Health Canada Santé Canada

Protected A

Labels and Packages Certification Form for Prescription Products

Drug Product Information	
Submission Type	
Brand, Proprietary or Product Name (as per Field #8 on the Drug Submission Application Form)	
Proper, Common or Non-proprietary Name (as per Field #9 on the Drug Submission Application Form)	

Note: This Certification Form outlines the requirements as per Health Canada's Guidance Document, Questions and Answers: Plain Language Labelling Regulations for Prescription Drugs (Q&A: PLL).

Attestation	
○	Attestation A*: New Drug Submission (NDS), Extraordinary Use New Drug Submission (EUNDS), Abbreviated New Drug Submission (ANDS), Abbreviated Extraordinary Use New Drug Submission (AEUNDS), Supplement to a New Drug Submission (SNDS), Supplement to an Extraordinary Use New Drug Submission (EUSNDS), Supplement to an Abbreviated New Drug Submission (SANDS), Supplement to an Abbreviated Extraordinary Use New Drug Submission (SAEUNDS), Application for a Drug Identification Number (DINA and DINB)
○	Attestation B*: Notifiable Change (NC) or Post-Authorization Division 1 Change (PDC)
○	Attestation C: Submissions Processed Administratively

* Does not include submissions processed administratively. For those submissions, please use Attestation C.

Canada

Attestation A – NDS, EUNDS, ANDS, AEUNDS, SNDS, EUSNDS, SANDS, SAEUNDS, DINA, DINB	
I, the undersigned, certify, in regards to all original and solicited information, that:	
Inner and Outer Label and Package Mock-Ups	
Labels should only be provided if they are impacted by the proposed changes within this submission. If it is determined during screening or review that enclosed labels are not impacted, they will be requested to be removed from the submission. Professional samples intended for distribution to patients are not required to be submitted if the criteria outlined in Section 5.8 of Health Canada's Guidance Document, Q&A: PLL have been met.	
At time of filing: (select one option)	
○	All inner and outer label and package mock-ups associated with this product are enclosed i**n both official languages** Any necessary clarifications have been provided within a Note to Reviewer in Module 1.3.2.
○	A mock-up of only the smallest label and/or package for each dosage form and strength has been provided **in both official languages**, as • there are no differences other than pill count or volume on the labels/packages; and • all the other labels/packages will have identical text, format, size, layout, color, etc. Any minor differences have been clearly cited within a Note to Reviewer in Module 1.3.2.
○	Inner and outer label and package mock-ups have not been provided as they are not required for this submission (i.e. the proposed changes do not impact the labels)**.**
If labels have been provided, I certify the following (as per Health Canada's Guidance Document, Q&A: PLL):	
•	The second language translation of the enclosed inner and outer label and package mock-ups is, to the best of my knowledge, true and accurate.
•	Finalized versions of the inner and outer label and package mock-ups, including a true and accurate second language translation, will be submitted **prior to approval**.

The enclosed inner and outer label and package mock-ups (select all that apply)

- ☐ are in an editable (i.e. not locked) PDF format
- ☐ are full colour
- ☐ are actual size
- ☐ have the dimensions for each label stated (dimensions can be indicated directly on the mock-ups, or within a Note to Reviewer in Module 1.3.2).
- ☐ do not meet one or more of the requirements but a rationale has been provided within a Note to Reviewer in Module 1.3.2

The font size and style of the enclosed inner and outer label and packages

- ◯ meet the requirements outlined in the Q&A: PLL
- ◯ do not meet the requirements outlined in the Q&A: PLL, but a rationale has been provided within a Note to Reviewer in Module 1.3.2.

Have the enclosed inner and outer label and package mock-ups been submitted and approved since the Plain Language Labelling Regulations came in to effect on June 13, 2015?

- ◯ Yes
- ◯ No

If yes, have the design elements (i.e. font size, font type, colour and/or placement of text and graphics) been revised as a result of the changes proposed within this submission?

- ◯ Yes
- ◯ No

If yes, do the proposed changes **negatively** impact the legibility of the inner and outer label and package mock-ups (i.e., reduction in font size, white space or overall dimensions)?

- ◯ Yes
- ◯ No

Product Monograph/Prescribing Information

The Product Monograph/Prescribing Information should only be provided if it is impacted by the proposed changes within this submission. If it is determined during screening or review that enclosed Product Monograph/Prescribing Information is not impacted, it will be requested to be removed from the submission.

At time of filing: (select one option)

◯	The Product Monograph/Prescribing Information is enclosed **in both official languages.**
◯	The first language Product Monograph/Prescribing Information has been provided and the second language Product Monograph/Prescribing Information will be provided **within 20 days of the submission being accepted into review**.
◯	The Product Monograph/Prescribing Information has not been provided as it is not required for this submission (i.e. the proposed changes do not impact the Product Monograph/Prescribing Information)**.**

If a Product Monograph/Prescribing Information has been/will be provided, I certify the following (as per Health Canada's Guidance Document, Q&A: PLL):	
•	The second language translation of the Product Monograph/Prescribing Information is/will be, to the best of my knowledge, true and accurate.
•	A finalized second language translation of the Product Monograph/Prescribing Information that has been updated with any changes made during review and is, to the best of my knowledge, true and accurate, will be submitted **no later than 20 days following approval.**
Package Insert Mock-Up(s) (including, but not limited, to wallet cards, tear-off pads & hand-outs)	
The Package Insert should only be provided if it is impacted by the proposed changes within this submission. If it is determined during screening or review that enclosed Package Insert is not impacted, it will be requested to be removed from the submission.	

