

Consultation on Two New Tools ‘What We Heard’

Natural and Non-Prescription Health Products Directorate
October 3, 2025

Thank you for your comments and suggestions!

Monograph combination guide

- This guide is intended to help applicants determine the appropriate Class of application for their products, as well as situations in which a combination of monographs should be submitted as a Class III application.
- These rules are already used internally to determine whether a Class II application should be reviewed as a Class III application.
- Publishing these rules improves transparency and predictability regarding the Class system.
- Additional flexibility has been included to move more applications.
- This guide does not apply to labelling standards, which are not considered equivalent to the NNHPD's monographs. As such, they may only be used as part of Class III applications.
- This guide is intended to be a living document that will ultimately be posted as part of the NHPID; however, as a first step, it will be published on the NNHPD's guidance document webpage.
- Estimated publication timeline: End of October 2025.

Monograph combination guide

Comments	Decision	Revisions
Section 2 (Attestation to monograph): This section relates to information that is in the MAP or other guidance document and should be removed and placed in the MAP to reduce confusion.	✓	Most of the information from Section 2 was removed from the guide and some of this information was included in Appendix III ‘Attestation to monographs’ in the MAP. Suggested edits were applied. Information regarding specific qualifiers was kept in the guide, along with added examples and information on how to include them in the PLA form, as suggested.
General comments on Table format: Recommendation to remove the “Monographs” column to avoid listing specific ingredients in the examples. The statements and compatibility could be presented as broader categories.	✓	The ‘Monographs’ column was removed from the first Tables that illustrate contradictory or conflicting statements, so that the tables would focus solely on the statements. However, it was kept for tables that illustrate the additive rules.
Additive effects: Other than Appendix I, how will applicants know which ingredients have additive effects, and are the categories in Appendix I the only pharmacological effects we should be concerned with?	Clarification	Appendix 1 includes most of the monographed ingredients that are verified at Class II but it cannot be considered as an exhaustive list.

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Combination rules within monographs: There is no need to add text taken directly from specified monographs. If included in this guide, these details would also need to be updated if the monographs are updated in the future.	✓	Agreed. The rules that are mentioned in specific monographs have been removed from the guide except the rule for amino acids and protein that would also apply to ingredient that are not in the Workout Supplements monograph.
Free sugars: Is it <u>only</u> required to list the quantity of free sugars when making glucose-modifying claims?	✓	Yes, it only applies to the 2 monographs mentioned in the guide which include a medium-level glucose claim (helps improve) when free sugars are added to the product formulation. This is not a common scenario.
Free sugars: Determine the dose threshold at which NMI "free sugars" could reasonably affect blood sugar levels, necessitating reclassification as a Class III PLA.	X	Despite reviewing reputable guidelines (e.g., Diabetes Canada, World Health Organization), it is not currently possible to establish a cut-off/dose threshold because the available guidelines refer to daily sugar intake through food intake rather than sugar intake per dose. Therefore, due to the infrequency of these submissions and the lack of evidence to establish an NMI cut-off limit for this specific scenario, files falling under this scenario are expected to submit a Class III application.

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Beta-caryophyllene: The NHPID does not indicate that the source of beta-caryophyllene must be listed in the PLA.	✓	A note was added to NHPID regarding the NMI beta-Caryophyllene and removed from the guide.
Requirements for risk statements for sub-therapeutic ingredients: clarify and elaborate on the requirement for risk information for sub-therapeutic ingredients. Should we include all cautions and warnings, none, or only those that meet a specific threshold? This document would be a great resource for guiding the industry on sub-therapeutic risk information.	✓	We are considering including the 10% criterion applied internally in the guide. In most cases, a product supported by a combination of monographs only requires recommended conditions of use for an ingredient if the ingredient is present in an amount equal or greater than 10% of the minimum therapeutic dose, unless otherwise specified in a monograph. However, some statements are required regardless of the quantity of the ingredient (e.g., statement regarding pregnant and breastfeeding women). If added to the guide a non-exhaustive list of exclusions will be included.
Estrogenic or anti-estrogenic: Explain why this applies to all ingredients with estrogenic or anti-estrogenic effects, regardless of the dosage.	✓	It was revised to include combination tables to ensure that the sum of combination does not exceeding 100% in Class II. In addition, Brassica oleracea varieties were removed from the combination rule.

