Health Canada Santé Canada

Guidance Document

Questions and Answers: Plain Language Labelling Regulations for Non-prescription Drugs

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Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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Ligne directrice : Questions et réponses : Le règlement sur l'étiquetage en langage clair pour les médicaments vendus sans ordonnance

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Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document may be acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant programme area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy, or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable Guidance documents.

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Section 1: Overview

1.1 What is the purpose of this document?

This document provides information for industry on how Health Canada's Health Products and Food Branch interprets and applies the 2014 Regulations Amending the Food and Drug Regulations (Labelling, Packaging and Brand Names of Drugs for Human Use) for non-prescription (Over-the-Counter, OTC) drug products. These amendments are commonly referred to as the Plain Language Labelling (PLL) Regulations. This document does not address implementation for prescription products and those administered or obtained through a health professional.

Note: these will be referred to as the "PLL Regulations" throughout the document and the specific sections cited refer to the Food and Drug Regulations, hereon referred to as "the Regulations".

1.2 What are the Plain Language Labelling (PLL) Regulations and what is their purpose?

The PLL Regulations aim to improve the safe use of drugs by making drug labels and packaging easier to read and understand. The PLL Regulations impose new obligations on health products sponsors to:

- provide information in plain language
- assess the name of their health products to avoid confusion
- submit mock-ups of labels and packages for review
- indicate how to report harms on their product's label
- provide information in an easy-to-read format, and
- provide a Canadian Drug Facts Table (CDFT)

1.3 What products are within the scope of the PLL Regulations?

The PLL Regulations apply to prescription and non-prescription pharmaceutical drugs, biologic drugs, radiopharmaceuticals and disinfectants. However, there are specific requirements that only apply to subsets of these products. For example, the CDFT requirement only applies to non-prescription drugs. These PLL Regulations do not apply to medical devices, veterinary drugs, drugs that are represented as being solely for use as a disinfectant on hard non-porous surfaces or natural health products.

For additional information, refer to Section 1.2 of the Guidance Document: Labelling Requirements for Non-prescription Drugs.

1.4 When do the PLL Regulations come into force for non-prescription drugs?

For non-prescription products, the PLL Regulations came into force on June 13, 2017.

1.5 Will the PLL Regulations be applied retroactively?

New requirements will be applied to submissions received on or after the coming into force date. Please see implementation dates for compliance with the CDFT below.

Sponsors who have already aligned with the PLL requirements based on the GLPPG (2017) are not required to make another submission solely for the purpose of aligning with the PLL requirements described in the Guidance Document: Labelling Requirements for Non-prescription Drugs (2018). Any future submissions for these products must align with the new requirements described in the Guidance Document: Labelling Requirements for Non-prescription Drugs.

1.6 Implementation dates:

Transition Timeline for Plain Language Labelling (PLL) Requirements for All Non-prescription drugs:

- **Effective June 13, 2017:**
    - Any new Drug Identification Number (DIN) applications or (Supplemental) or (Abbreviated) New Drug Submissions including those processed administratively, submitted on and after June 13, 2017 must be in compliance with the PLL Regulatory requirement which includes the presence of a CDFT on the outer label. The revised Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products (GLPPG) will outline good labelling practices and the Guidance Document: Labelling Requirements for Non-prescription Drugs will outline the labelling and CDFT requirements.
    - This applies to new products, or marketed products with a substantive enough label change that the issuance of a Drug Identification Number (DIN) or a Notice of Compliance (NOC) is required.
    - The PLL Regulations require that the mock-up labels be in the final format representative of what will be available on the market. Therefore, a Drug Identification Number (DIN) and/or a Notice of Compliance (NOC) will not be issued without the approval of the final mock-up labels.
    - The requirements will not be applied retroactively or to submissions in queue when the Regulations came into force.

By June 30, 2021:

- At the retail level, all non-prescription drug products must be in full compliance with the PLL regulatory requirements which include the presence of Canadian Drug Facts Table (CDFT) on the outer label.

For information on implementation, please consult the Guidance Document: Labelling Requirements for Non-prescription Drugs (https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/labelling-requirements-non-prescription-drugs.html).

Section 2: General Plain Language Requirement

Section A.01.017 of the Regulations: Every label of a drug for human use in dosage form shall meet the following conditions:

(a) the information that is required by these PLL Regulations to appear on the label shall be
   i. prominently displayed on it,
   ii. readily discernible to the purchaser or consumer under the customary conditions of purchase and use, and
   iii. expressed in plain language; and

(b) the format of the label, including the manner in which its text and any graphics are displayed on it, shall not impede comprehension of the information referred to in paragraph (a).

2.1 What is the purpose of the general plain language requirement?

This broad requirement is intended to ensure that information on labels of drugs for human use can be easily understood by the target audience and that the format or presentation of labels does not impede comprehension. It underpins the more specific requirements included in the PLL Regulations.

2.2 What information will support this plain language requirement?

The Guidance Document: Labelling Requirements for Non-prescription Drugs (formerly the Guidance Document: Drug Facts Table for Non-prescription Drugs) includes Facts Tables for medicinal ingredients found in non-prescription drugs in Canada. This guidance will assist manufacturers, packagers, and distributors of non-prescription drugs in developing plain language labelling content for a Facts Table in a standardized format so that consumers can find important product information quickly and easily.

The content (including the warnings, directions, etc.) in the Guidance Document: Labelling Requirements for Non-prescription Drugs reflects the most current labelling information for the listed non-prescription drug ingredients, based on the current safety profiles, use of plain language, international alignment, and experience to date. Health Canada strongly recommends sponsors to use the Guidance Document: Labelling Requirements for Non-prescription Drugs information as much as possible for their submissions, however compliance with the language verbatim is not a requirement, as statements to the effect of those included in the ingredient CDFTs may be considered with justification. As Health Canada works to update the OTC Monographs/Labelling Standards, they will use information/wording present in the Guidance Document: Labelling Requirements for Non-prescription Drugs as a starting point.

It is to the benefit of sponsors to stay as close as possible to the Guidance Document: Labelling Requirements for Non-prescription Drugs content.

The Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products (GLPPG) (https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/good-label-package-practices-guide-non-prescription-drugs-natural-health-products.html) describes evidence-based good practices to support the design and development of labels and packages that are clear, easy to read and understand.

Section 3: Brand name assessment requirement

Section C.01.014.1 (2) of the Regulations: An application under subsection (1) shall be made to the Director in writing and shall set out the following information:

- in the case of a drug for human use, an assessment as to whether there is a likelihood that the drug will be mistaken for another drug for which a drug identification number has been assigned due to a resemblance between the brand name that is proposed to be used in respect of the drug and the brand name, common name or proper name of the other drug.

Section C.08.002 (2) of the Regulations: A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:

- in the case of a new drug for human use, an assessment as to whether there is a likelihood that the new drug will be mistaken for another drug for which a drug identification number has been assigned due to a resemblance between the brand name that is proposed to be used in respect of the new drug and the brand name, common name or proper name of the other drug.

