Health Canada Santé Canada

Guidance Document

Administrative Processing of Submissions and Applications Involving Human or Disinfectant Drugs

Date adopted: 2017/10/27
Date posted: 2020/10/01
Effective date: 2020/10/01

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.

Également disponible en français sous le titre :
Ligne directrice : Traitement administratif des présentations et des demandes concernant les médicaments destinés aux humains ou les désinfectants

To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: hc.publications-publications.sc@canada.ca

Publication date: October 2020

Cat.: H13-9/25-2020E-PDF

ISBN: 978-0-660-35890-1

Pub.: 200167

Document change log

Date	Change	Location (section, paragraph)	Nature of and/or reason for change
February 16, 2019	Remove references to contact lens disinfectants.	Sections 2.6 and 4, and footnotes under sections 1.2 and 2.3.	Effective February 2018, high level and contact lens disinfectants have been removed from the guidance and are no longer in scope.
June 28, 2019	Minor revisions to improve clarity.	Throughout the document.	Revisions to clarify the submission requirements for submissions processed administratively.
April 1, 2020	Minor revisions, including to remove Notifiable Changes.	Throughout the document	Revisions to reflect the coming into force of updated Cost Recovery regime in April 2020.
October 1, 2020	Minor revisions for Regulatory Enrolment Process.	Throughout the document.	Revisions to reflect the coming into force of the mandatory Regulatory Enrolment Process.

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.

Table of Contents

1. Introduction

Pursuant to Part C, Division 1 and Division 8 of the Food and Drug Regulations (hereafter the Regulations), no manufacturer shall sell a drug in Canada unless a Drug Identification Number (DIN) [C.01.014 (1)] or DIN and Notice of Compliance (NOC) [C.08.002 (1)] have been issued by Health Canada, which grants market authorization for that product. Manufacturers must notify Health Canada of information changes pertaining to the manufacturer and drug product as set out by paragraph C.01.014.4 (b) of the Regulations. For Division 1 drugs, these information changes must, in some cases, be supported by a new DIN Application or Post-Authorization Division 1 Change (PDC) Submission. For Division 8 drugs [C.08.003 (1)], an Extraordinary Use New Drug Submission (EUNDS), New Drug Submission (NDS), Abbreviated NDS (ANDS), Abbreviated EUNDS (AEUNDS)), or applicable Supplement, NC (quality changes for biologics and radiopharmaceuticals) may be required.

For the purpose of this guidance document, Health Canada has determined that certain submissions and applications involving human or disinfectants drugs may be submitted for administrative processing as they do not contain scientific data. These submissions and application should be filed to the Office of Submissions and Intellectual Property (OSIP) of the Resource Management and Operations Directorate (RMOD).

1.1 Policy objective

To clarify the requirements for eligible drug submissions and applications that will be processed under the administrative pathway.

The only policy that explicitly governs the administrative processing of submissions and applications is the Changes in Manufacturer's Name and/or Product Name (CMPN) Policy, written in 1998 and updated in 2001, 2015[1] and 2017[1]. The Policy outlined the conditions and procedures by which Health Canada processed administratively a change in manufacturer name or product name as a result of certain business circumstances, when there were no deviations to the product.

This guidance document supersedes the above-noted Policy.

1.2 Policy statements

To be eligible for administrative processing, all aspects of the submission and application pertaining to the drug product, except for the manufacturer name and/or product name, must be identical to those previously authorized for that product. These include, but are not limited to, the submission type, all clinical data, chemistry and manufacturing data, product formulation(s), strength(s), route(s) of administration, dosage form(s), authorized indication(s) and condition(s) of use as well as all product labels[2]. Any deviations from the previously authorized product will not be acceptable under the administrative pathway.

Submissions and applications may be processed administratively only if the original manufacturer's drug product has received authorization from Health Canada [i.e., a DIN for Division 1 drugs and a DIN/NOC for Division 8 drugs]. DINs associated with the administrative filing must not have a cancelled status at the time of submission or application filing. For more information on DIN re-issuance, refer to the Guidance Document: Regulatory Requirements for Drug Identification Numbers (DINs).

Health Canada has the regulatory authority to consider brand names when making a decision on whether or not to grant a DIN or DIN/NOC to a manufacturer.

For application of the Patented Medicines (Notice of Compliance) Regulations, refer to the Guidance Document: Patented Medicines (Notice of Compliance) Regulations.

