

NHP Management of Applications Policy What We Heard



Health
Canada

Santé
Canada

Canada 

Overview of NHP MAP update

- The NHP MAP was revised to reflect:
 - Administrative changes
 - Current state of application management
 - Process improvements, including new forms to reduce burden and red tape
 - New Company Registration Form, NHPID Request Form, updated PLA and ANF, Withdrawal, Discontinuation
- Industry associations were consulted on these revisions from June 19 – July 21
 - Four industry associations provided comments
 - Industry comments fall into two categories:
 - Clarification or additional information needed
 - Request for change or reduced burden (Quick wins to be addressed in Wave 1, others to be analyzed in Wave 2)
- This deck focuses on key changes made post-consultation

NHP MAP revisions post consultation

Section	Comment	Revision
Guidance and supporting documents	Request to add existing (2006) labelling guidance as it still applies during the transition period until 2028.	Revised labelling section with updated information on the Ministerial Order and the new Labelling Guidance Document. ADDED reference to existing guidance document.
Pre-submission meetings	The term “Novel NHPs” should be removed and revised to refer to products containing novel ingredients that have been recently added to the NHPID Should retain the option for a meeting	REVISED to include: • New active ingredient or dosage form • Combination of active ingredient that has not been licensed • Use or purpose that has not been assessed CLARIFIED that the applicant may request a meeting if a written response does not provide sufficient guidance

NHP MAP revisions post consultation (cont'd)

Section	Comment	Revision
Master File	Requested additional clarification on the processing of Master Files and what will be communicated to the MF holder	ADDED information on: • How a MF is processed • Information required with a submission • Communication with MF holder and PL applicant
Cover Letter	Noted that the scope of the cover letter was too narrow and there is an inconsistency within the MAP regarding when a cover letter is required	ADDED information on the cover letter contents (e.g. may include the requested Table of Contents for the submission package, and additional context if necessary) CLARIFIED when a cover letter is required

NHP MAP revisions post consultation (cont'd)

Section	Comment	Revision
Summary Report	Noted that the example provided was helpful, but that it could be achieved through the cover letter and not necessarily a separate document	CLARIFIED that the summary report could be included in the cover letter and that the template is an example and not a prescribed format
Designated Party Authorization (DPA)	Requested information on how to revoke a DPA	ADDED information on the DPA process, including how to revoke one

NHP MAP revisions post consultation (cont'd)

Section	Comment	Revision
Processing and Assessment of Applications	Requested clarity as to when an IRN would first be issued versus an immediate notice of refusal. Comments gave the impression that all deficiencies would result in an automatic notice of refusal.	CLARIFIED that not all deficiencies result in an immediate notice of refusal. Generally, those that are black and white do. • Administrative deficiencies <u>will</u> result in a Notice of Refusal • Screening deficiencies <u>may</u> result in a Notice of Refusal (i.e., critical deficiencies) • Review deficiencies <u>may</u> result in a Notice of Refusal

NHP MAP revisions post consultation (cont'd)

Section	Comment	Revision
Workload Management	Requested an adjustment to the prioritization criteria for amendments. There are situations where an amendment is required prior to marketing the product. Recommended revisiting the 6-month timeframe and incorporating within the PLA form	ADJUSTED the criteria for amendments to include: • Changes to an authorized NHP that <u>will be</u> sold in Canada ADJUSTED to 12-month timeframe for prioritization

NHP MAP revisions post consultation (cont'd)

Section	Comment	Revision
NHPID Modification Process	Request for specificity regarding the type of additional information/evidence that can be requested when submitting a change to the NHPID An individual email would be preferable to advise when updates are made or alternatively, publish updates on the first of the month instead of random days	ADDED information on additions/modifications to the NHPID, including the type of evidence accepted To maintain consistency in the process, the MAP will continue to reflect that the NHPID will be updated on the last Friday of each month
Amendments	Associations are unclear how amendments are to be processed (i.e., the class)	NEW table added listing types of amendments and their classes