C.08.003 (3.1) A supplement to a submission referred to in subsection (1) shall contain, as the case may be,

(b) if the supplement concerns the brand name of a new drug for human use:

i. an assessment as to whether there is a likelihood that the new drug will be mistaken for another drug for which a drug identification number has been assigned due to a resemblance between the brand name that is proposed to be used in respect of the new drug and the brand name, common name or proper name of the other drug.

3.1 What is the purpose of the brand name assessment requirement?

This requirement obliges sponsors to provide Health Canada with evidence that a drug will not be confused with another drug because of similar names.

3.2 What is the meaning of Look-Alike Sound-Alike (LASA) names?

Look-alike sound-alike (LASA) drug product names refer to names of different drug products that are similar when written or spoken. These similarities may cause confusion and result in errors when self-selecting, prescribing, transcribing, dispensing or administering a drug product. The end result of product name confusion may be that the patient/consumer takes the wrong product. Such an error may result in harm to a patient by depriving them of the benefit of the correct treatment and/or may subject them, unknowingly, to possible additional risks (including adverse effects) as a consequence of using the mistakenly selected product. Such errors may cause harm, up to and including death.

For non-prescription products, a LASA name assessment may be required if the proposed brand name is not exclusively descriptive per the proposed claim(s) and/or proper or common name(s) of the ingredient(s) in the product.

3.3 Where can we find more information about brand name assessments?

Current practice for how brand names are assessed will not change. Please consult Appendix 1: Brand Name Screening Criteria and Appendix 2: Product Name Review Process of this document for guidance as to what is expected.

The following guidance documents may be consulted for more information on brand name assessments:

Guidance for Industry: Review of Drug Brand Names (https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/guidance-document-industry-review-drug-brand-names.html)

Frequently Asked Questions - Guidance Document for Industry - Review of Drug Brand Names (https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/frequently-asked-questions-guidance-document-industry-review-drug-brand-names.html)

Section 4: Contact Information Requirement

Section C.01.004.01 (1) of the Regulations: Every label of a drug for human use in dosage form shall display the following:

a. a telephone number, email address, website address, postal address or any other information that enables communication with a contact person in Canada; and
b. statement to the effect that any injury to a person's health that is suspected of being associated with the use of the drug may be reported to the contact person.

(2) Subsection (1) does not apply to:

a. the labels of a drug that is listed in Schedule C or D to the Act and that is in dosage form.

4.1 What is the purpose of the contact information requirement?

This requirement is intended to ensure that Canadians are given information on drug labels that will allow them to contact someone who is responsible for the product in Canada, if they experience a problem [for example (e.g.) adverse reaction, medication error that led to taking the wrong drug or the wrong dose] or have a question or concern.

It is expected that the information will be gathered and reported in a manner that is in compliance with existing Canadian regulations and requirements.

4.2 In order to comply with this requirement, how many means of contact must be listed?

Sponsors need to provide, in both official languages, at least one method of contacting the person in Canada. Therefore, providing the information by just one of these means (e.g. toll-free number, email address, website) would be considered sufficient. A toll-free number, email address or website are the recommended means of contact. However, in cases where there is limited spacing on a package label, the sponsor may wish to use their postal address to satisfy both the PLL Regulations (C.01.004.01(1)) and the Regulations (C.01.004.1(c)(i)).

For products with a Product Monograph (PM), sponsors must comply with the existing and applicable PM guidance documents.

4.3 Is there particular wording that is required?

The following wording would be considered sufficient: “For questions or to report problems, please contact…,” “Questions or concerns” or “Questions” followed by the contact information. The name of the contact person does not need to be listed.

4.4 Who can the contact person be?

The sponsor can decide who the initial contact person will be; however, this person is required to be located in Canada.

For private brand labels, the contact under “Questions” should be the DIN owner contact or the DIN Owner can decide who the initial contact person will be. However, this person is required to be located in Canada.

4.5 Where does the contact information need to appear?

The contact information should be on the inner and outer labels to ensure that consumers and health care professionals have access to the information even if the packaging has been discarded.

4.6 How can the contact information be displayed in a Canadian Drug Facts Table?

For text in the Canadian Drug Facts Table, please consult the Guidance Document: Labelling Requirements for Non-prescription Drugs.

4.7 Does the current regulatory exemption (C.01.004 (3)) for special containers (e.g. blister packs) and for small containers still apply?

Yes, the exemption still applies.

Section 5: Mock-up Requirement

Section C.01.014.1. (2) of the Regulations: An application under subsection (1) shall be made to the Minister in writing and shall include the following information and material:

- (m.1) in the case of a drug for human use, mock-ups of every label to be used in connection with the drug - including any package insert and any document that is provided on request and that sets out supplementary information on the use of the drug - and mock-ups of the drug’s packages;

Section C.08.002. (2) of the Regulations: A new drug submission shall contain sufficient information and material to enable the Minister to assess the safety and effectiveness of the new drug, including the following:

- (j.1) in the case of a new drug for human use, mock-ups of every label to be used in connection with the new drug - including any package insert and any document that is provided on request and that sets out supplementary information on the use of the new drug - and mock-ups of the new drug’s packages;

Section C.08.003 (3.1) of the Regulations: A supplement to a submission referred to in subsection (1) shall contain, as the case may be,

a. if, due to a matter specified in subsection (2) - other than the brand name of a new drug for human use - that the supplement concerns, it is necessary to modify a new drug's labels:

    ii. in the case of a new drug for human use, mock-ups of every label to be used in connection with the new drug - including any package insert and any document that is provided on request and that sets out supplementary information on the use of the new drug - and mock-ups of the new drug's packages; or

b. if the supplement concerns the brand name of a new drug for human use:

    ii. mock-ups of every label to be used in connection with the new drug - including any package insert and any document that is provided on request and that sets out supplementary information on the use of the new drug - and mock-ups of the new drug's packages.

5.1 What is the purpose of the mock-up requirement?

This requirement obliges sponsors to provide Health Canada with mock-ups of labels and packages, so that information filed with submissions represents the information that consumers and health professionals will see. These mock-ups will be reviewed by Health Canada.

5.2 Is the requirement to submit mock-ups retroactive?

No. This requirement will not be applied retroactively. Mock-ups will be required for submissions that are filed on or after June 13, 2017.

5.3 How will Health Canada review mock-ups?

In addition to making sure labels comply with existing regulatory requirements on labelling, the review of the design elements will focus on (but is not limited to) the following, as they relate to the key elements of an inner/outer label or package mock-up:

- font size
- font type
- colour, and
- placement (including proximity, overlap, and panel location)

For more information on the key elements and good label design, please see the Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products and the Guidance Document: Labelling Requirements for Non-prescription Drugs on the Health Canada Website.