1.3 Scope and application

This guidance document applies to drug submissions and applications involving biologics, radiopharmaceuticals, and pharmaceuticals for human use (includes prescription and non-prescription drugs) and disinfectants regulated under the Food and Drugs Act. More specifically, it captures a DIN Application [C.01.014.1 (1)] and PDC, EUNDS [C.08.002.01 (1)], NDS [C.08.002 (1)], ANDS or AEUNDS [C.08.002.1 (1)], including Supplements [C.08.003 (1)].

For disinfectant drugs, the implementation date of the guidance document is April 1, 2020.

1.4 Definitions

Brand Name[3] (or proprietary drug name) -

C.01.001 (1) of the Food and Drug Regulations states that a "brand name" means, with reference to a drug, the name, whether or not including the name of any manufacturer, corporation, partnership or individual, in English and/or French:

a. that is assigned to the drug by its manufacturer,
b. under which the drug is sold or advertised, and
c. that is used to distinguish the drug.

Change in Product Ownership -

When a manufacturer transfers the possession of and responsibility for a product to another manufacturer.

Cross-licensed product -

Is a drug product (for which a licensee is seeking market authorization) where all aspects of the submission or application are identical to that of the licensor in terms of all clinical data, chemistry and manufacturing data, product formulation, strength, route of administration, dosage form, authorized indication(s) and condition(s) of use as well as all product labels[2]. For a cross-licensed product to be eligible for administrative processing the licensor's product must have received authorization from Health Canada; its DIN must not have a cancelled status at the time of the licensee's submission or application filing.

Division 1 drug -

A drug authorized pursuant to the requirements of Division 1 in Part C of the Food and Drug Regulations.

Division 8 drug -

A drug authorized pursuant to the requirements of Division 8 in Part C of the Food and Drug Regulations.

Dormant DIN -

Refers to a DIN that was previously marketed in Canada but for which there have been no sales for a period of at least 12 months. The DIN is considered active as the drug is still authorized for sale in Canada and could be marketed again.

Drug Identification Number (DIN) -

A computer-generated 8 digit number assigned by Health Canada to a drug upon market authorization under subsection C.01.014.2 (1) of the Food and Drugs Regulations. It identifies each drug under the Food and Drug Regulations, sold in a dosage form in Canada, and is located on the package label of prescription and non-prescription drugs that have been evaluated and authorized for sale in Canada.

A DIN uniquely identifies the following characteristics:

- Product Name
- Manufacturer Name
- Active Ingredient(s)
- Strength of Active Ingredient(s)
- Dosage Form
- Route(s) of Administration
- Species (for veterinary drugs only)

Drug Product Market Notification -

Form issued by Health Canada in accordance with section C.01.014.2 (1) of the Food and Drug Regulations that contains the DIN assigned for a drug, as well as some of the information included in the drug submission.

In accordance with section C.01.014.3 of the Food and Drug Regulations, the manufacturer must, within 30 days after the day on which the drug is first sold, date and sign the completed Drug Notification Form (DNF) and return it to Health Canada with a statement it that the information it contains is correct and with an indication of the date of that first sale.

Label -

As per the Food and Drugs Act, is interpreted to include labels affixed to the container or packaging of the drug, any separate package inserts[4], product monographs, prescribing information, fact sheets, consumer information/patient medication information (i.e., patient leaflets), patient diaries, or other material containing information specific to the drug product. These separate package labels generated by the manufacturer/sponsor may be included in the packaging or supplied to the consumer at the time of dispensing.

Licensing Agreement -

An agreement between two manufacturers whereby one manufacturer (licensor) supplies a drug product to another manufacturer (licensee) for sale under the second manufacturer's name.

Manufacturer or Distributor (as per section A.01.010 of the Regulations) -

Means a person, including an association or partnership, who under their own name, or under a trade, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug. This is the person or company, to which the DIN is issued.

For the purpose of this guidance document, manufacturer may include an agent authorized to act on their behalf.

Merger or Buyout -

The combining of two or more manufacturers into one, through a purchase, acquisition or a pooling of interests or purchase of controlling interest in one manufacturer by another manufacturer, in order to take over assets and/or operations.

Notice of Compliance -

A notice issued under section C.08.004 or C.08.004.01 of the Food and Drug Regulations to a manufacturer following the satisfactory review of a drug submission for a New Drug.

1.5 Background

The 1998 Changes in Manufacturer's Name and/or Product Name Policy (CMPN) governs the administrative processing of submissions and applications. Since the implementation of the CMPN policy, the number of drug submissions and applications filed under the administrative pathway increased significantly. The guidance document addresses certain policy gaps that were identified throughout the years.

