

Summary of draft updates to the Natural Health Products Management of Applications Policy

General remarks about the draft updates	
The revisions to the NHP Management of Applications Policy (MHP MAP) will take place in two waves. In Wave 1 (current wave), the revisions are administrative in nature, are intended to reflect the current processes in place, and provide additional clarification.	
Guide Section	Highlights
2 – Scope	Added: Contact information for the NHP Site Homologation, Issuance, Evaluation and Licensing Decision Unit
3 – Class of Applications	Clarified wording Moved information regarding the Compendium of Monographs to s.4 (Pre-submission Information) to have all relevant regulatory information together in one section
3.1 – Class I	Clarified wording
3.2 – Class II	Added: principles that guide the combination of substances from different monographs Added: reference to new monograph combination guide [separate consultation underway] Added: clarity on the addition of edible plant parts that are consumed by humans as food Clarified wording
3.3 – Class III	Clarified wording Added: clarity on products formulated in a dosage form designed to alter the bioavailability Added: reference to new monograph combination guide [separate consultation underway]
4 – Pre-submission Information	Clarified wording
4.1 – Guidance and Supporting Documents	Added: information on the Natural Health Products Ingredient Database Added: information on NNHPD's Compendium of Monographs Added: guidance released since last MAP update Added: Schedule A and Section 3 to the Food and Drugs Act Guidance Document Clarified: information regarding quality Updated: information regarding labelling
4.3 – Requesting a Pre-Submission Meeting	Added: a pre-submission meeting is strongly encouraged for novel NHPs
4.3.1 – Pre-submission Meeting Request	Clarified: a pre-submission meeting request must be submitted no less than 30 calendar days prior to the proposed meeting date Added: information that should be included in the meeting request (e.g., international status)

	Added: information regarding NNHPD's prioritization of meeting requests that impact the filing of a submission or those relating to an existing licence Clarified: a request may be responded to in writing if NNHPD determines that it would be more efficient to do so, based on the questions posed Updated to reflect current practice of holding pre-submission meetings via video conference
4.3.2 – Pre-submission Package	Updated to reflect current process Added: information that should be contained in the pre-submission package (e.g., list of ingredients)
4.3.3 – Pre-submission Meeting	Updated to reflect current process Clarified: minutes taken during the meeting do not constitute a regulatory decision
4.4 – Product Classification	Added: information regarding product classification to help companies determine the appropriate classification
4.5 – Master File	Clarified wording
4.5.1 – Submitting a Master File	Updated to reflect current process (e.g., NNHPD only accepts MFs electronically) Updated: name of ePost Connect to Connect (to align with Canada Post)
4.5.2 – Processing a Master File	Clarified: there is no service standard for the processing of MFs Clarified: when and to whom a decision is communicated on a MF
4.5.3 – Referencing a Master File	Clarified: Letter of Access must be no older than 2 years
4.6 – The NHPID	Clarified: prior to submitting a PLA, the ingredient(s) that are proposed to be used in the NHP must be found in the NHPID Added: Additional information on the NHPID
4.6.1 – NHPID Modification Process	Updated to reflect current process and timing Added: link to new NHPID Request Form [link pending] Added: prioritization of ingredient requests Clarified wording
4.7 – New Company Registration	Updated to reflect current process Added: link to new Company Registration Form [link pending]
5.1 – Application Requirements	Clarified: use of official language, when a cover letter is needed, recommended use of table of contents Table 5.1 moved to Appendix
5.1.1.1 – Application Forms	Clarified wording Added: information regarding who to contact about technical issues Updated: naming convention for PLA file
5.1.1.3 – Summary Report	Updated: strongly encouraged for all Class III submissions Added: details in a summary report and an example of a summary table in appendix II

