Health Canada Santé Canada

Protected A (When Completed)

Labels and Packages Certification Form for Non-prescription Drugs

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 Labels and Packages Certification Form outlines the requirements as per Health Canada's Guidance Document, Questions and Answers: Plain Language Labelling Regulations for Non-prescription Drugs (Q&A: PLL).

Attestation	
☐	Attestation A*: New Drug Submission (NDS), Abbreviated New Drug Submission (ANDS), Supplement to a New Drug Submission (SNDS), Supplement to an Abbreviated New Drug Submission (SANDS), Application for a Drug Identification Number (DINA)
☐	Attestation B*: 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, ANDS, SNDS, SANDS, DINA

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

Inner and Outer Label and Package Mock-Ups

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. Any necessary clarifications should be provided within a Note to Reviewer in Module 1.3.2.
○	Written text of all inner and outer labels and packages associated with this product has been enclosed in both official languages. Note: Depending on the type of submission, a Screening Deficiency Notice (SDN) or a Notice of Deficiency (NOD) will be issued requesting finalized versions of inner and outer label and package mock-ups in both official languages.
○	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 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 Documents, Q&A: PLL Regulations for Non-prescription Drugs and the Labelling Requirements for Non-prescription Drugs, and the Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products (GLPPG)).

•	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 bilingual version of the inner and outer label and package mock-ups, will be submitted prior to approval.

The enclosed inner and outer label and package mock-ups

☐ are in an editable (i.e., not locked) PDF format. The mock-ups are full colour and actual size, with 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).

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

☐ meet the requirements outlined in the Guidance Document: Labelling Requirements for Non-prescription Drugs and the Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products (GLPPG).

Product Monograph/Prescribing Information

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 15 days of the submission being accepted into review.
○	The Product Monograph/Prescribing Information 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 Regulations for Non-prescription Drugs):

•	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)

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

○ Product Monograph Part III/Consumer Information
○ Product Monograph Patient Medication Information
○ Other (e.g., Package Insert for Division I products if applicable*)*
○ This product does not have a Package Insert

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.

○	Written text of Package Insert is enclosed in both official languages. Note: A Screening Deficiency Notice (SDN) will be issued requesting finalized versions of inner and outer label and package mock-ups in both official languages.
○	The first language Package Insert mock-up (Part III of the Product Monograph only) has been provided and the second language Package Insert mock-up will be provided within 15 days of the submission being accepted into review.
○	The first language Package Insert written text (Part III of the Product Monograph only) has been provided and the second language Package Insert written text will be provided within 15 days of the submission being accepted into review. Note: A Notice of Deficiency (NOD) will be issued requesting finalized versions of inner and outer label and package mock-ups in both official languages.
○	A mock-up of the Package Insert 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 Regulations for Non-prescription Drugs):	
•	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.
•	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 ☐ is in an editable (i.e., not locked) PDF format. The mock-up is full colour and actual size, with the dimensions stated (dimensions can be indicated directly on the mock-up, or 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 Guidance Document: Labelling Requirements for Non-prescription Drugs and the Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products (GLPPG).	

Attestation B – PDC	
I, the undersigned, certify, in regards to all original and solicited information, that:	
Inner and outer label and package text	
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 is not required for this submission (i.e., the proposed changes do not impact the labels).
○	For Division 1 products approved prior to PLL Regulations using any graduated flexibilities, all inner and outer label and package mock-ups associated with this product are enclosed in both official languages (for compliance with PLL regulations only).
If written text labels have been provided, I certify the following (as per Health Canada's Guidance Document, Q&A: PLL Regulations for Non-prescription Drugs):	
•	The second language translation of the enclosed inner and outer labels and packages is, to the best of my knowledge, true and accurate.
•	Finalized bilingual version of the inner and outer labels and packages text will be submitted prior to approval.
•	For Division 8 products, design element label changes that require filing of a supplement are not required as a result of the proposed changes to the inner and outer labels and packages text. This includes, but is not limited to those described in Heath Canada's Post-Notice of Compliance (NOC) Changes: Safety and Efficacy Document or Guidance Document Post-Drug Identification Number (DIN) Changes or Q&A PLL.
Product Monograph/Prescribing Information	
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 15 days of the submission being accepted into review.
○	The Product Monograph/Prescribing Information 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 Regulations for Non-prescription Drugs):	
•	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)	
At time of filing, if a Package Insert exists for this product: (select one option)	
☐	A written text of the Package Insert is enclosed in both official languages.
☐	A Package Insert is not required for this submission (i.e., the proposed changes do not impact the Package Insert).
If a Package Insert exists for this product, I certify the following (as per Health Canada's Guidance Document, Q&A: PLL Regulations for Non-prescription Drugs):	
•	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	
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 are not required for this submission. Note: For PDC submissions processed administratively, text versions of the labels should be provided in lieu of mock-ups.
If labels have been provided, I certify the following (as per Health Canada's Guidance Document, Q&A: PLL Regulations for Non-prescription Drugs):	
•	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 location and size of graphics, text and logos on the inner and outer labels and packaging are similar to the parent product.
•	Design element label changes, including, but not limited to those described in Heath Canada's Post-Notice of Compliance (NOC) Changes: Safety and Efficacy Document, or Guidance Document Post-Drug Identification Number (DIN) Changes or Q&A PLL are not included in this submission processed administratively. Such changes would require the filing of a S(A)NDS or a DINA.
•	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.
•	The font size and style of the enclosed inner and outer label and packages are similar to the parent product.
•	For submissions using a URL, the content of the URL is enclosed and meets the requirements of the Guidance Document: Labelling Requirements for Non-prescription Drugs, and the URL naming convention follows the requirements stated in the Guidance Document: Electronic Canadian Drug Facts Table (eCDFT) Technical Standards.

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 Regulations for Non-prescription Drugs):	
•	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)	
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 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 Regulations for Non-prescription Drugs):	
•	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.
•	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)