The CMPN policy replaced the policy entitled, Therapeutic Products Directorate Policy Issues: Changes in Manufacturer's Name, January 18, 1996.

2. Guidance for Implementation

2.1 When to file drug submissions and applications for administrative processing

1. Manufacturer name change and/or product name change[5]. These include:
    - Changes in product ownership (i.e., Change in DIN holder)
    - Mergers and buyouts
2. Additional product names[5]
3. Licensing agreements between two manufacturers. These include:
    - Post-authorization labelling changes
    - Post-authorization chemistry and manufacturing updates [Only for products regulated under Schedules C and D of the Food and Drugs Act]

Health Canada will not process drug submissions and applications under the administrative pathway that reference only certain aspects of the cross-referenced drug product (i.e., strengths, dosage forms, routes of administration or indications).

For Division 8 drugs, when a product is authorized for marketing, a NOC will be issued indicating the reason for the submission. For example, if a manufacturer files a submission under the administrative pathway as a result of a licensing agreement between two manufacturers, the NOC will indicate, under the Reason for Submission section, "Administrative - Licensing Agreement between two Manufacturers". Although not exhaustive, a list of examples for different types of administrative changes is included below:

- Administrative - Manufacturer Name Change
- Administrative - Product Name Change
- Administrative - Changes in Product Ownership (i.e. Change in DIN Holder)
- Administrative - Merger/Buyout
- Administrative - Additional Product Name
- Administrative - Licensing Agreement between two Manufacturers
- Administrative - Label Update (to match licensor)
- Administrative – Chemistry and Manufacturing Update (to match licensor – for Schedule C and D products)

2.2 Roles and responsibilities of manufacturers

Manufacturers must meet the pre and post market requirements set out in the Food and Drugs Act and its Regulations.

These include, but are not limited to:

- Keeping the product's safety information up-to-date and filing the appropriate drug submission or application where changes to product labels are required;
- Obtaining authorization from Health Canada for chemistry and manufacturing changes before implementing changes to marketed products, as required by the Regulations (and explained in the Post-DIN and Post-NOC guidance documents).
- Ensuring that Schedule D products meet the requirements of the Biologics and Genetic Therapies Directorate (BGTD)'s lot release program prior to the sale of the lot in Canada.
- Applying for, and obtaining, a Drug Establishment License (DEL) [C.01A.001][6,7], as part of the regulatory requirements associated with selling a drug.
- Complying with Good Manufacturing Practices (GMP) requirements under Division 2 of Part C of the Regulations[7,8].
- Having systems in place to handle complaints, report and monitor the safety and efficacy of drugs (i.e., pharmacovigilance activities), and manage recalls.

2.2.1 Additional responsibilities for licensors and licensees

In addition to the regulatory responsibilities listed above, for licensing agreements:

- Licensors and licensees must have a direct relationship whereby the licensor grants permission to a licensee(s) via a Letter of Authorisation (LoA) to reference their drug submission or application in support of the cross-licensed product. It is not permitted to cross-license an already cross-licensed product.

- Licensors are expected to provide their licensees with the most up-to-date submission or application information to: support the filing of an administratively complete submission or DIN Application; support the development and maintenance of product labels for the cross-licensed product(s); and, ensure consistency with that of the Canadian reference product (CRP), if applicable. Failure to update product labels may impact the approval of the licensee's drug submission or application.
- Licensees must have all required documents available on the premises as prescribed by Division 2 of the GMP Regulations[9].
- Licensees are expected to update their product labels consistently with those of the licensor (refer to 2.4.5.1 Post-Authorization Labelling Changes for timelines). Approvability of the licensee's drug submission or application is contingent on the licensor's product labels being up-to-date. In cases where the licensor's product is a generic drug, it is expected that the licensor's product labels be up-to-date with those of the CRP.
- For licensing agreements involving biologics and radiopharmaceuticals, licensees are expected to file post-DIN and post-NOC chemistry and manufacturing changes accompanied by a LoA and an updated Certified Product Information Document (CPID) (Schedule C and D drugs).

