

# Monograph Attestation Form

<b>Primary Brand Name(s):</b>		
<b>Application Type</b>		
<input type="checkbox"/> Product licence application <input type="checkbox"/> Post-licence amendment		
<b>Attestation Conditions</b>		
<p>When submitting a product licence application in respect of a natural health product for which one or more Natural and Non-prescription Health Products Directorate (NNHPD) monographs exist in the Compendium of Monographs:</p> <p>(a) I attest that the information provided in this product licence 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.] respects the information contained in one or more NNHPD monograph(s);</p> <p>(b) I attest that the non-medicinal ingredients in the product are present and compliant with the Natural Health Product Ingredients Database (NHPID) 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 for the formulation, do not adversely affect the bioavailability, pharmacological activity or safety of the medicinal ingredients, and that they are safe;</p> <p>(c) I attest that the label text is acceptable as per sections 86-94 of the Natural Health Products Regulations and that the information on the label text is consistent with the information provided in this product licence application;</p> <p>(d) I attest that the natural health product's brand name(s) submitted in this product licence application is consistent with the information provided in this product licence application (e.g. recommended purpose, quantities, etc.), does not pose a risk to health and safety, and is not false and misleading;</p> <p>(e) I attest to selling this product within the conditions of this attestation and the terms of market authorisation (product licence). I fully understand that if I were to operate outside of this attestation that I may be subject to compliance and enforcement.</p> <p><input type="checkbox"/> My product is supported solely by NNHPD Monograph(s) and the above conditions apply to the application in its entirety; OR</p> <p><input type="checkbox"/> My product is supported by a combination of NNHPD Monograph(s) and evidence which I have provided in support of the product's safety, efficacy and/or quality that is subject to assessment. Condition (a) of this attestation applies to the medicinal ingredients in support of safety, efficacy and/or quality as indicated in the table on page two of this form.</p>		
<b>Signature Block</b>		
Name (Print)	Company	Position
Signature	Date (yyyy/mm/dd)	