Design elements will be evaluated to determine whether they support or impede legibility and understanding of the label. Label reviewers will communicate any concerns to sponsors via clarification requests or via Screening Deficiency Notices. The review of label information and key design elements will be conducted as per current processes.

Finalized versions of the inner and outer labels in both official languages must be provided before the Notice of Compliance (NOC), DIN or No Objection Letter (NOL) can be issued.

5.4 What flexibilities are available for submitting a full colour mock-up labels at the time of filing?

As per C.01.014.1 (2) (m.1) of the Regulations, an application for a drug identification number shall include mock-up labels. It is recommended that full color 2-dimensional mock-up labels be included at the time of filing so that they can be reviewed for comprehension, legibility and to confirm accurate and valid application of the CDFT.

In circumstances whereby it is not possible to provide full colour mock-ups at the time of filing, draft text labels only can be provided at the time of filing and they will be reviewed for content. Draft text labels can be submitted using any software (e.g., word, pdf, etc.) at the discretion of the sponsor and should include font type, font size, headings, line width, etc. (i.e., CDFT format) including information on all other panels of the label. To facilitate this review, it is recommended that applicants submit draft text labels that closely match the CDFT and PLL requirements.

All deficiencies identified during the draft text labels review will be communicated to the applicant at which time the full color mock-up label will also be requested. Depending on the type of submission, this will be done by sending a Screening Deficiency Notice (SDN) or a Notice of Deficiency (NOD) since the mock-up labels in the final format representative of what will be available on the market is a requirement of the PLL Regulations. Applicants will have 45 to 90 calendar days, depending on the type of submission, to provide a full response, but may request an extension consistent with Health Canada's current practice.

A Drug Identification Number (DIN) and/or a Notice of Compliance (NOC) will not be issued without the approval of the final label. Review timelines will be according to Health Canada's applicable service standards.

In connection with the mock-up requirement, the PLL Regulations repeal the requirement at C.01.014.3 to submit final labels after the drug is available for sale. Therefore, sponsors who file submissions for non-prescription products on or after June 13, 2017 will not be required to submit final marketed labels with their market notification, as labels will need to be reviewed and finalized prior to approval. Sponsors are asked not to send in final marketed labels with their market notification.

5.5 What flexibilities are available for the Canadian Drug Facts Table?

As indicated in Section 2.4.4 in the Guidance Document: Labelling Requirements for Non-prescription Drugs, graduated flexibilities may be applied as indicated below.

Use of graduated flexibilities

All products under the scope of the PLL Regulations must apply the CDFT format. However, some products and package sizes may not present sufficient space to accommodate the CDFT in the standard format on the label.

In some cases, an innovative label may be the most effective way to accommodate the space requirements of the CDFT. This determination should be made early in the label and package development process. In other cases, a modified format with graduated flexibilities may be considered according to the criteria outlined in Table 3 of the Guidance Document: Labelling Requirements for Non-prescription Drugs. Sponsors must apply the CDFT accurately and completely prior to requesting graduated flexibilities. The purpose of the proposed modifications is to gain space on the label, and in some cases, may prevent the need for innovative labels or increased package sizes.

5.6 For the Category IV monograph products, will the URL be reviewed and when should the URL be live?

Sponsors may include a prompt to an eCDFT within the CDFT. On the CDFT, there must be a placeholder for the URL, as indicated in the revised Guidance Document: Labelling Requirements for Non-prescription Drugs. For the content of the URL, a "standard CDFT" must be submitted at the time of filing for review. The URL must be live at the time of marketing of the product. There is no requirement to submit a submission for the review of the live-URL.

For guidance on URL, please consult the Guidance Document: Electronic Canadian Drug Facts Table Technical Standards.

For submissions using the URL, the content of the URL must be enclosed with the submission and must follow the URL naming convention requirements stated in the Guidance Document: Electronic Canadian Drug Facts Table (eCDFT) Technical Standards. Health Canada will not review conformance to the eCDFT technical standards as part of the submission review process. Instead, Health Canada will review and approve the content of the eCDFT only. The URL Link location must be present on the heading 'Drug Facts' of the CDFT with the following statement (or other approved text per the Guidance Document: Labelling Requirements for Non-prescription Drugs) directing the consumers to the electronic eCDFT:

For full (Canadian Drug Facts) Table, visit xxx / Pour le tableau (Info-médicament canadien) complet, visitez xxx.

Applicants are expected to comply with the technical web publishing standards upon deployment of their website.

5.7 What is an acceptable format in which to submit electronic mock-up labels?

For submissions submitted in electronic Common Technical Document (eCTD) format or non-eCTD electronic only format, files should be submitted in Portable Document Format (PDF). PDF versions of documents should be generated from electronic source documents and not from scanned material. Sponsors should submit editable labels (i.e., not locked PDF files) which enable reviewers to verify the font type and sizes. A locked file impedes reviewers from making annotations to the labels.

5.8 What is SKU?

SKU stands for Stock-Keeping Unit. A product SKU is a string representing the product unique identifier.

A representative draft label is not an acceptable replacement for multiple labels representing different SKUs (see below for note on submission of smallest label for identical label format).

The following should be submitted with your drug submission:

- Bilingual full colour mock-ups of inner and outer labels and colour representations of packages incorporating the proposed text, and placeholders for lot number, expiry date, and DIN.
- All sides of the package should be visible in the mock-ups.
- The expiry date placeholder should show the descriptor (e.g., EXP), and the format to be used (e.g., YYYY/MM/DD).

Mock-up of only the smallest label with identical label format and/or package for each dosage form should be submitted provided 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.

For new submissions, if a Standard CDFT is used for the label (with no flexibilities applied as per the Guidance Document: Labelling Requirements for Non-prescription Drugs), then one representative label with identical label format can be submitted.

5.9 Is it acceptable to submit bilingual mock-up labels for a private brand as representative labels?

No, it is not acceptable to submit bilingual mock-up labels for a private brand as representative labels

Marketed private brand products coming into compliance are not required to file a submission solely for the purpose of complying with PLL, provided there are no substantive label changes (i.e. label changes that would require a DIN or NOC) and that labels follow the “standard CDFT format specifications”.

Marketed Category IV products, mouthwashes, and toothpastes under a private brand are not required to file a submission solely for the purpose of complying with PLL, provided that labels follow either the standard CDFT format specifications, or the tailored flexibilities for Category IV Products, mouthwash and toothpaste” (Sec 2.5 of the Guidance Document: Labelling Requirements for Non-prescription Drugs).

Category IV products include all products in compliance with the following monographs: Acne Therapy, Sunscreen Monograph, Medicated Skin Care Products, Diaper Rash Products, Anti-dandruff Products, Antiseptic Skin Cleansers, Athlete Foot Treatments, Throat Lozenges.

If there are substantive changes that would require a DIN or NOC or the company plans to use the flexibilities outlined in Section 2 of the Guidance Document: Labelling Requirements for Non-prescription Drugs, or an innovative label is used (Section 2.7 of the Guidance Document: Labelling Requirements for Non-prescription Drugs), a submission will need to be filed. The submission type would be a PDC (post Division 1 change) or an SNDS Labelling Only (Division 8 Drug products).