2.3 General document requirements

Manufacturers must satisfy the conditions for obtaining market authorization from Health Canada and are responsible for the quality and completeness of their drug submission or application. Health Canada will not process drug submissions and applications under the administrative pathway that do not include the fully required documents as listed below:

- a signed Administrative Certification Form For Human or Disinfectant Drugs for each drug product, certifying that all aspects of the drug submission or application pertaining to the drug product and product labels[10] are identical, except for manufacturer name and/or product name[2]
- a fully completed Regulatory Transaction Template and Product Information Template under the Regulatory Enrolment Process (REP)[11]
- all proposed labels, including mock-ups as applicable[12]
- a Labels and Packages Certification Form stating that the label and packaging material are similar to the original product with respect to size and placement of graphics, logos and font, as applicable
- a Letter of Authorization (LoA) as applicable and,
- a CPID for Schedules C and D products

2.4 Additional document requirements and submission/application types

2.4.1 Manufacturer name changes

When there is a change to the manufacturer's name or a change to both the manufacturer's and product names[5], manufacturers must file a DIN Application for Division 1 drugs and an EUNDS, NDS, ANDS or AEUNDS for Division 8 drugs. Authorization from Health Canada must be obtained before any changes are made to labels on the market.

2.4.2 Product name changes

When there is a change to an existing product name[5], manufacturers must file a DIN Application for Division 1 drugs or a Supplement to an EUNDS, NDS, ANDS or AEUNDS for Division 8 drugs. Authorization from Health Canada must be obtained before any changes are made to labels on the market.

2.4.3 Changes in product ownership

For changes in product ownership[13] [i.e., Change in DIN holder], it is understood that one manufacturer is acquiring ownership of a product from another manufacturer. For Division 1 drugs, the manufacturer must file a DIN Application. For Division 8 drugs, the manufacturer must file an EUNDS, NDS, ANDS or AEUNDS. Authorization from Health Canada must be obtained before any changes are made to labels on the market.

In addition to the general document requirements, the divesting company must provide an LoA (refer to Appendix 1) stating that it is transferring ownership of its product and associated DIN(s) to the acquiring manufacturer.

2.4.4 Mergers and buyouts

For mergers and buyouts[13], it is understood that the new manufacturer (i.e., acquiring or merged firm) will be the DIN holder and will assume all regulatory responsibilities for product(s) once authorized.

Following a merger or buyout, the new manufacturer must file, for all affected products regardless of market status[14], a DIN Application for Division 1 drugs or an EUNDS, NDS, ANDS or AEUNDS for Division 8 drugs. Authorization from Health Canada must be obtained before any changes are made to labels on the market.

Manufacturers are encouraged to contact Health Canada to discuss filing strategies when a large number of products are affected.

In addition to the general document requirements, the original manufacturer must provide a written confirmation stating that there is a changed business circumstance from the original DIN holder and authorization is given to the new manufacturer (i.e., acquiring or merged firm) to access the drug submission or application.

2.4.5 Licensing agreements

For licensing agreements[13], it is understood that the final dosage form is being supplied by a licensor to the licensee (i.e., the drug is in a form which is ready for use by the consumer without requiring any further manufacturing). For Division 1 drugs, the manufacturer must file a DIN Application. For Division 8 drugs, the manufacturer must file an EUNDS, NDS, ANDS or AEUNDS.

In addition to the general document requirements, the following is required as part of the submission:

An LoA (refer to Appendix 2) from the licensor (i.e., original DIN holder) confirming that:

- Permission is granted to the licensee to reference its drug submission or application for the cross-licensed product and to Health Canada to access the submission or application in support of the licensee's filing
- Labelling information will be kept up-to-date and any label updates will be communicated to licensees to allow them to file identical updates with Health Canada, and
- Any updates to the chemistry and manufacturing information and product formulation will be communicated to licensees to allow them to remain in compliance[15]. For Schedules C and D products, refer to section 2.4.5.3 Post-Authorization Chemistry and Manufacturing Updates [Only for Schedules C and D drug products]

2.4.5.1 Post-Authorization labelling changes

All manufacturers are required under the Regulations to ensure that drug product labels, including the product monograph or prescribing information, are up-to-date and support the products' safe conditions of use.

For licensing agreements, where product labelling identicality is maintained throughout the products' life-cycle, licensees are expected to reflect the licensors' label changes - meaning they should submit identical safety and efficacy updates for their cross-licensed products **within 30 days of the licensors' updates.** For Division 1 drugs, the manufacturer must file a DIN Application or PDC. For Division 8 drugs, the manufacturer must file a Supplement to an EUNDS, NDS, ANDS, or AEUNDS. Authorization from Health Canada must be obtained before any changes are made to labels.

