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# **GUIDANCE DOCUMENT**

## **Administrative Processing of Submissions and Applications Involving Human or Disinfectant Drugs**

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**Health Products and Food Branch**

<p>Our mission is to help the people of Canada maintain and improve their health.</p> <p style="text-align: right;"><i>Health Canada</i></p>	<p>The Health Products and Food Branch's mandate is to take an integrated approach to the management of the risks and benefits to health related products and food by:</p> <ul style="list-style-type: none"> <li>• minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and</li> <li>• promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.</li> </ul> <p style="text-align: right;"><i>Health Products and Food Branch</i></p>
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*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*

## 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's 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.

**Document Change Log**

<b>Date</b>	<b>Change</b>	<b>Location (section, paragraph)</b>	<b>Nature of and/or Reason for Change</b>
February 16, 2018	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.

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## 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). 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), Supplement or Notifiable Change (NC) 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 applications should be filed to the Office of Submissions and Intellectual Property (OSIP) of the Therapeutic Products Directorate (TPD).

### 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 Policy (CMPN)*, written in 1998 and updated in 2001, 2015<sup>1</sup> and 2017<sup>1</sup>. 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.

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<sup>1</sup> 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)*.

## 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, strength, route of administration, dosage form, authorized indication(s) and condition(s) of use as well as all product labels<sup>2</sup>. Any deviations from the previously approved 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.

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, human pharmaceuticals (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)] and NCs.

For disinfectant drugs, the implementation date of the guidance document is April 1, 2019.

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<sup>2</sup> 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.

## 1.4 Definitions

Brand Name<sup>3</sup> (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<sup>2</sup>. 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. Dormant DINs do not have a cancelled status.

*Drug Identification Number (DIN)* - a computer-generated eight digit number assigned by Health Canada to a drug product prior to being marketed in Canada. It uniquely identifies all drug products sold in a dosage form in Canada and is located on the label of prescription and over-the-counter drug products that have been evaluated and authorized for sale in Canada. A DIN uniquely identifies the following product characteristics: manufacturer; product name; active ingredient(s); strength(s) of active ingredient(s); pharmaceutical form; and route of administration.

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<sup>3</sup> For the purpose of this guidance document, brand name and product name are interchangeable.

*Drug Product Market Notification* - the manufacturer notifies Health Canada of the date of first sale pursuant to section C.01.014.3 of the *Food and Drug Regulations*.

*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<sup>4</sup>, 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. For the purpose of this document, a manufacturer is a DIN holder.

*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.

## 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.

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<sup>4</sup> 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.

## 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<sup>5</sup>. These include:
  - Changes in product ownership (i.e., Change in DIN holder),
  - Mergers and buyouts;
2. Additional product names<sup>5</sup>;
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 *Regulations*].

*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 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)

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<sup>5</sup> Certain product names cannot be processed administratively. Refer to section 2.6 on Labelling.

## 2.2 Roles and Responsibilities of Manufacturers

As DIN holders, 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]<sup>6,7</sup>, 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*<sup>7,8</sup>;
- Having systems in place to handle complaints, report and monitor the safety and efficacy of drugs (i.e., pharmacovigilance activities), and manage recalls.

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<sup>6</sup> 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)" at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/application-package-importers-distributors-wholesalers.html>.

<sup>7</sup> Except for low-level disinfectants, which are exempt from these *Regulations*.

<sup>8</sup> For further information on GMPs, consult the GUI-0001 - Good Manufacturing Practices Guidelines at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents.html>.

### 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 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*<sup>9</sup>.
- 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 an LoA and an updated Certified Product Information Document (CPID) (Schedule C and D drugs).

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<sup>9</sup> For further information on GMP, consult "Good Manufacturing Practices (GMP) Questions and Answers" at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/questions-answers/good-manufacturing-practices-questions-answers.html>.

## 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 by providing the following documentation to OSIP:

- 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<sup>10</sup> are identical, *except for manufacturer name and/or product name*<sup>2</sup>;
- a completed *Drug Submission Application (3011) Form*;
- all proposed labels, including mock-ups as applicable<sup>11</sup>;
- 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 completed *Submission Fee Application Form* and the relevant fee (not applicable to PDCs and NCs);
- a Letter of Authorization (LoA) as applicable; and,
- a Certified Product Information Document (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<sup>5</sup>, 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.

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<sup>10</sup> Refer to section 1.4 on Definitions.

<sup>11</sup> 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*.

### **2.4.2 Product Name Changes**

When there is a change to an existing product name<sup>5</sup>, 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<sup>12</sup> [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<sup>12</sup>, it is understood that the new manufacturer (i.e., acquiring or merged firm) is the DIN holder.

Following a merger or buyout, the new manufacturer must file, for all affected products regardless of market status<sup>13</sup>, 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.

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<sup>12</sup> Refer to section 1.4 on Definitions.

<sup>13</sup> Refer to section 2.5.4 Administrative Changes to Products where the Drug Identification Number (DIN) is Cancelled.

## 2.4.5 Licensing Agreements

For licensing agreements<sup>12</sup>, 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<sup>14</sup>. 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 identity 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, AEUNDS or NC.

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<sup>14</sup> To exercise due diligence, Health Canada may request an attestation of product identity from the licensee at any time during the products' life-cycle.

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, 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 filing that is required.

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.

