of concern based on current experience and regulatory requirements; and
- provide the NHPD an opportunity to re-align resources, if necessary, to accommodate the arrival of the application.

Best practices will be followed to ensure meetings are well-organized, efficient, productive, and properly documented.

Meeting requests

Meeting requests are to be submitted to the same address as identified above in section 4.1.2 or by email. Requests are to be made no less than one (1) month prior to the proposed meeting date and should include the following information:

- the purpose of the meeting;
- a brief description of the product to be discussed at the meeting; and
- three (3) proposed dates for the meeting.

In order to ensure efficient use of NHPD resources, requests should include adequate information to determine the utility of the meeting and to identify appropriate staff to discuss proposed issues.

Pre-submission packages

Applicants will be requested to submit a pre-submission meeting information package at least two (2) weeks in advance of the meeting. Packages should contain the following information:

- a cover letter;
- an agenda for the meeting;
- a list of specific issues the applicant would like to discuss or have addressed;
- a brief summary of the NHP for which the meeting is being called;
- proposed strengths and dosages;
• an overview of the market history of the product, including the foreign regulatory status of the product;
• identification of the indication(s) for which authorization is sought; and
• brief summaries of the safety and efficacy data relating to the product.
Appendix II - Attestation to NHPD monographs

When attesting to a monograph several items on the PLA must match the monograph content exactly or fall within its parameters. Some monographs contain elements which permit “statements to the effect” of certain parameters (e.g. use or purpose) which allows applicants to alter the wording, but not the intent of the monograph elements. The following parameters of a monograph must be met upon attestation:

- **Proper name:** The proper name must be chosen from one of the proper name options provided in the monograph.

- **Common name:** The common name must be chosen from one of the common name options provided in the monograph.

- **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 in the PLA form reflect the same dose and/or use or purpose on the referenced monograph.

- **Route of administration:** The route of administration must be chosen from the options provided in the monograph. Please see the Controlled Vocabulary section of the NHPID for a description of the routes of administration.

- **Dosage form:** The dosage form must be chosen from the options provided on the monograph and must reflect the route of administration for the product. The dosage form must be chosen from the list of recognized dosage forms, found in the NHPID under the Controlled Vocabulary section.

Please note that a NHP in a liposomal formulation is not considered equivalent to a NHP in a non-liposomal formulation. Therefore applicants cannot attest to a monograph for safety and efficacy of an ingredient unless the monograph specifically states that liposomal formulations are acceptable. Products with liposomal formulations must be submitted through the appropriate application type with specific evidence to support the liposomal formulation.

- **Recommended use or purpose:** Claims have been identified for each monographed ingredient based on the NHPD’s evaluation of the safety and efficacy data. Applicants may choose one or more claims provided in the monograph or create an alternative using a “statement to the effect of”, if permitted by the monograph. Applicants must ensure that any conditions surrounding the claim (dose, source material, etc.) are met.

- **Dose:** The total daily dose must be equal to that noted in the monograph, or, when a range is specified, fall within the range indicated in the monograph. The dose indicated on the monograph may be specific to:
  - **Subpopulation:** All monographs are intended for adults, unless otherwise
specified.

- **Method of preparation**: Must be chosen from the list of acceptable methods, if indicated. Furthermore, to make a traditional use claim, the method of preparation must be one that was traditionally used. Please see the [Pathway for Licensing NHPs 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.

- **Frequency**: The frequency must be the same as or fall within the range of the frequency on the monograph, when specified. When the monograph specifies a divided dose, the frequency must be more than once daily. If no frequency is specified, the applicant may select an appropriate frequency.

- **Directions of use**: Where specified, all directions of use must be included in the PLA. The directions of use may be identical to that on the monograph or may be a “statement to the effect of”, depending on the requirement of the monograph.

- **Duration of use**: When the monograph includes a duration of use, it must be included on the PLA.

- **Risk information**: All risk information contained in the monograph must be included in the PLA, as applicable. The risk information may be identical to that on the monograph, or may be a “statement to the effect of”, depending on the requirement of the monograph.

- **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 potentially significant 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 topical product submitted in the compendial stream. If the hotlist specifies certain conditions for an ingredient, or label requirements, it is the responsibility of the licence holder to ensure that the ingredient meets the conditions outlined.

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

- **Storage conditions**: When the monograph includes storage conditions, they must appear on the product label as per Section 87 of the NHPR.

- **Specifications**: Note that certain monographs include additional specifications relevant to that ingredient or product. This information should be considered when establishing product specifications.

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

- The risk information being omitted is considered less stringent and covered by the risk information required by another monograph attested to within the application.
  - E.g. “If you are pregnant or breastfeeding, consult a health care practitioner prior to use” is considered less stringent and covered by “if you are pregnant or breastfeeding, do not use.”

- The duration of use being omitted relates to the efficacy of the claim and is shorter than the duration of use relating to efficacy required by another monograph attested to within the application.
  - E.g. “Use for a minimum of 3 months to see beneficial effects” relates to the efficacy of the claim and is shorter than “use for a minimum of 6 months to see beneficial effects.”

- The duration of use being omitted relates to the safety of the ingredient and is longer than the duration of use relating to safety required by another monograph attested to within the application.
  - E.g. “Consult a health care practitioner for use beyond 1 month” relates to the safety of the ingredient and is longer than “consult a health care practitioner for use beyond 1 week.”

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

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