For additional information, refer to the Guidance Document on Post-Drug Identification Number (DIN) Changes and the Post-Notice of Compliance (NOC): Safety and Efficacy Document.

When filing these changes, a licensee must obtain permission from the licensor through a LoA to make reference to its drug submission or application and to allow Health Canada to access the submission or application in support of the licensee's post-authorization labelling change.

2.4.5.2 Post-Authorization deviations to labelling and chemistry and manufacturing

After obtaining market authorization for the cross-licensed product, all aspects of the authorization for the licensee's product must remain identical in every way to that of the licensor's throughout the product's life-cycle, with the exception of the manufacturer name and/or product name.

Should a licensee wish to deviate from the licensor in terms of indication, strength, route of administration, dosage form, labels (for example: changes to label content, addition of packaging size(s), novel label format(s), private label branding etc.), chemistry and manufacturing information or product formulation, these changes will not be eligible for processing under the administrative pathway and will require a drug submission or application with supporting data. Licensees are advised to contact the relevant review bureau to determine the type of submission or DIN Application that should be filed.

In cases where deviations from the licensor's product are filed and approved, the cross-licensed product would no longer be eligible for any future post-authorization filings under the administrative pathway for labelling or chemistry updates to match the licensor, as aspects of the authorization would no longer be considered identical to the licensor. For all drug submissions and applications for cross-licensed products, an Administrative Certification Form and an LoA must be filed when applicable.

Note: Health Canada recognizes that deviations exist for some cross-licensed products approved under the old 1998 CMPN policy. As a result, previously authorized submissions and applications under the old policy that have deviated in the past (prior to the implementation of this guidance document) will be grandfathered and will continue to be eligible for administrative processing provided there are no further deviations and/ or changes to any existing licensing agreements (i.e., change in licensor or new licensing agreements).

2.4.5.3 Post-Authorization chemistry and manufacturing updates [only for Schedules C and D drug products]

For licensing agreements involving biologics and radiopharmaceuticals, licensees are expected to file a drug submission or application following the reporting categories outlined in the Post-Notice of Compliance (NOC) Changes: Quality Document. In the absence of a guidance document specific to quality changes to drugs which were authorized through a DIN Application - Biologics (DIN-B drugs), the Post-Notice of Compliance (NOC) Changes: Quality Document applies to those products.

When filing these changes, a licensee must obtain permission from the licensor through a LoA to make reference to its drug submission or application and to allow Health Canada to access the submission or application in support of the licensee's post-market chemistry and manufacturing change.

Licensees must provide an updated CPID at time of filing, if applicable. For general enquires regarding filing requirements for Schedule C and D drugs, please contact the BGTD by email at hc.bgtd.ora.sc@canada.ca.

2.5 Drug Identification Number (DIN) issuance and notifications

2.5.1 Manufacturer and/or product name changes (including changes in product ownership and mergers / buyouts)

When the appropriate regulatory steps are taken, Health Canada will issue a revised new Drug Notification Form (DNF) with the same sequence of numbers as the original DIN.

These may involve:

- an approved product which is **not marketed** (DIN with an approved or dormant status):

  After the product is authorized for sale, when the manufacturer markets its drug product, it must notify Health Canada within 30 days of the sale of the product [C.01.014.3].

- an approved product which is **marketed**:

  After the change to the product has been authorized for sale, once the manufacturer begins to sell the drug product with the new manufacturer and/or product name, it must notify Health Canada within 30 days of the sale of the product [C.01.014.3].

  Health Canada recommends that there is a 6 month phase-in period to replace the original product labels with the new product labels. Products that are imported without new product labels may face delays or refusals at the border.

  Manufacturers are required to submit a notification to Health Canada when a product has not been sold for a period of 12 consecutive months. Please refer to the Guidance Document: Regulatory Requirements for Drug identification Numbers (DINs).

- a drug product with a **cancelled DIN** (refer to section 2.5.4 Administrative Changes of Products where the DIN is Cancelled).

  If, at any time after the product is authorized for sale, a manufacturer discontinues the sale of its drug product, it must notify Health Canada within 30 days of the discontinuance of sale [C.01.014.7]. This will result in DIN cancellation.

2.5.2 Additional product names

When manufacturers request an additional product name (same product and supplier) through a DIN Application or an EUNDS, NDS, ANDS or AEUNDS, Health Canada will issue a new DIN that has its own unique sequence of numbers in the form of a DNF to the product bearing the additional name to ensure that one DIN is associated to one product name (refer to Section 2.6 on Labelling).