Note: Health Canada recognizes that deviations exist for some cross-licensed products approved under the old 1998 CMNP 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 BGTD\_ORA@hc-sc.gc.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 new DIN 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 product is authorized for sale, if the manufacturer continues to market its drug product, 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: Cancellation of a Drug Identification Number (DIN) and Notification of the Discontinuation of Sales*.

- 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 (with its own unique sequence of numbers) to the product bearing the additional name to ensure that one DIN is linked 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 (with its own unique sequence of numbers) to licensees entering first time licensing agreements.

For pharmaceuticals, 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 drug submission or application must be filed that meets the conditions of this guidance. In this case, licensees may request that a new DIN be issued with the same sequence of numbers, or its own unique sequence of numbers.

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 will result in the issuance of a new DIN (the same sequence of numbers may be used depending on the change) upon approval. 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  
Therapeutic Products Directorate  
Address Locator: 0201A1  
101 Tunney's Pasture Driveway  
Ottawa Ontario  
K1A 0K9

Email: SIPD-DINrequest@hc-sc.gc.ca  
Telephone: 613-941-7281  
Fax: 613-941-0825

For additional information with respect to DIN cancellations, refer to Health Canada's *Guidance Document: Cancellation of a Drug Identification Number (DIN) and Notification of the Discontinuation of Sales*.

##### *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.

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 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. However, they will also be required to certify that the new labels and packaging are similar to those currently approved 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).

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 on issues 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 Drug Submissions and Applications, How to Pay Fees to the Health Products and Food Branch*, and the *Guidance Document: Fees for the Right to Sell Drugs*. For fee reduction information, refer to the *Guidance Document: Fees for the Right to Sell Drugs* and the *Right to Sell Drug Fee Remission Request and Attestation Form*.

## **3. CONTACT INFORMATION**

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

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

Email: [osip-bppi@hc-sc.gc.ca](mailto:osip-bppi@hc-sc.gc.ca)  
Telephone: 613-941-7281  
Fax: 613-946-5610

## **4. REFERENCES**

### **Submission/Application Related Documents:**

- Administrative Certification Form for Human or Disinfectant Drugs, [https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt\\_formats/pdf/prodpharma/applic-demande/form/certname\\_attnom\\_2017-eng.pdf](https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/form/certname_attnom_2017-eng.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>
- Drug Submission Application (3011) Form [2013-12-12], [https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt\\_formats/pdf/prodpharma/applic-demande/form/hc3011\\_sc3011-eng.pdf](https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/form/hc3011_sc3011-eng.pdf)

- Guidance Document: Fees for the Review of Drug Submissions and Applications [2015-11-20], <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fees/fees-review-drug-submissions-applications.html>
- Guidance Document: Fees for the Right to Sell Drugs [2017-03-14], <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fees/guidance-document-fees-right-sell-drugs.html>
- Guidance Document: Post-Drug Identification Number (DIN) Changes [2013-12-19], <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 [2016-10-27], <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/patented-medicines/notice-compliance-regulations.html>
- Guidance for Industry: Management of Drug Submissions [2013-12-20], <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/management-drug-submissions/industry.html>
- Guidance for Sponsors: Lot Release Program for Schedule D (biologic) Drugs [2005-06-01], <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 to the Health Products and Food Branch [2016-10-19], <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/cost-recovery/pay-fees.html>
- Guidance Document: Post-Notice of Compliance (NOC) Changes: Safety and Efficacy Document [2016-02-02], <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/post-notice-compliance-changes/safety-efficacy-document.html>
- Guidance Document: Post-Notice of Compliance (NOC) Changes: Quality Document [2009-09-02], <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/post-notice-compliance-changes/quality-document.html>

- Right to Sell Drugs Fee Remission Request and Attestation Form [2011-05-30], <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/forms/right-sell-drugs-remission-request-attestation-form.html>
- Drug Submission Application Fee Form, [http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/pdf/prodpharma/applic-demande/form/feef\\_fraisf-eng.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/form/feef_fraisf-eng.pdf)

**Labelling Related Guidance Documents:**

- Guidance Document for Industry: Review of Drug Brand Names [2014-07-02], <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 [2015-06-13], <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 [2013-09-12], <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/product-monograph/product-monograph.html>
- Guidance Document: Questions and Answers: Plain Language Labelling Regulations [2016-09-08], <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/questions-answers-plain-language-labelling-regulations.html>
- Guidance Document: Questions and Answers: Plain Language Labelling Regulations for Non-prescription Drugs [2017-01-19], [http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/guid\\_qa\\_pll\\_qr\\_elc-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/guid_qa_pll_qr_elc-eng.php)
- Frequently Asked Questions - Guidance Document for Industry: Review of Drug Brand Names, [http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/\\_guide/2014-review-examen\\_drug-medicament\\_names-marques/faq-eng.php](http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2014-review-examen_drug-medicament_names-marques/faq-eng.php)
- Mock-Up Labels and Packages Certification Form, [http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/pdf/prodpharma/applic-demande/guide-ld/form-formulaire-mock-labels-packages-maquettes-etiquettes-emballages-eng.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/form-formulaire-mock-labels-packages-maquettes-etiquettes-emballages-eng.pdf)

### **Legislation and Regulations:**

- *Food and Drugs Act*, <http://laws-lois.justice.gc.ca/eng/acts/f-27/>
- *Food and Drug Regulations*, ([http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C\\_c.\\_870/index.html](http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C_c._870/index.html))
- *Patented Medicines (Notice of Compliance) Regulations* (<http://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 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)