NHP MAP revisions post consultation (cont'd)

Section	Comment	Revision
Refusal criteria - Brand names	Concerned with including the brand name as a deficiency that is grounds for refusal given inconsistent application.	CLARIFIED to stipulate brand names that exceed the scope of or contradict the conditions of use of a product. NNHPD is exploring options to provide further guidance on brand names.
Withdrawal timelines	Requested timeline for when companies will be notified that their withdrawal has been processed.	ADDED new automated notification process and timelines

NHP MAP revisions post consultation: Reduced burden

Item	Comment	Revision
File name format	Added burden due to having to rename the PLA form to align with the current MAP expectation.	CHANGED the file naming convention to that which is automatically created by Connect, thus eliminating the added burden.
Identification of class	Remove the requirement to identify the submission class on the Connect message and/or cover letter.	REMOVED the requirement to identify the class on the Connect message. The requirement to identify the class on the cover letter applies in case of a form limitation.
Finished Product Specifications (FPS)	Noted lack of coherence in FPS expectations for Class I: FPS is not required for Class I applications but is so for Class I amendments.	REMOVED need to provide FPS when submitting a Class I amendment. Further: Class I amendments limited to FPS changes only would not need to be submitted; FPS to be made available upon request.

NHP MAP comments to be reviewed: Wave 2 or beyond

Item	Comment
Definition of Class II	Include common spices and herbs and tea ingredients. • Associations to be asked to produce a list of ingredients, quantities, additional labelling for NNHPD's review. Include applications that reference NPNs already approved by NNHPD and applications that attest to a monograph for safety and efficacy, but not quality. Address unresolved issue pertaining to the Homeopathy monograph.
Statements to the effect	With the new “List of Interchangeable Terms” tool, the use of “statements to the effect of” should once again be accepted for Class I applications.
Class of amendments	Class determination should be based on type of change rather than “original review stream” (e.g., Labelling Only, Quality Change).
Application for kits	Recommend that the option for kit products be built into the ePLA to avoid having to complete multiple ePLA forms.
Pre-cleared information	Detail how industry can suggest changes to pre-cleared information.

NHP MAP comments to be reviewed: Wave 2 or beyond

Item	Comment
Information Request Notices & Refusals	NNHPD should reconsider automatic refusals and give the opportunity for corrections within a specified timeline. Should also revisit the approach to request the removal of claims to meet service standards and introduce pause-the-clock with longer IRNs.
Ingredient hotlist	Standardize the process of including ingredient hotlist restrictions, so that the NHPID serves as the single source for assessing NMI compliance.
NHPID reviews & updates	There should be another mechanism, such as email, to notify affected stakeholders beyond the “What’s New” webpage when modifications are made to existing NHPID entries. Review the NHPID entry in parallel with a PLA referencing a tracking number for the new/modified ingredient (as is done for OTC Master Files).
“Table of contents”	Provide a standard template recommended to use.
Technical issues	Provide a timeline for responding to technical issue inquiries.
Class I acknowledgment	Issue an Application Acknowledgement Letter for Class I applications, like is done for Class II and III.

NHP MAP comments: No change proposed

Item	Comment	Rationale
Pre-submission product classification (PC)	It is time-consuming and resource-intensive to put together submissions only to be told the classification is incorrect, especially now that submission fees will be required.	The regulations require a PC determination when an application is received. We need to ensure that PCs are done on products that will be sold in Canada. NHP fees are on hold.
Service standards	Service standards should be established and provided for both administrative verification and regulatory screening.	NNHPD's current capacity does not allow for service predictability. To be revisited should ongoing efforts to reduce workload enable us to provide timelines.
Notifications	Notifications should have an established service standard.	NNHPD's current capacity does not allow for service predictability. To be revisited should ongoing efforts to reduce workload enable us to provide a timeline.
Safety & Efficacy Assessment Report	Reinstate the option to request a copy of the SEAR for licensed products.	NNHPD does not have the capacity. The obligation to provide a copy would only arise in case of refusal.

Questions?