2.5.3 Licensing agreements

If the drug submission or application is authorized, Health Canada will issue a new DIN that has its own unique sequence of numbers in the form of a DNF to licensees entering first time licensing agreements.

When licensees make changes to their licensing agreements and wish to change from one licensor to another, this is considered a new licensing agreement and a new submission or application must be filed that meets the conditions of this guidance. At the request of the licensees, Health Canada may issue a revised DNF with a DIN that the same sequence of numbers, or a new DIN that has its own unique sequence of numbers in the form of a DNF. When a new DIN that has its own unique sequence of numbers is issued in the form of a DNF, the licensee must discontinue their DIN(s) from the previous licensing agreement.

Manufacturers may not be permitted to retain the same sequence of numbers for the DIN and the same brand name as a result of a new licensing agreement for products approved under different regulatory pathways and requirements (i.e. full safety, efficacy and quality data package for an NDS versus comparative bioequivalence data to a CRP for an ANDS).

2.5.4 Administrative changes to products where the Drug Identification Number (DIN) is cancelled

An administrative change to a product where the DIN is cancelled will require a drug submission or application which, upon approval, may result in the issuance of a new DIN with the same sequence of numbers. The submission type and data requirements (if applicable) to support the administrative change will be considered on a case-by-case basis. For more information, contact the DIN Division at the following address:

Office of Submissions and Intellectual Property
Health Products and Food Branch
Resource Management and Operations Directorate
Address Locator: 0201A1
101 Tunney's Pasture Driveway
Ottawa Ontario
K1A 0K9

Email: hc.DIN.sc@canada.ca
Telephone: 613-941-7281
Fax: 613-941-0825

For additional information with respect to DIN cancellations, refer to Health Canada's Guidance Document: Regulatory Requirements for Drug Identification Numbers (DINs).

2.5.4.1 Licensing agreements

When a licensor's DIN is cancelled by Health Canada for safety reasons, Health Canada will cancel the licensee's DIN because the safety data for the cross-licensed product relies on the safety data of the licensor.

When a licensor notifies Health Canada of the discontinuance of sale of its product [C.01.014.7], Health Canada will cancel the licensor's DIN and the licensee will be required to:

a. discontinue the sale of their cross-licensed product, which would result in Health Canada cancelling the DIN following notification from the licensees
b. enter in a new licensing agreement and file a submission/application accordingly, or
c. file their own drug submission or application with supporting data

2.6 Labelling

For manufacturers who are transitioning products due to new business arrangements, Health Canada recommends that there is a 6 month phase-in period to replace the original product labels with new product labels. Products that are imported without new product labels may face delays or refusals at the border.

With the coming into force of the Regulations Amending the Food and Drug Regulations (Labelling, Packaging and Brand Names of Drugs for Human Use), for human prescription products and products administered or obtained through a health professional and human non-prescription products, all manufacturers are required to file mock-ups of their inner and outer labels and packaging in both English and French as part of their submission package at the time of filing.

If a product is sold in multiple package sizes, the submission should include mock-up label(s) of the smallest package size(s) representing identical labels. Mock-ups of the smallest label submitted should be of an identical label format and/or package to each of the other package sizes. 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. In addition, the PM should reflect only those packaging types and sizes being proposed.

Manufacturers will still be required to certify that all aspects of the drug submission or application pertaining to their product remain the same as was previously authorized. In addition, manufacturers will also be required to certify that the proposed labels and packaging are similar to those currently authorized with respect to location and size of the text and graphics (including logos). Manufacturers who wish to change the location and/or size of text and/or graphics are required to file a Labelling Only submission with the appropriate fees (including the Administrative Certification Form and LoA when applicable).

For cross licensed products where an administrative S(A)NDS, DINA or PDC is being filed for labelling updates to match the licensor, mock ups of the inner and outer labels and package inserts do not need to be filed if they were not filed for the cross-referenced product and submission (i.e. the licensor's submission). Sponsors are required to attest to this on the Label and Packages Certification Form for Prescription Drugs.

Where a sponsor is proposing an additional brand name or a change to an existing brand name, if the brand name does not fit within the exemptions set out in the Frequently Asked Questions - Guidance Document for Industry: Review of Drug Brand Names, the submission should be filed as **Labelling Only** submission and should include evidence supporting the product name(s) submitted along with the appropriate fee.