If a product is sold in multiple package size(s), the submission should include mock-up label(s) of smallest package size(s) representing identical labels.

Mock-up of the smallest label submitted should be of an identical label format and/or package for each of the other package sizes including the format of the CDFT. There should be 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.

If the design elements are different for each private label brand, the submission should include final full colour mock-up labels for each private label brand.

If additional private brands are introduced to the market following issuance of a DIN, the fabricator (DIN Owner) is required to submit a PDC submission for Division 1 Drugs in order to get approval for any additional private brands not submitted with the initial submission. For Division 8 Drugs, an SNDS Labelling Only submission is required. For both submission types, final full colour mock-up labels are required for compliance with the PLL Regulations.

For new products, the mock-up label(s) of what will be available on the market is a requirement of the PLL Regulations, therefore black and white representative labels with placeholder text for the private label brands are not acceptable. If private brand full colour mock-up labels are not available at the time of submission, the submitted plain labels will be reviewed for content only. The private brand full colour mock-up labels will be requested by Screening Deficiency Notice (SDN) and/or Notice of Deficiency (NOD) since the mock-up labels in the final format representative of what will be available on the market is a requirement of the PLL Regulations. Applicants will have 45 to 90 calendar days, depending on the type of submission, to provide a full response, but may request an extension consistent with Health Canada's current practice.

In order to avoid obtaining a NOD or SDN, DIN owners are encouraged to work with the private brand retailers prior to submitting a DIN submission as the mock-up labels of all private brands must be submitted in order to be in compliance with PLL Regulations.

In order to facilitate review, a Note to Reviewer should be included indicating the flexibilities being used on all private label brands and/or indicating which labels are mock-up label(s) of smallest package size(s) representing identical labels. The Note to Reviewer should be placed in section 1.3.2 of a CTD submission.

By using the same CDFT flexibilities on multiple private brand labels, sponsors can reduce the time needed to prepare the mock-up labels and in turn help facilitate review efficiency. Sponsors should clearly indicate which mock-ups follow the same format in the Note to Reviewer.

5.10 Is it acceptable for Generic Products to comply with the PLL Regulations prior to the Canadian Reference Product (CRP)?

To accommodate the retail deadline for PLL compliance, it is acceptable for generic products to submit label updates in advance of the Canadian reference product (CRP) in order to align with PLL. Generic products can make label changes to incorporate a Canadian Drug Facts Table (CDFT) on their outer labels before the CRP, as long as the information on the labels is consistent with the CDFT requirements outlined in the Guidance Document: Questions and Answers: Plain Language Labelling Regulations for Non-prescription Drugs and Guidance Document: Labelling Requirements for Non- prescription Drugs.

Any PLL-related revisions made to the CRP's will necessitate manufacturers of generic products to file labelling updates for generic products to re-align and ensure consistency with the CDFT labelling of the CRP.

The submission type for the above changes would be S(A)NDS Labelling Only.

5.11 What type of mock-ups should sponsors submit for non-prescription products?

For (A)NDS, S(A)NDS and DINA submission types, sponsors should submit the following:

a. mock-ups of the inner and outer labels and packages
b. mock-ups of the Package Insert (s), if applicable and
c. the Product Monograph, if applicable.

For information on submission types with different requirements (Post-Authorization Division 1 Change, Labelling Only and Submissions filed administratively), please see section 5.13.

For information on the Labels and Packages Certification Form (see 5.13 (d)).

(a) Inner/Outer Label Mock-ups

Sponsors are to submit inner/outer label mock-ups at the time of filing.

Mock-ups of the inner/outer label should be representative of the package. They should be bilingual, full colour and actual size. They should contain:

- the proposed text
- placeholders for lot number, expiry date, and DIN XXXXXXXX including the descriptor (e.g., EXP) and the format to be used (e.g. YYYY/MM/DD), and
- the dimensions of the labels

All sides of the package should be visible in the mock-ups.

Annotated bilingual versions of the Inner/Outer label mock-ups may be requested in order to facilitate review.

Where there are no differences other than pill count or volume on the label, submitting the smallest format and attesting that the other labels will have identical text, format, size, layout, colour, etc. (with all minor differences clearly cited) is acceptable, within reason. If a standard Canadian Drug Facts Table is used for the label (with no flexibility as per the Guidance Document: Labelling Requirements for Non-prescription Drugs), then one representative label for SKUs with identical label format can be submitted.

For more information on designing labels and packages, please see 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.

Table 2 of the Guidance Document: Labelling Requirements for Non-prescription Drugs provides details about the type style and size for labels.

(b) Package Inserts (Consumer Information or Patient Medication Information) Mock-Ups

Health Canada recommends the use of largest type size possible for package inserts. A point size of less than 6 will not be accepted.

For Division 1 products, bilingual package inserts should be provided at time of filing if:

- a package insert exists for the product

Products that will need to introduce an insert due to the inability to include all information in the CDFT must include an insert with the entire CDFT using the "standard format". For Division 8 products, sponsors are to submit the first language or bilingual package insert at the time of filing if:

- the changes to the labelling proposed within the submission (such as revisions to Part III of the PM) affect the content of the package insert

If the mock-up of a package insert is not included at the time of filing, the sponsor should confirm that either the product does not have a package insert or that the submission does not impact the package insert, as applicable.

If not provided at the time of filing, the second language package insert is to be submitted up to 15 days following acceptance of the submission into review. When sponsors submit second language documents during the review period; they should identify the documents as "Second Language Labels Pre-Approval" in their cover letter. Health Canada recommends that sponsors file second language documents (Product Monograph and package insert) together as one regulatory transaction, when applicable.

An annotated version in the first official language may be requested in order to facilitate review.

The sponsor should attest in the Labels and Packages Certification Form that the content of the package insert matches the content of the Product Monograph. Health Canada label reviewers will assess the package insert for legibility, and content as needed.

For more information on package inserts, please see section 5.4.2 of the Guidance Document: Labelling of Pharmaceutical Drugs for Human Use.

When sponsors submit final second language package inserts, these should be identified as "Second Language Labels Post-Approval" in their cover letter. Health Canada recommends that sponsors file final second language documents (Product Monograph and package insert) together as one regulatory transaction, when applicable. Sponsors are to file these documents no more than 20 days after the receipt of the DIN, No Objection Letter (NOL) or NOC.

(c) Product Monograph

Sponsors are to submit first language Product Monographs (PM) at the time of filing. The PM is to comply with the version of the Product Monograph guidance and templates that apply at the time of filing. For additional guidance on Product Monographs, please see the Guidance Document - Product Monograph (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/product-monograph/guidance-document-product-monograph.html).