Please check the option that best describes the content of the Package Insert for this product:

- ○ Prescribing Information
- ○ Product Monograph Part I
- ○ Product Monograph Part III/Consumer Information
- ○ Product Monograph Part I and Part III/Consumer Information
- ○ Patient Medication Information
- ○ Product Monograph Part I and Patient Medication Information
- ○ Other (specify within a Note to Reviewer in Module 1.3.2)
- ○ This product does not have a Package Insert

If the product has more than one Package Insert, or an abbreviated package insert, please specify the content within a Note to Reviewer in Module 1.3.2

At time of filing, if a Package Insert exists for this product: (select one option)	
○	A mock-up of the Package Insert is enclosed **in both official languages**. Any necessary clarifications have been provided within a Note to Reviewer in Module 1.3.2.
○	The first language Package Insert mock-up has been provided and the second language Package Insert mock-up will be provided **within 20 days of the submission being accepted into review**.
○	A mock-up of the Package Insert has not been provided as it is not required for this submission (i.e. the proposed changes do not impact the Package Insert).
If a Package Insert has been/will be provided, I certify the following (as per Health Canada's Guidance Document, Q&A: PLL):	
•	The second language translation of the Package Insert mock-up is/will be, to the best of my knowledge, true and accurate.

•	The content of the Package Insert matches the content of the Product Monograph/Prescribing Information.
•	A finalized first language (or bilingual) Package Insert mock-up, reflecting all applicable revisions that have been requested to the Product Monograph/Prescribing Information throughout review, will be submitted **prior to approval**.
•	If a bilingual Package Insert is not provided prior to approval, a finalized second language translation mock-up of the Package Insert that has been updated with any changes made during review and is, to the best of my knowledge, true and accurate, will be submitted **no later than 20 days following approval.**

The enclosed Package Insert mock-up (select all that apply)

- ☐ is in an editable (i.e. not locked) PDF format
- ☐ is full colour
- ☐ is actual size
- ☐ has the dimensions stated (dimensions can be indicated directly on the mock-up, or within a Note to Reviewer in Module 1.3.2).
- ☐ does not meet one or more of the requirements but a rationale has been provided within a Note to Reviewer in Module 1.3.2

The font size and style of the enclosed Package Insert

- ◯ meet the requirements in the Q&A: PLL.
- ◯ do not meet the requirements in the Q&A: PLL, but a rationale has been provided within a Note to Reviewer in Module 1.3.2.

Has the enclosed Package Insert been submitted and approved since the Plain Language Labelling Regulations came in to effect on June 13, 2015?

- ◯ Yes
- ◉ No

If yes, have the design elements (i.e. font size, font type, colour and/or placement of text and graphics) been revised as a result of the changes proposed within this submission?

- ◉ Yes
- ◉ No

If yes, do the proposed changes negatively impact the legibility of the Package Insert (i.e., reduction in font size, white space or overall dimensions)?

- ◉ Yes
- ◉ No

Attestation B – NC, PDC

I, the undersigned, certify, in regards to all original and solicited information, that:

Inner and outer label and package text

NC and PDC submissions are excluded from the Plain Language Labelling mock-up requirement; text versions of the labels should be provided in lieu of mock-ups to meet the provision, if required. If sponsors submit mock-ups in place of annotated text, only the written text will be reviewed; comments may not be provided on the design elements.

Labels should only be provided if they are impacted by the proposed changes within this submission. If it is determined during screening or review that enclosed labels are not impacted, they will be requested to be removed from the submission.

At time of filing: (select one option)

○	Written text of all inner and outer labels and packages associated with this product has been enclosed **in both official languages**. Any necessary clarifications should be provided within a Note to Reviewer in Module 1.3.2.
○	Written text of the inner and outer labels and packages has not been provided as it is not required for this submission (i.e. the proposed changes do not impact the labels).

If written text labels have been provided, I certify the following (as per Health Canada's Guidance Document, Q&A: PLL):

•	The second language translation of the enclosed inner and outer labels and packages is, to the best of my knowledge, true and accurate.
•	Finalized versions of the inner and outer labels and packages text, including a true and accurate second language translation, will be submitted **prior to approval**.
•	Level I design element label changes, including, but not limited to those described in Section 5.11 of Health Canada's Guidance Document, Q&A: PLL, are not required as a result of the proposed changes to the inner and outer labels and packages text.