For Division 1 non-prescription products, changes to brand names that cannot be processed administratively, should be filed as DINA Labelling Standard or Labelling Only. The submission class would depend on the original submission class for the product or if brand name assessment data is submitted (refer to the Guidance Document: Questions and Answers: Plain Language Labelling Regulations for Non-prescription Drugs).

Manufacturers are also required to file the Labels and Packages Certification Form with their submission package which includes an attestation to the accuracy of translation.

For additional information about changes resulting from the Plain Language Labelling amendments, consult the Guidance Document: Questions and Answers: Plain Language Labelling Regulations and the Guidance Document: Questions and Answers: Plain Language Labelling Regulations for Non-prescription Drugs.

2.7 Fees

For information related to drug submission/application evaluation fees and annual authority to sell fees, refer to current versions of the Guidance Document: Fees for the Review of Human and Disinfectant Drug Submissions and Applications. How to Pay Fees for Health Products, and the Guidance Document: Fees for the Right to Sell Drugs.

3. Contact information

Questions or comments related to this guidance document should be directed to:

Bureau of Gastroenterology, Infection and Viral Diseases
Health Products and Food Branch
Therapeutic Products Directorate
Address Locator: 0201A1
101 Tunney's Pasture Driveway
Ottawa Ontario
K1A 0K9

Email: hc.bgivd.enquiries.sc@canada.ca
Telephone: 613-941-2566
Fax: 613-941-1183

4. References

Submission/application related documents:

- Administrative Certification Form for Human or Disinfectant Drugs (https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/drug-products/applications-submissions/form/certname-attnom-updated.pdf)
- Blank Certified Product Information Document (Schedule D Drugs) (CPID (Schedule D Drugs)) Template in the CTD Format [2004-05-25] (https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/certified-product-information-document-template-format.html)
- Guidance Document: Fees for the Review of Drug Submissions and Applications (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fees/fees-review-drug-submissions-applications-2019/document.html)
- Guidance Document: Fees for the Right to Sell Drugs (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fees/right-to-sell-drugs-2019/document.html)
- Guidance Document: Post-Drug Identification Number (DIN) Changes (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/post-drug-identification-number-changes.html)

- Guidance Document: Patented Medicines (Notice of Compliance) Regulations (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/patented-medicines/notice-compliance-regulations.html)
- Guidance Document: Management of Drug Submissions and Applications (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/management-drug-submissions/management-drug-applications-2019/document.html)
- Guidance for Sponsors: Lot Release Program for Schedule D (biologic) Drugs (https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/release/guidance-sponsors-program-schedule-biologic-drugs.html)
- How to Pay Fees for Health Products (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/cost-recovery/pay-fees-2019.html)
- Guidance Document: Post-Notice of Compliance (NOC) Changes: Safety and Efficacy Document) (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)
- Guidance Document: Post-Notice of Compliance (NOC) Changes: Quality Document (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/post-notice-compliance-changes/quality-document.html)
- Guidance Document: Regulatory Requirements for Drug Identification Numbers (DINs) (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/regulatory-requirements-drug-identification-numbers/document.html)
- Regulatory Enrolment Process (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/regulatory-enrolment-process.html)

Labelling related guidance documents:

- Guidance Document 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)
- 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)
- Guidance Document: Questions and Answers: Plain Language Labelling Regulations for Prescription Drugs (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/questions-answers-plain-language-labelling-2019/document.html)

- Guidance Document: Questions and Answers: Plain Language Labelling Regulations for Non-prescription Drugs (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/questions-answers-plain-language-labelling-non-prescription-drugs-2019/document.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)
- Labels and Packages Certification Form for Prescription Drugs (https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/drug-products/applications-submissions/forms/labels-packages-certification-form-prescription-products-eng.pdf)
- Labels and Packages Certification Form for Non-prescription Drugs (https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/drug-products/applications-submissions/forms/labels-packages-certification-form-non-prescription-drugs.pdf)

Legislation and regulations:

- Food and Drugs Act (https://laws-lois.justice.gc.ca/eng/acts/f-27/)
- Food and Drug Regulations (https://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/index.html)
- Patented Medicines (Notice of Compliance) Regulations (https://laws-lois.justice.gc.ca/eng/regulations/SOR-93-133/FullText.html)

5. Appendices

Appendix 1: Sample - Attestation - Change in Product Ownership or Merger/Buyout (Divesting Manufacturer)

Appendix 2: Sample - Letter of Authorization (Licensing Agreement)

Appendix 1: Sample - Letter of Authorization - change in product ownership or merger/buyout (divesting manufacturer)

Office of Submissions and Intellectual Property
Health Products and Food Branch
Therapeutic Products Directorate
Address Locator: 0201A1
101 Tunney's Pasture Driveway
Ottawa Ontario
K1A 0K9

Dear Sir or Madam:

RE: (Name of Product)

We confirm that the ownership of the product (state specific product name and DIN) is being transferred to (Acquiring Manufacturer) and acknowledge that Health Canada will issue the same DINs (with the same sequence of numbers) to (Acquiring Manufacturer).

