Non-prescription drug monograph attestation form

All fields are required. **PROTECTED B when completed.***

Brand name:

Application type: ☐ **Drug Identification Number application**

Attestation conditions:

When submitting a Drug Identification Number application in respect to a Division 1 drug for which a monograph exists:

(a) I attest that the information provided in this DIN application [proper name(s), common name(s), source material(s), route(s) of administration, dosage form(s), use(s) or purpose(s), dose(s), duration of use, risk information, etc.] is complete, accurate and represents the information presented in the monograph;

(b) I attest that the non-medicinal ingredients in the product are present and compliant with the Natural Health Products Ingredients Database (NHPID), do not contain colouring agents except those listed in Section C.01.040.2 of the *Food and Drug Regulations* and do not exhibit pharmacological effects, do not have any effect contradictory to the product's recommended purpose, do not exceed the minimum concentration required to provide their intended effect, do not adversely affect the bioavailability, pharmacological activity or safety of the medicinal ingredients, and that they are safe;

(c) I attest that the label text is acceptable as per sections A.01.014-A.01.016, A.01.061-A.01.063, C.01.004, C.01.005, C.01.014 of the *Food and Drug Regulations* and that the information on the label text is consistent with the information provided in this DIN application; I attest that the product and the label information respect section 9 of the *Food and Drugs Act*;

(d) I attest that the brand name submitted in this DIN application is consistent with the information provided in this DIN application, does not pose a risk to health and safety, and is not false or misleading;

(e) I attest that the manufacturing site where the product is manufactured is in compliance with Canadian Good Manufacturing Practices (GMP) as required under Part C, Division 2 of the *Food and Drug Regulations*;

(f) I attest that the stability data supports the labelled expiration date of the drug product. In addition, a Continuing Stability Programme will be implemented for the drug product to ensure compliance with the approved shelf life specifications;

(g) I attest that my product does not contain any prohibited ingredients as per section C.01.036, C.01.038, C.01.040 and C.01.040.1 of the *Food and Drug Regulations;*

(h) I attest that I have submitted the information required to support the safety of any animal tissue(s) present in the finished product or used as intermediates during manufacturing (Appendix 4 of the Drug Submission Application HC-SC 3011 Form and valid European Directorate for the Quality of Medicines & HealthCare (EDQM) Certification of Suitability attached);

(i) I attest that the product complies with applicable Health Canada guidelines and policies (e.g. those pertaining to labelling)*;*

(j) I attest to selling this product within the conditions of this attestation and the terms of market authorisation. I fully understand that if I were to operate outside of this attestation that I may be subject to compliance and enforcement.

☐ My application solely contains information that is supported by the following product monograph and the above conditions apply to the application in its entirety:

Name of Monograph | Date of Monograph[1]:

Signature block

Name (Print)	Company	Position

Signature | Date (yyyy/mm/dd)

*Note: All information collected on this form will be protected according to Government of Canada security standards. - All government departments have to abide by the Access to Information and Privacy (ATIP) regulations that require us to protect private information.

[1] For secondary sunscreens, applicants must attest to the *Sunscreen Monograph – Version 2.0* (2013) and meet all 2013 monograph requirements with the exception of Directions for Use and Risk Information for which applicants must meet the *Sunburn Protectants* (2006) monograph requirements.

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