	Clarified wording
5.1.1.4.1 – Attesting to NNHPD Monographs	Added: information on Class I validation as per the current process Clarified attestation requirements for Classes I to III
5.1.2 – Letter of Access (Application)	Updated to reflect current process (must be no older than 2 years)
5.1.3 – Designated Party Authorization Forms	Clarified wording Clarified the applicant and licensee responsibility when using a DPA form
5.1.4 – Site Information	Clarified wording Added: contact information for the NHP Site Homologation, Issuance, Evaluation and Licensing Decision Unit
5.2 – Submitting an Application	Clarified wording Updated to reflect current process (e.g., NNHPD only accepts applications electronically)
5.2.1 – Submitting applications by secure email	Section removed and content moved to 5.2
6.1 – Processing Applications	Clarified wording
6.1.1 – Administrative Verification	Updated: list of critical administrative deficiencies, under Notice of Refusal (Administrative Deficiency) to reflect the current process Clarified wording
6.1.2 – Regulatory Screening	Updated to reflect current process (e.g., validation of Class I applications) Updated list of screening deficiencies under Notice of Refusal (screening stage) to reflect the current process
6.1.3 – Assessment	Updated: to clarify requests for a Risk Management Plan Updated: list of review deficiencies, under Notice of Refusal (assessment stage) to reflect the current process Clarified wording
6.1.4 – Information Request Notice (IRN)	Clarified wording Updated to reflect current process (e.g., when an IRN may be issued)
6.1.4.1 – Responses to an IRN	Clarified wording
6.1.4.2 – Request for an IRN response extension	Updated to reflect current process (e.g., how to request an extension)
6.1.5 – Service standards	Updated to reflect current process (e.g., no service standard for notifications) Added: Class-specific information, including prioritization for Classes II and III, and ability to prioritize submissions based on public health needs Moved table to Appendix

6.2.1 – Application status updates	Updated to reflect current process (e.g., for prioritized submissions)
6.2.3 – Request for records	Clarified wording Updated to reflect current process (e.g., licensing decisions are sent via Connect)
6.3.1 – Issuance of a licence	Clarified wording Updated to reflect current process (e.g., status in the LNHPD)
6.3.2 – Licence correction requests	Clarified wording
6.3.3.1 – Request for reconsideration	Clarified the three possible outcomes of a Request for Reconsideration Updated: Link to Reconsideration of Decisions Issued for Human Drug and Natural Health Product Submissions
6.3.4 – Safety and Efficacy Assessment Report	Clarified that a request for a copy of the SEAR can be received in the case of a refusal
6.4 – Withdrawal of an Application	Updated to reflect current process (e.g., request must be made by the senior official or designated company official) Added: link to new NHP Application Withdrawal Request Form [link pending]
7 – Post-Licensing Activities	Clarified language throughout the section
7.1.3 – Notifications	Updated to reflect current process (e.g., may prioritize company updates, an updated licence is not issued)
7.1.3.1 Non-notifiable changes	Added: reference to list of non-notifiable changes related to quality (located in Appendix V)
7.1.3.2.1 – Determining that a company is no longer in operation	Added: new section to reflect current process
7.1.3.2.2 – Company transfer or merger	Updated to reflect current process (e.g., transfer in the case of a compliance issue) Distinguished between pre-licence versus post-licence transfer or merger
7.2 – Monograph Updates	Added: information regarding product quality Added: process for suggesting revisions to currently published monographs and suggestions for ingredients that could be the subject of a monograph
7.3 – Discontinuing a product licence	Updated to reflect current process (e.g., no service standard for processing a discontinuation request) Added: link to new NHP Discontinuation Request Form [link pending]
7.4 – Post-Licensing Audit	Updated to reflect past practice (e.g., process to address discrepancies)
7.5 – Post Licensing Market Notification	Added: new section to reflect current process

7.6 – Post Licensing NNHPD Initiated Activities	Updated to reflect current process (e.g., when PLIRNs may be used, their exclusion from serviced standards, and possible impacts to submissions in queue)
Appendix I – Application requirements by class and application type	Moved from main body of MAP Updated to reflect current process (e.g., incorporated workload management forms)
Appendix II – Class III Summary Report	Added: example of a Class III summary table
Appendix IV – Service Standards	Moved from main body of MAP
Appendix V – Post Licence Changes and Associated Regulatory Requirements	Added: non-notifiable changes regarding product quality