Product Monograph/Prescribing Information

The Product Monograph/Prescribing Information should only be provided if it is impacted by the proposed changes within this submission. If it is determined during screening or review that enclosed Product Monograph/Prescribing Information is not impacted, it will be requested to be removed from the submission.

At time of filing: (select one option)

○	The revised Product Monograph/Prescribing Information is enclosed **in both official languages**.

○	The revised first language Product Monograph/Prescribing Information has been provided and the second language Product Monograph/Prescribing Information will be provided **within 20 days of the submission being accepted into review**.
○	The Product Monograph/Prescribing Information has not been provided as it is not required for this submission (i.e. the proposed changes do not impact the Product Monograph/Prescribing Information)**.**
If a Product Monograph/Prescribing Information has been/will be provided, I certify the following (as per Health Canada's Guidance Document, Q&A: PLL):	
•	The second language translation of the Product Monograph/Prescribing Information is/will be, to the best of my knowledge, true and accurate.
•	A finalized second language translation of the Product Monograph/Prescribing Information that has been updated with any changes made during review and is, to the best of my knowledge, true and accurate, will be submitted **no later than 20 days following approval**
Package Insert(s) (including, but not limited, to wallet cards, tear-off pads & hand-outs)	
A Package Insert is not required for NC and PDC submissions and should not be submitted.	
If a Package Insert exists for this product, I certify the following (as per Health Canada's Guidance Document, Q&A: PLL):	
•	The content of the Package Insert will be updated to reflect all applicable revisions to the Product Monograph/ Prescribing Information that are approved as a result of this submission.
•	The font size and/or style will not need to be revised as a result of the proposed changes to the Package Insert text.

Attestation C – Submissions Processed Administratively	
I, the undersigned, certify, in regards to all original and solicited information, that:	
Inner and Outer Label and Package Mock-Ups	
NC and PDC submissions processed administratively are excluded from the Plain Language Labelling mock- up requirement; text versions of the labels should be provided in lieu of mock-ups to meet the provision, if required. For cross-licensed products where an administrative S(A)NDS is being filed for labelling updates to match the licensor, mock-ups of the inner and outer labels do not need to be filed if they are not affected by the change.	
At time of filing: (select one option)	
○	All inner and outer label and package mock-ups associated with this product are enclosed **in both official languages.**
○	Inner and outer label and package mock-ups have not been provided as they are not required for this submission.
If labels have been provided, I certify the following (as per Health Canada's Guidance Document, Q&A: PLL):	
•	The second language translation of the enclosed inner and outer label and package mock-ups is, to the best of my knowledge, true and accurate.
•	The font size and style as well as the location and size of graphics, text and logos on the inner and outer labels and packaging are similar to the parent product.
•	Level I design element label changes, including, but not limited to those described in Section 5.11 of Heath Canada's Guidance Document, Q&A: PLL, are not included in this submission processed administratively. Such changes would require the filing of a S(A) NDS.
•	The enclosed inner and outer label and package mock-ups are in PDF format. The mock-ups are full colour and actual size, with the dimensions for each label stated.
Product Monograph/Prescribing Information	
At time of filing: (select one option)	
○	The Product Monograph/Prescribing Information is enclosed **in both official languages**.

○	The Product Monograph/Prescribing Information is not required for this submission.
If a Product Monograph/Prescribing Information has been provided, I certify the following (as per Health Canada's Guidance Document, Q&A: PLL):	
•	The second language translation of the Product Monograph/Prescribing Information is, to the best of my knowledge, true and accurate.
Package Insert Mock-Up(s) ***(including, but not limited, to wallet cards, tear-off pads & hand-outs)***	
A Package Insert is not required to be submitted within NC and PDC submissions processed administratively. For cross-licensed products where an administrative S(A)NDS is being filed for labelling updates to match the licensor, mock-ups of the Package Insert do not need to be filed if they are not affected by the change.	
At time of filing, if a Package Insert exists for this product: (select one option)	
○	A mock-up of the Package Insert is enclosed **in both official languages**.
○	A mock-up of the Package Insert has not been provided as it is not required for this submission.
If a Package Insert has been provided, I certify the following (as per Health Canada's Guidance Document, Q&A: PLL):	
•	The second language translation mock-up of the Package Insert is, to the best of my knowledge, true and accurate.
•	The content of the Package Insert matches the content of the Package Insert of the parent product.
•	Level I design element label changes, including, but not limited to those described in Section 5.11 of Heath Canada's Guidance Document, Q&A: PLL, are not included in this submission processed administratively. Such changes would require the filing of a S(A)NDS.
•	The enclosed Package Insert mock-ups are in PDF format. The mock-ups are full colour and actual size, with the dimensions stated.
•	The font size and/or style have not been revised as a result of this submission processed administratively.
•	The font size and style of the Package Insert are similar to the parent product.

Authorized Signing Official

Title	Name of Authorized Signing Official	Position Held

Telephone Number	Fax Number	Email Address

Company Name	Country

Address *(*Street/Suite/PO Box*)*

City/Town	Province/State	Postal/Zip Code

Signature	Date (YYYY/MM/DD)