Monograph combination guide

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Conflicting durations of use: The following are not mutually exclusive: “Use for at least 3 months to see beneficial effects” and “Ask a healthcare practitioner about use beyond 3 months.” They only instruct you to consult a health care practitioner if you wish to do so.	Clarification	These statements are deemed conflicting and likely confusing to consumers. They do not provide clear labelling information to help them make informed choices.
Definition of prolonged use (few months): This term is vague (3-6 can be considered “a few”). Provide a timeline that would be used in review to determine if the chosen statement in a submission is appropriate.	Clarification	The definition was removed from the guide. It was not possible to establish a timeline that would fit all the affected medicinal ingredients. Therefore, this “undefined duration of use” statement will therefore be removed from monographs and replaced with a specific duration of use when possible.
Additional risk statements for the combination of diuretics (and licorice): Rationale was not provided.	✓	A rationale was added as a footnote (i.e., mechanisms of action/dose-response relationship generally not known; no safety evidence available supporting such combination).
Bleeding/clot formation (no comments received; however, we revised this section)	Note	This rule was removed because it is not currently part of the Class II rules, and it may be too restrictive based on the common combinations seen in NHPs.

Monograph combination guide

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Subpopulation-specific risk information: It is recommended that an example be provided for products intended for children and adolescents regarding cautions and contraindications during pregnancy and breastfeeding. Define the age cutoff for this risk information (e.g., over 16 years of age).	✓	An example was included. The caution will not be required for children up to 11 years old; however, based on the information reviewed, the caution will be required for adolescents (12-17 years old).
Stimulant laxatives: A combined dose of 100% or more implies that if the product contained a lower dose of each Senna and Cascara than considered effective per their individual monographs, the applicant could still attest to the monographs for efficacy in a Class II based on the combined dose. Please clarify whether this is the case.	Clarification	A scenario in which the efficacy is based on the additive effects of sub-therapeutic medicinal ingredients would not be accepted at Class II. This was clarified by including this note: <i>Note that at least one of the stimulant laxatives must meet the minimum therapeutic amount.</i> And Column E was revised to: more than 100%
Modified Product Formulations/preparation: It seems outdated to classify modified-release products as Class III when they have been marketed for many years, and the delayed or extended release does not affect the daily dosage or safety. Would the NNHPD consider amending this requirement?	Clarification	Modified-release dosage forms will remain excluded from monographs unless otherwise specified. Please note that last month, enteric-coated softgels were added to the monographs for marine oils (i.e., fish, seal, krill, cod liver, fixed oil), garlic, and probiotics.

Monograph combination guide

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Laxatives at sub-therapeutic dose: The monographed directions for use for the stimulant laxative medicinal ingredients should be removed since linked to a therapeutic effect except ‘Take a few hours before or after taking other medications or health products’: If this is the case, the monograph itself should clarify which statements are associated only with specific claims. Historically, applicants have not been permitted to omit monograph statements in a Class II stream unless specifically permitted under the monograph.	✓	Several monographs may need to be adjusted to ensure consistency with the guide. In the meantime, including these rules in a centralized document would provide guidance for applicants.
Caffeine rule > 400 mg/day (caffeine related claims only): What about products like pre-workout supplements containing caffeine and carbohydrates that only claim to improve acute workout performance, as supported by the NNHPD Workout Supplement Monograph? There is no reason why this combination should require additional assessment.	✓	Combination of caffeine > 400 mg and ingredients from the Workout Supplements monograph have been licensed with claims other than caffeine related claims ‘for occasional use only’. We plan to update the WS monograph to include a list of WS claims that would be acceptable for such use and adjust the caffeine rule accordingly.