If not provided at the time of filing, the second language PM is to be submitted up to 15 days following acceptance of the submission into review. When sponsors submit second language

documents during the review period; they should identify the documents as “Second Language Labels Pre-Approval” in their cover letter. Health Canada recommends that sponsors file second language documents (PM and package insert) together as one regulatory transaction, when applicable.

The review of the PM will be conducted as per current Health Canada processes.

When sponsors submit final second language PMs, these should be identified as “Second Language Labels Post-Approval” in their cover letter. Health Canada recommends that sponsors file final second language documents (PM and package insert) together as one regulatory transaction, when applicable. Sponsors are to file these documents no more than 20 days after the receipt of the DIN, NOL or NOC.

(d) The Labels and Packages Certification Form for Non-prescription Drugs

The Labels and Packages Certification Form for Non-prescription Drugs is to be included with the submission at the time of initial filing.

The form certifies:

1. the fidelity of translation(s)
2. the commitment to provide the second language PM and/or second language package insert documents within the first 15 days after the submission has been accepted into review
3. the commitment to update the second language PM and/or package insert documents with any changes made during the PM review process
4. the commitment to file the second language version of the final approved PM and package insert no later than 20 days following the date of the issuance of the:
    - Notice of Compliance (NOC)
    - No Objection Letter (NOL) and/or
    - DIN
5. the font size and type style of the mock-up labels
6. the font size and type style of the package insert, and
7. the content of the first and second language package inserts

(e) What should be submitted and when for (A)NDS and S(A)NDS (Division 8)?

***For submissions processed administratively, please see section 5.13.**

DIVISION 8

Time point	Inner/Outer labels	Package Inserts	Product Monograph	Labels and Packages Certification Form
Filing	• Bilingual mock-ups required	• Bilingual mock-ups preferred • Minimum is first language mock-up	• Clean (non-annotated) text version of the PM in first official language. • Annotated version of the PM in first official language.	Completed certification form
Up to 15 days after acceptance into review	N/A	Second language mock-up (if not already provided)	Second language PM (if not already provided)	N/A
Prior to issuance of NOC or DIN	Final mock-ups	Final bilingual or first language mock- up	Final bilingual or first language PM	N/A
20 days after issuance of NOC or DIN	N/A	Final second language mock-up	Final second language PM	N/A

(f) What should be submitted and when for DINA (Division 1)?

***For PDC submissions and submissions processed administratively, please see section 5.13.**

DIVISION 1

Time point	Inner/Outer labels	Package Inserts	Mock-up Labels and Packages Certification Form
Filing	Bilingual mock- ups required	Bilingual mock- ups required	Completed certification form
Prior to issuance of DIN	Final bilingual mock-ups	Final bilingual mock-up	N/A

5.12 Can DINs be issued prior to providing the final bilingual mock-ups?

No, the DIN is issued after the approval of the submission. You are not required to include the actual DIN on the mock-ups, it is acceptable to submit "DIN XXXXXXXX" as placeholders.

5.13 How will the mock-up provision be applied for other submission types?

(a) Notifiable Change* (NC) submissions or Post-Authorization Division 1 Change (PDC) submissions

The Labels and Packages Certification Form should be included with the submission (see section 5.11 (d)).

* Effective April 1, 2020, Notifiable Changes will no longer exist for safety and efficacy changes to human drug submissions and instead should be filed as per the Post Notice of Compliance (NOC) Safety and Efficacy Guidance (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/post-notice-compliance-changes/safety-efficacy-2019/document.html). As such they will be subject to the requirements to submit mock-ups, as applicable, as outlined in 5.11 above.

i. Inner/Outer Labels

For PDCs, if the labels are impacted by the updates proposed within the submission, clean (non-annotated) bilingual text versions of the proposed inner/outer label are to be submitted at the time of filing.

Health Canada will accept annotated written text, in lieu of mock-ups, to reflect proposed changes to the inner/outer labels. If sponsors submit mock-ups in place of annotated text, the written text will be reviewed. Annotated text versions may be requested in order to facilitate review.

Sponsors should ensure that any proposed changes to the inner/outer label and package text do not inadvertently result in accompanying design element changes requiring a Level I submission (see Section 5.11 (c)). Such changes would exceed the scope of a Level II NC or PDC submission.

ii. Package Insert

For PDCs, if the package inserts are impacted by the updates proposed within the submission, clean (non-annotated) bilingual text versions of the package inserts are to be submitted at the time of filing.

The proposed changes should not result in a decrease in font size or a change to font type of the Package Insert text. Such changes would be considered a Level I, and therefore exceed the scope of a PDC submission.

iii. Product Monograph

Sponsors are to submit the following at the time of filing:

- Clean (non-annotated) text version of the proposed PM in the first official language
- Annotated version of the proposed PM in the first official language

The second language PM may be submitted up to 15 days following acceptance of the submission into review, if not already provided at filing.

For products already approved as per the mock-up requirement, sponsors are expected to continue to maintain the compliance of their labels and package insert with PLL principles (e.g. maintaining font size, legibility, colour, layout, format, plain language, etc.), even in the absence of filing a mock-up with their PDC submission. In addition, the content of the package insert should be kept up to date following revisions to the PM that affect the package insert's text.

(b) Administrative Submissions

As per section C.01.014.2 (1)(b) of the Regulations, a DIN identifies the following product characteristics:

- manufacturer
- brand name
- medicinal ingredient(s)
- strength of medicinal ingredient
- pharmaceutical form and
- route of administration

Where any of these product characteristics differ, a new DIN is required as per section C.01.14.2 (1) (1) of the Food and Drug Regulations.

As a result, for submissions filed and processed under administrative pathway (previously the Changes in Manufacturer's Name and/or Product Name policy), the following must be submitted at the time of filing:

- mock-ups of the bilingual inner/outer labels and packages (including CDFT table)
- mock-ups of the first and second language (or bilingual) package inserts
- first and second language PMs, and
- the Labels and Packages Certification Form for Non-prescription Drugs

Please refer to the Guidance Document: Administrative Processing of Submissions and Applications Involving Human or Disinfectant Drugs (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/administrative-processing-human-disinfectant-drugs-2019/document.html) for the filing requirements for Administrative Submissions.

To be eligible for processing under the administrative pathway, sponsors will certify that all aspects of the product are identical to those previously authorized, including the conditions of manufacture and sale. To meet the purpose of the PLL Regulations, sponsors will also certify that the general layout of their label has remained the same.

For example, in the case of a sponsor name change, sponsors will be able to change their label to reflect the trade dress of the new sponsor; however the font and graphic size, as well as the placement of information on the label should be the same as the initial approved label.

If sponsors want to change the location or size of graphics or font of their label, they will need to file a Labelling Only submission and pay the related fees.

Additionally, submissions which include a product name change or additional product name where a brand name or LASA name assessment is required will be ineligible for administrative processing. For Division-8 drugs, these types of changes should be filed as “Labelling Only” submissions.

