



Mock-Up Labels and Packages Certification Form

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DRUG PRODUCT INFORMATION	
Submission Type	
Brand or Proprietary or Product Name (same as brand name on the HC 3011 form and labels)	
Proper, Common or Non-proprietary Name	

ATTESTATION		
1. Product Monograph(s)		
I, the undersigned, certify that, in regards to all original and solicited information and material:		
<p>This submission is for a product without a previously approved Product Monograph.¹</p> <p>The <u>second language</u> Product Monograph is enclosed.</p>	<ul style="list-style-type: none"> The enclosed second language translation of the previously filed Product Monograph is, to the best of my knowledge, true and accurate. The second language Product Monograph will be updated to match the final Product Monograph and will be submitted no later than 10 days following approval (receipt of the NOC/NOL). 	
<p>This submission is for a product with a previously approved Product Monograph.</p> <p>Revised Product Monographs <u>in both official languages</u> are enclosed.</p>	<ul style="list-style-type: none"> The second language translation of the enclosed Product Monograph is, to the best of my knowledge, true and accurate. A final copy of the second language Product Monograph will be submitted no later than 10 days following approval (receipt of the NOC/NOL). 	
<p>Product Monographs are not required for this submission (e.g.: Division 1 application).</p>	<ul style="list-style-type: none"> N/A 	

AUTHORIZED SIGNING OFFICIAL		
Name of Authorized signing Official	Signature	Date (YYYY/MM/DD)
Title	Company Name and Address	
Telephone Number	Fax Number	Email Address

¹ If this applies, do not fill in the Product Monograph portion of this form until filing the second language Product Monograph (15 days after submission has been accepted into review). At that point in time, please resubmit this attestation form.

ATTESTATION		
2. Inner and outer label(s) and package(s)		
I, the undersigned, certify that, in regards to all original and solicited information and material:		
All inner and outer label and package mock-ups associated with this drug are enclosed, <u>in both official languages</u> .	<ul style="list-style-type: none"> The second language translation of the text in the enclosed inner and outer label and package mock-ups is, to the best of my knowledge, true and accurate. Upon Health Canada request, finalized versions of the inner and outer label and package mock-ups will be re-submitted for review. 	
Inner and outer label and package mock-ups are not required for this submission.	<ul style="list-style-type: none"> N/A 	

AUTHORIZED SIGNING OFFICIAL		
Name of Authorized signing Official	Signature	Date (YYYY/MM/DD)
Title	Company Name and Address	
Telephone Number	Fax Number	Email Address

ATTESTATION		
3. Package Insert(s)		
I, the undersigned, certify that, in regards to all original and solicited information and material:		
This submission is for a product without a previously approved Product Monograph. ² Mock-ups of the <u>second language</u> Package Insert(s) are enclosed.	<ul style="list-style-type: none"> The enclosed second language translation of the previously filed Package Insert is, to the best of my knowledge, true and accurate. The second language Package Insert will be updated to match the final Package Insert and will be submitted no later than 10 days following approval (receipt of the NOC/NOL). 	
Mock-ups of the Package Insert(s) are enclosed <u>in both official languages</u> .	<ul style="list-style-type: none"> The second language translation of the enclosed Package Insert mock-up is, to the best of my knowledge, true and accurate. If changes to the information in the Product Monograph result in any deviations to the design elements of the Package Insert mock-up(s), updated copies will be resubmitted for review. 	
Mock-ups of the Package Insert are not required for this submission.	<ul style="list-style-type: none"> N/A 	

AUTHORIZED SIGNING OFFICIAL		
Name of Authorized signing Official	Signature	Date (YYYY/MM/DD)
Title	Company Name and Address	
Telephone Number	Fax Number	Email Address

² If this applies, do not fill in the Package Insert portion of this form until filing the second language Package Insert (15 days after submission has been accepted into review). At that point in time, please resubmit this attestation form.