List of interchangeable terms

- The list was developed in response to a request from the industry to use the U.S. list of interchangeable terms for over-the-counter drugs. This will help align labelling requirements between Canada and the United States under the Canada-United States-Mexico Agreement (CUSMA).
- The list will provide more flexibility, allowing some adjustments beyond the terms of market authorization.
- Additional terms were added that go beyond what is included on the U.S. list.
- The intention is to post it as part of the NHPID; however, as a first step, it will be published on the NNHPD's guidance document webpage.
- Estimated publication timeline: End of October 2025.

List of interchangeable terms

Comments	Decision	Revisions
Intent of the List: There is no objection to this base principle if the terms of market authorization mean a product license for NHPs and the final label mock-ups from applications for a DIN for NPDs. However, an important piece of the puzzle is missing from the introduction. The present proposal needs to include the following detail: “Despite term(s) indicated in a market authorization, this guidance document affords flexibility to the terms you may utilize in your on-pack labelling and advertising.	✓	The introduction was revised to start as follows: Table 1 below contains an exhaustive lists of terms for labelling that may be updated from time to time. <i>Despite the term(s) indicated in a market authorization, this guidance document allows flexibility in the terms you may use for on-pack labelling.</i>
Intent of the List: The list of interchangeable terms should be considered a set of examples rather than an exhaustive list, especially in advertising, as long as it complies with Section 9 of the Food and Drug Act.	Clarification	The list is an exhaustive list of interchangeable terms. However, it was clarified in the introductory section of the document that it <i>only applies to labelling</i>. We agree that other rules may apply for advertising. While the terms may also apply to advertising, specific advertising policies and guidance are also applicable.

List of interchangeable terms

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Dentist: The current Oral Health Care Products monograph allows the flexible term “dentist” as an option to the standard practitioners list. The term dentist needs to be listed as an interchangeable term.	✓	‘Dentist’ was added.
Why are NPD mock-ups excluded from interchangeable terms? Given this principle and the fact that mock-ups are only a regulatory requirement for NPDs, not NHPs, despite what is indicated in the market authorization, there must be flexibility between the market authorization, on-pack information, and advertising.	✓	This approach was adjusted to indicate that, in cases where mock-up labels and/or leaflets are reviewed and approved prior to licensing (e.g. NPDs; some NHPs), any changes should be included in the next filing.
Requirement for a notification: Confirm that no Notification is expected from licence holder when using interchangeable terms and no issues will be raised if labels don't match exactly the license and label texts NNHPD has on file.	✓	Revised to say: <i>In general, no notification or post-licence change is required for NHPs when using interchangeable terms. However, for any cases in which mock-up labels and/or leaflets are reviewed and approved prior to licensing (e.g. NPDs; some NHPs), any changes should be included in the next filing.</i>

List of interchangeable terms

Comments	Decision	Revisions
It is not consistent to add a recommendation to use the terms doctor/physician NPDs.	✓	This recommendation was removed.
Does the flexibility of interchangeable terms apply to all sections of the label or PFT? (e.g., claims, directions, risk information, etc.)	Clarification	No, it does not apply to claims for which the exact wording expressed in your market authorization terms must be used.
We are cautious about how this list may be applied to advertising. Advertising often requires concise and accessible language that is tailored to specific platforms, audiences, and formats.	✓	The list is exhaustive for labelling, and revisions were made to clarify that it may also apply to advertising . However, specific advertising policies and guidance documents also apply.
Rather than treating the list of interchangeable terms as a one-time consultation with static guidance as the output, it would be useful to develop it as a living repository. This would allow sponsors to request additions to the list over time, ensuring that the list remains relevant and that interchangeable terms can be applied to product labelling.	✓	The intent is to adjust it periodically; however, it should remain concise and applicable to both NHPs and NPDs.