We confirm that we have provided (Acquiring Manufacturer) with the most complete and up-to-date drug submission or application information to: support the maintenance of product labels; and, ensure consistency with that of the Canadian Reference Product, if applicable.

Yours sincerely,

(Authorized signature - Divesting Manufacturer)

(Signee's Name and Title)

Appendix 2: Sample - Letter of Authorization (licensing agreement)

Office of Submissions and Intellectual Property
Health Products and Food Branch
Therapeutic Products Directorate
Address Locator: 0201A1
Ottawa, Ontario
K1A 0K9

Dear Sir or Madam:

RE: (Name of Cross-licensed Product)

(Licensor) hereby authorizes the licensee to reference, and Health Canada to access, (submission type), (Product name), (Control #), and subsequent drug submission or application updates for the product, in order to support the submission or application filed by (licensee) that will be processed administratively for their (product name).

(Licensor) certifies that (Licensee) (product name) will be manufactured, controlled and packaged as per (licensor) using the systems and procedures submitted and authorized by Health Canada.

We confirm that we have provided (Licensee) with the most complete and up-to-date submission or application information to: support the filing of an administratively complete submission or DIN application; support the development and maintenance of product labels for the cross-licensed product(s); and, to ensure consistency with that of the Canadian Reference Product, if applicable. We understand that failure to keep our product labels up-to-date may impact the approval of the licensee's drug submissions or applications.

As the licensor, we acknowledge our responsibility to ensure that:

- Product labels are kept up-to-date and any safety and efficacy updates are communicated to the licensee upon approval.
- Any post-authorization updates to the chemistry and manufacturing data and product formulation are communicated to the licensee.

Yours sincerely,

(Authorized signature - Licensor)

(Signee's Name and Title)

[1] The Policy was updated with the coming into force on June 13, 2015 and June 13, 2017 of the Regulations Amending the Food and Drug Regulations (Labelling, Packaging and Brand Names of Drugs for Human Use).

[2] Due to the regulatory mock-up requirements under the Regulations Amending the Food and Drug Regulations (Labelling, Packaging and Brand Names of Drugs for Human Use), for human prescription and products obtained or administered through a health professional and human non-prescription products, manufacturers are required to certify that the new labels and packaging are similar to those initially approved with respect to location and size of the text and graphics (including logos). Refer to section 2.6 on Labelling.

[3] For the purpose of this guidance document, brand name and product name are interchangeable.

[4] Note that the package inserts could also include wallet cards, tear-off pads and hand-outs directed to the consumer and whose content is Part III of the Product Monograph.

[5] Certain product names cannot be processed administratively. Refer to section 2.6 on Labelling.

[6] For the minimum requirements that must be in place prior to the filing of a DEL Application, consult the document "Drug Establishment Good Manufacturing Practices - Pre-Application Package (Importers, Distributors and Wholesalers)".

[7] Except for low-level disinfectants, which are exempt from these Regulations.

[8] For further information on GMPs, consult the GUI-0001 - Good Manufacturing Practices Guidelines

[9] For further information on GMP, consult "Good Manufacturing Practices (GMP) Questions and Answers".

[10] Refer to section 1.4 on Definitions.

[11] All sections of the Regulatory Transaction Template and Product Information Template are to be completed with requested information by the manufacturer.

[12] For human prescription products and products administered or obtained through a health professional, refer to the Guidance Document Questions and Answers: Plain Language Labelling Regulations. For non-prescription products, refer to the Guidance Document Questions and Answers: Plain Language Labelling Regulations for Non-prescription Drugs.

[13] Refer to section 1.4 on Definitions.

[14] Refer to section 2.5.4 Administrative Changes to Products where the Drug Identification Number (DIN) is Cancelled.

[15] To exercise due diligence, Health Canada may request an attestation of product identicality from the licensee at any time during the products' life-cycle.