For Division-1 drugs, the submission class (DINF / DINA Labelling Standard or Labelling Only) would depend on the original submission class for the product or if brand name assessment data is submitted.

(c) SNDS or PDC submissions

Post-market changes made exclusively to label design elements should be filed as S(A)NDS labelling only (Division 8 Drugs) or PDC submissions (Division 1 Drugs). Mock-ups are only required in PDCs where the purpose of the submission is to 1) apply graduated flexibilities to non-Cat IV products, or 2) include the CDFT on an innovative outer label. For all other PDCs, bilingual label text is accepted. For all other design element changes to Division 1 Drug products (i.e. no CDFT incorporation), the criteria in the Post-DIN Changes Guidance (2009) should be referred to for whether or not filing to Health Canada is required. The label text information should remain the same as in the previously approved label. Sponsors are encouraged to file mock-ups of labels which indicate the font size and type style, along with copies of previously approved labels to facilitate timely review.

Some examples of when S(A)NDS Labelling Only or PDC submissions should be filed include, but are not limited, to:

- Adding new graphics or symbols (other than symbols required by regulations) or changing locations of graphics within the inner or outer label (e.g. addition of a symbol that relates to the type of packaging being used).
- Changing the size or colour of text or background in connection with product name (proprietary and non-proprietary), warnings, dosage, expression of strength, route of administration, population, and storage.

- Reordering text on the label necessary for the safe and effective use of the product
    - moving label information to different panels;
    - changing the order of information presented on the principal display panel including product name (proprietary and non-proprietary), warnings, dosage, expression of strength, route of administration, population, and storage.
- Reducing overall label size.
- Changing the package design, where the package is the immediate container.
- Increasing the size of company logo/graphics.
- In response to a Health Canada-issued advisement letter specifically soliciting a labelling-only S(A)NDS.
- Adding an innovative label to a package.

This list is not exhaustive; it is meant to provide guidance on the types of changes which will require submissions for review. Sponsors are encouraged to contact Health Canada should they require further direction on the most appropriate manner to file.

(d) Office of Submissions and Intellectual Property (OSIP) Notification (Division 1) and Level III Safety and Efficacy Changes (Division 8)

- For Division 1 products, some changes to inner/outer labels which do not necessitate assessment [as per the Guidance Document on Post-Drug Identification Number (DIN) Changes] and for Division 8 products, Level III Safety and Efficacy changes [as per the Guidance on Post-Notice of Compliance (NOC) Changes: Safety and Efficacy Document] should not be filed at the time the changes are made.
- Any notifications or Level III type changes that do not require the filing of a drug submission can be incorporated into the next submission filed for the product.

If a “Not for Resale” sticker is placed over a UPC code, Health Canada does not consider this a change in design element.

5.14 For a marketed product where a change to the Chemistry and Manufacturing only has been filed, and no change to the label has been made, should sponsor comply with the PLL regulatory requirement?

For Division-8 drug submissions with change in Chemistry & Manufacturing; the labels must comply with PLL regulations if:

- it is necessary to modify a new drug’s labels, then the labels and packaging should comply with the PLL regulations (C.08.003 (3.1) (a) (ii))
- it necessitates issuance of a DIN due to change in C.01.014.1 (2) listed below, the product labels must comply with the PLL regulations

Section C.01.014.4 of the Regulations then provides that if any of the following information in paragraphs (a) to (f) of C.01.014.1 (2) change, a new DIN must be obtained:

- manufacturer; brand name; route of administration; medicinal ingredient(s); strength of medicinal ingredient; and pharmaceutical form.

In those cases where a new DIN application is required, the requirements set out in Section C.01.014.1 (1) of the Regulations, including mock-ups [Section C.01.014.1 (2) (m.1)] must be met.

5.15 What Health Canada guidance documents will help sponsors prepare mock-ups?

The Good Label and Package Practices Guide for Non-Prescription Drugs and Natural Health Products (https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/good-label-package-practices-guide-non-prescription-drugs-natural-health-products.html) provides more detailed information about the design of safe health product labels and packages.

The Guidance Document: Labelling Requirements for Non-prescription Drugs provides information on the regulatory requirements pertaining to labelling and on the content of labels and packaging, and information on aligning with PLL, including the formatting specifications for the CDFT.

The Guidance Document: Labelling of Pharmaceutical Drugs for Human Use (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/labelling-pharmaceutical-drugs-human-use-2014-guidance-document.html) provides information on the regulatory requirements pertaining to labelling and on the content of labels and packaging.

The Guidance Document: Product Monograph (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/product-monograph/guidance-document-product-monograph.html) provides direction on the content and format of these documents and also references sources of information on plain language labelling.

The Labels and Packages Certification Form (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/product-monograph/guidance-document-product-monograph.html) is required when filing submissions.

The Guidance document: Electronic Canadian Drug Facts Table Technical Standards (https://www.canada.ca/en/health-canada/services/drugs-health-products/reports-publications/medeffect-canada/guidance-electronic-canadian-drug-fact-table-technical-standards.html) provides the technical information required for generating an eCDFT, including templates.

Section 6: Canadian Drugs Facts Table (CDFT)

Section C.01.004.02 (1) of the Regulations state that: In addition to the requirements of section C.01.004, the outer label of a drug for human use in dosage form shall display, either one bilingual table, placed on any panel, that contains only the following information in both English and French or one table in English and one table in French, each of which is placed on any panel, that contains only the following information:

a. adequate directions for use of the drug;
b. a quantitative list of the drug's medicinal ingredients by their proper names or, if they have no proper names, by their common names;
c. the drug's non-medicinal ingredients listed in alphabetical order or in descending order of predominance by their proportion in the drug, preceded by words that clearly distinguish them from the medicinal ingredients; and
d. the information referred to in subsection C.01.004.01(1).

Non-prescription drug samples, other than those administered only under the supervision of a practitioner, must still comply with the PLL Regulations, including sections A.01.017 and C.01.004.02 of the Regulations.

6.1 What products are exempt from the CDFT requirements?

As per Section C.01.004.02 (6) of the Regulations, a CDFT is not required for (a) prescription drugs; (b) drugs that are permitted to be sold without a prescription but that are administered only under the supervision of a practitioner; and (c) drugs that are represented as being solely for use as a disinfectant on hard non-porous surfaces.

"Practitioner" means a person who (a) is entitled under the laws of a province to treat patients with a prescription drug, and (b) is practising their profession in that province (Section C.01.001.(1) of the Regulations).

Ethical-prescription drugs are exempt from the regulatory requirement of Section C.01.004.02 (1) of the Regulations, therefore, a CDFT is not required on the outer label of these drugs, e.g., Nitroglycerin, Insulin, Injectable epinephrine etc.

6.2 What are the specifications for the CDFT requirements?

For more information on formatting specifications with respect to the CDFT, please refer to the Guidance Document: Labelling Requirements for Non-prescription Drugs.

Table 1 provides formatting specifications for the Standard Canadian Drugs Fact Table.