List of interchangeable terms

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Request to extend the flexibility of interchangeable terms to the titles, headings, and subheadings of a facts table (e.g., "doctor" vs. "physician," "active" vs. "medicinal," and "inactive" vs. "non-medicinal").	✓	The interchangeability of “active ingredient/medicinal ingredient” and “inactive ingredient/non-medicinal ingredient” was added for NPDs; however, since the PFT heading “medicinal ingredient” is listed in the NHPR, this cannot currently be applied to NHPs.
The preamble indicates that applicants must consider whether the use of such terms alters the meaning of the product's terms of market authorization. This reduces the guidance's effectiveness and utility.	Clarification	While some of these terms can be used interchangeably depending on the context, they are not exactly synonymous. Therefore, it is important to remember not to alter the meaning of information approved and licensed by HC.
Indication/Use/Recommended use (or purpose)	Note	It was removed from the list because it is mainly part of the one of the PFT headings that should not be changed.

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Health Canada has always interpreted the terms "preventative" and "treatment" as used in the Food and Drugs Act to include "risk reduction" and "symptomatic treatment," respectively.	Clarification	This statement from the Canada Gazette Part II, is made regarding Schedule A claims. It is true that ‘preventative’ includes ‘risk reduction’; however, these terms are not synonyms and cannot be deemed interchangeable because switching these terms may alter the meaning of a claim i.e., ‘prevent’ being stronger than ‘reduce the risk’.
Suggestions for the addition of abbreviations.	Clarification	This initial list of interchangeable terms does not include abbreviations. However, we noted that clarifications regarding the use of abbreviations on labels are needed.

List of interchangeable terms

Revised introductory information:

Table 1 below contains an exhaustive lists of terms for labelling that may be updated from time to time. Despite the term(s) indicated in a market authorization, this guidance document allows flexibility in the terms you may use for on-pack labelling.

Although these interchangeable terms may also apply for advertising, specific advertising policies and guidance documents are also applicable, including the [Guidelines for Consumer Advertising of Health Products for Nonprescription Drugs, Natural Health Products, Vaccines and Medical Devices](#).

These terms may be used interchangeably (A, B, C, D, E of each row, when applicable) in the labelling of Natural Health Products (NHPs) and Non-Prescription Drugs (NPDs), affording flexibility, provided that such use does not alter the meaning of the product's terms of market authorization issued by Health Canada under the [Natural Health Products Regulations](#) or [Food and Drug Regulations](#), respectively. As such, regardless of whether identified as interchangeable in the table below, the context in which the terms are used is always to be considered to determine whether such terms are indeed conveying the same meaning and therefore appropriate for product labelling. Indeed, as per section 9 of the [Food and Drugs Act](#), *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*.

However, it is important to note that it does not apply to 'uses/indications' (i.e., claims) for which the exact wording as expressed in your terms of market authorization must be used. In addition, the title, headings, and subheadings of the Canadian Drug Facts Table for NPDs or the Product Facts Table for NHPs cannot be changed beyond adjusting the interchangeable terms 'ask/consult', 'health care practitioner/health care provider/health care professional/doctor/physician/dentist'. For NPDs, the terms 'active/medicinal ingredient(s) and/or 'inactive/non-medicinal ingredient(s)' may also be used interchangeably. No other changes are permitted.

In general, no notification or post-licence change is required for NHPs when using interchangeable terms. However, for any cases in which mock-up labels and/or leaflets are reviewed and approved prior to licensing (e.g. NPDs; some NHPs), any changes should be included in the next filing.

Table 1 should also be used in conjunction with the [Guidance document: Labelling of Natural Health Products](#) and the [Labelling Requirements for Non-prescription Drugs Guidance Document](#).

QUESTIONS?