Table 3 provides formatting specifications for the graduated flexibilities of the Canadian Drug Facts Table.

Table 4 provides the tailored flexibilities for Category IV monograph products.

Table 6 provides the flexibilities for products using innovative labels.

Labelling content for medicinal ingredients found in non-prescription drugs in Canada can be found in the Guidance Document: Labelling Requirements for Non-prescription Drugs.

Sponsors should note that, for text found in the CDFT, outer labels, and inner labels, the term doctor may be replaced by the term physician, health care practitioner, health care provider, or health care professional, subject to review. Depending on the nature of the product, the term doctor may be replaced by the term dentist, dental care practitioner, dental care provider, or dental care professional, subject to review. The term ask may be replaced by the term consult. This is subject to review.

6.3 What are the requirements for currently authorized products?

Marketed Category IV products as well as mouthwashes and toothpastes will not be required to file a submission solely for the purpose of complying with the " Tailored flexibilities for Category IV Products, mouthwash and toothpaste" (Section 2.5 of the Guidance Document: Labelling Requirements for Non-prescription Drugs).

Category IV products include all products in compliance with the following monographs: Acne Therapy Products, Sunscreen Products, Medicated Skin Care Products, Diaper Rash Products, Anti-dandruff Products, Antiseptic Skin Cleansers, Athlete Foot Treatments, Throat Lozenges.

If there are substantive changes that would require a DIN or Notice of compliance (NOC) or the company plans to use the graduated flexibilities outlined in the guide (Section 2.4 of the Guidance Document: Labelling Requirements for Non-prescription Drugs) or an innovative label is used (Section 2.7 of the Guidance Document: Labelling Requirements for Non-prescription Drugs), a submission will need to be filed.

The submission type options would be either a PDC (Division 1 Drug products) or an SNDS Labelling Only (Division 8 Drug products).

Sponsors who have already aligned with the PLL requirements based on the GLPPG (2017) are not required to make another submission solely for the purpose of aligning with the PLL requirements described in the Guidance Document: Labelling Requirements for Non-prescription Drugs (2018).

Any future submissions for these products must align with the new requirements described in the Guidance Document: Labelling Requirements for Non-prescription Drugs.

Please note that all products must be compliant at the retail level by June 30, 2021.

6.4 Where should the CDFT be located?

As per the PLL Regulations, the CDFT is required on the outer label of non-prescription drugs.

6.5 For Division 8 drugs, where should the standard CDFT be located if the outer label cannot fit the entire CDFT?

For Division 8 drugs, the CDFT is required to be located on the outer label. However, if required information cannot fit the standard CDFT, available flexibilities should be applied or innovative label can be used (see Appendix 3, Section 2.4 and 2.7 of the Guidance Document: Labelling Requirements for Non-prescription Drugs). When flexibilities are used to move point-of-use information to the package insert of a Division 8 product, sponsors should note that the package insert should follow the format of Part III of the Product Monograph, which is required to be included in the packaging for all Division 8 drugs. Sponsors should ensure that the Part III of the Product Monograph is up-to-date and contains all of the necessary warning information.

6.6 What are the requirements for small packages?

Please refer to the Section 3.6.2 of the Guidance Document: Labelling of Pharmaceutical Drugs for Human Use (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/labelling-pharmaceutical-drugs-human-use-2014-guidance-document.html). Additional guidance on graduated label flexibilities and innovative labels is available in the Section 2.4 of the Guidance Document: Labelling Requirements for Non-prescription Drugs.

Section 7: Labelling for Low Risk Non-prescription Drugs (i.e. Self-Care Framework Category 1 Products)

7.1 What are the labelling requirements for non-prescription drug products proposed to be included in Category 1 of the Self-Care Framework?

Effective December 7, 2018, select Category IV products, mouthwashes and toothpastes that are considered to be low risk and align with the applicable monograph, will be considered as Category 1 products under the Self Care Framework. These products will not be required to present the labelling information in a tabular format.

Only those products that fully align with the following monographs will be subject to the flexibilities described in Table 5 of the Guidance Document: Labelling Requirements for Non-prescription Drugs: Acne Therapy, Anti-Dandruff Products, Antiseptic Skin Cleansers (Domestic/Personal Care Use), Diaper Rash Products, Oral Health, Medicated Skin Care Products, Sunscreen Products.

Unless otherwise noted in the Guidance Document: Labelling Requirements for Non-prescription Drugs, sponsors must include all labelling as required by the Regulations. Sponsors may use the formatting flexibilities identified in Table 5 in order to facilitate the labelling of their Category I products.

Minimum formatting requirements for these Category I products include 6 point sans- serif font, with 6.5 point leading minimum; headings and subheadings that are left justified and in bold font style; and print with 100% line black on a white substrate (alternative ink colours are acceptable when 100% line black is unavailable). Further, the warning information must be kept together (i.e. uninterrupted and on the same panel).

7.2 How do sponsors know if a non-prescription drug will fall into Category 1?

Sponsors must refer to the latest monographs in order to identify whether a product can be labelled using the flexibilities and minimum formatting requirements described in Table 5 of the Guidance Document: Labelling Requirements for Non-prescription Drugs. If the product under consideration does not fully align with the monograph information, the product label is not permitted to employ the Table 5 flexibilities.

7.3 What will Health Canada assess for future Category 1 non- prescription drugs?

Assessment of labelling will remain unchanged. Refer to Section 5.3 of this guidance document.

7.4 When will the new labelling flexibilities for future Category 1 Self Care products be made available?

Submissions made on or after December 7, 2018, can use the new labelling flexibilities. Responses to SDNs after December 7, 2018, may also use the new labelling flexibilities.

7.5 How will the new labelling flexibilities for future Category I Self Care products affect the current flexibilities for Category IV products, mouthwashes and toothpastes?

Effective December 2018, select Category IV products, mouthwashes, and toothpastes that are considered to be low-risk and that align with the applicable monograph, will be considered as Category I products under the Self Care Framework. These products will not be required to present the labelling information in tabular format and will have access to the flexibilities listed in Table 5.

As of December 7, 2018, any Category IV product, mouthwash, or toothpaste that does not align with the applicable monograph can only be labelled using only the flexibilities listed in Table 3 (Canadian Drug Facts Table Format with Graduated Flexibilities), Table 6 (Flexibilities Available for Innovative Labels), or until November 30, 2018, Table 4 (Tailored Flexibilities for Category IV Products, Mouthwashes and Toothpastes).

As of December 7, 2018, the Category IV products, mouthwashes, and toothpastes flexibilities will no longer be available. Sponsors who have filed a submission before December 7, 2018, using these tailored flexibilities will not be required to make another submission in order to align with the updated guidance. Any submission made on or after December 7, 2018, including future submissions associated with products which previously used the Category IV flexibilities, will be required to align with the flexibilities as they are listed in the Guidance Document: Labelling Requirements for Non- prescription Drugs.

Section 8: Glossary

Canadian Drug Facts Table:

A table on the outer label of a non-prescription drug that displays information in a standardized, easy-to-read format. (Tableau canadien d'information sur le médicament)

Inner label:

The label on or affixed to an immediate container of a drug. (étiquette intérieure)

Mock-up:

A full-colour, actual-size copy of the labels and a colour representation (e.g., photograph or PDF) of the packages intended to be used for the sale of the drug, including all presentation and design elements, proposed graphics, fonts, colours, dimensions and text (with a place holder for expiry date, DIN, and lot number). (maquette)

Outer label:

The label on or affixed to the outside of a package of a drug. (étiquette extérieure)

Package:

Includes anything in which any food, drug, cosmetic or device is wholly or partly contained, placed or packed. This does not include cargo or shipping containers. (emballage)

Package insert:

The package insert for non-prescription drugs is usually labelling information that cannot fit on small packages or it is Patient Medication Information (Part III: Consumer Information) of the Product Monograph for Division 8 products. (dépliant d'accompagnement)

Patient leaflet:

A term that is sometimes used to describe printouts of the Product Monograph Part III (Consumer Information) or Patient Medication Information. (dépliant pour le patient)

Plain language:

Plain language is a clear writing style designed to be easy to read and understand by the intended audience. It includes how information is organized and displayed within a space, such as the use of white space, fonts, 'active' instead of 'passive' voice for instructions, design elements, and colour. (langage clair)

Product Monograph:

A factual, scientific document on the drug product that, devoid of promotional material, describes the properties, claims, indications, and conditions of use for the drug, and that contains any other information that may be required for optimal, safe, and effective use of the drug. (monographie de produit)

Appendix 1: Brand Name Screening Criteria

Criteria used to screen a proposed brand name. A 'yes' response to any of these questions would indicate an unacceptable name characteristic:

Screening Criteria	YES	NO
Is the name/modifier overly fanciful, implying unique effectiveness or composition?		
Does the name/modifier overstate product efficacy, minimizes the risk, broadens product indication or makes unsubstantiated superiority claims?		
For a product line extension: Does the product contain a different medicinal ingredient or combination of medicinal ingredients from the established parent product?		
Was the exact name used previously for a well-known product (with a different active ingredient) which is no longer available on the market (i.e. discontinued, inactivated, DIN cancelled, etc.)?		
Does the modifier contain a single letter or number?		
Is the modifier ambiguous and not aid the health professional/consumer in selecting the appropriate medication.		
Does the modifier describe an active ingredient that is not included in the product?		
Does the name contain a medical and/or scientific term or acronym?		
Does the name contain a product name abbreviation?		

Appendix 2: Product Name Review Process in the Non-prescription Drugs Evaluation Division (NDED)

Product name review in the NDED is part of Health Canada's pre-market regulatory approval process. The principal guidance for product name assessment is subsection 9 (1) of the Food and Drugs Act which states "No person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety."

The Act requires that drug names not be misleading with respect to the therapeutic benefits; composition or safety of the product. Currently, in NDED, all proposed brand / product names are assessed using the following criteria:

Potentially Misleading Promotional Terms and Other Terms:	
Misleading with respect to composition	Proposed product name that implies or includes the name of an ingredient that is not included in the drug product
Exaggeration of product merit	Terms/modifiers such as "Severe migraine pain"
Unsubstantiated superiority claims	Terms/modifiers such as "better" or "richer", "stronger"
Minimization of product risk	Terms/modifiers such as "side effect free" "safe"
Implying that the product is therapeutically more effective	Terms/modifiers such as Concentrated, Potent, Strong
Terms such as advanced, improved, maximum strength, original, etc.	The Guidance Document: Labelling of Pharmaceutical Drugs for Human Use (provides conditions under which these terms may be used in product name.
Therapeutic Superlatives	Terms such as "amazing," "fantastic," "remarkable," "wonderful" and other superlative terminology

<table>
<tr><th colspan="2">Potentially Misleading Promotional Terms and Other Terms:</th></tr>
<tr><td>Undue Emphasis</td><td>Highlighting only:
one ingredient in a multi-ingredient product;
one indication in a product treating several symptoms;
A secondary attribute (e.g. non-drowsy); and a non-therapeutic aspect at the expense of the therapeutic purpose (e.g. cleansing ability of a medicated shampoo).</td></tr>
<tr><th colspan="2">Broadening of product indication</th></tr>
<tr><td colspan="2">Safety concerns and potential confusion with another drug product:

• Product name is assessed to minimize the potential risk of confusion with the name of another product.</td></tr>
<tr><th colspan="2">Product Line Extension:</th></tr>
<tr><td>Two or more products containing a root name and a modifier to create a range of products sharing a common active ingredient or combination of medicinal ingredients. The modifier is intended to expand the conditions of use of the initial product by:
1) Containing additional medicinal ingredients (e.g. Root Name dual action - Two active ingredients with different modes of action), examples:

• Route name Allergitidine traditionally associated with ingredient Loratadine with additional medicinal ingredient line extension would be Allergitidine Dual Action (loratadine + Pseudoephedrine hydrochloride)

2) Having differing strengths, examples:

• Root Name Extra Strength

3) Modifying onset of action, examples:

• Root Name Controlled release</td><td>Product line extension that contains a drug product with a different medicinal ingredient or combination of medicinal ingredients from the established parent drug product is not acceptable.</td></tr>
</table>

Potentially Misleading Promotional Terms and Other Terms:	
• Root Name Extended Release 4) Added therapeutic benefit, examples: • Root Name Plus • Root Name Advanced Root Name: An overarching brand name used across a product line.	
Similarity with other products names:	

• In general when assessing the potential for such confusion, the following aspects of the proposed drug product are taken into consideration:
  ○ indication
  ○ target population
  ○ dosage form
  ○ route of administration
  ○ strength
  ○ placement on retail shelf
  ○ packaging
  ○ potential for confusion with a high alert medication.
• Same/similar name used previously for a product that is no longer available on the market (i.e. discontinued).	

Appendix 3: Standard Canadian Drug Facts Table (CDFT) Format

For the Standard CDFT format, refer to Table 2 of the Guidance Document: Labelling Requirements for Non-prescription Drugs.

For the CDFT graduated flexibilities, refer to Table 3 of the Guidance Document: Labelling Requirements for Non-prescription Drugs.

For the CDFT tailored flexibilities for Category IV products, mouthwashes and toothpastes, refer to Table 4 of the Guidance Document: Labelling Requirements for Non-prescription Drugs.

For the flexibilities for labelling of low risk non-prescription drugs (i.e., Self-Care Framework Category 1 Products), refer to Table 5 of the Guidance Document: Labelling Requirements for Non-prescription Drugs.

For the CDFT flexibilities for products using an innovative label, refer to Table 6 of the Guidance Document: Labelling Requirements for Non-prescription Drugs.