DRAFT GUIDANCE DOCUMENT
Administrative Processing of Submissions and Applications Involving Human or Disinfectant Drugs

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Health Products and Food Branch
Our mission is to help the people of Canada maintain and improve their health. 

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The Health Products and Food Branch’s (HPFB) mandate is to take an integrated approach to managing the health-related risks and benefits of health products and food by:

- minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and,
- promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.

| Health Products and Food Branch |

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Également disponible en français sous le titre : Ébauche de la Ligne directrice : Traitement administratif des présentations et des demandes de drogues à usage humain ou pour produits 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.
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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 grant market authorization for that product. Paragraph C.01.014.4 (b) of the Regulations sets out obligations for manufacturers to notify Health Canada of information changes pertaining to the manufacturer and drug product. These information changes must, in some cases, be supported by a new DIN application or Post-Authorization Division 1 Change (PDC) for Division 1 drugs. 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 to the Office of Submissions and Intellectual Property (OSIP) of the Therapeutic Products Directorate (TPD). These submissions and applications do not contain scientific data, or require regulatory review.

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 Change in Manufacturer’s / Product Name Policy (CMPN), written in 1998 and updated in 2001. The Policy outlines the conditions and procedures by which Health Canada processes administratively a change in manufacturer name or product name as a result of certain business circumstances, when there are no deviations to the product.

Once finalized, the guidance document will supersede 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, strength, route of administration, dosage form, authorized indication(s) and condition(s) of use as
well as all product labels\textsuperscript{1}. 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 undergone a full review and received authorization from Health Canada [that is (i.e.), a DIN for Division 1 drugs and a DIN/NOC for Division 8 drugs]. This policy does not apply to secondary licensing agreements between licensees and third-parties.

In addition, for licensing agreements, the licensor’s drug product must be marketed in Canada and market notified with Health Canada [C.01.014.3] at the time of the licensee’s 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 \textit{Patented Medicines (Notice of Compliance) Regulations}, refer to the Guidance Document: \textit{Patented Medicines (Notice of Compliance) Regulations}.

\subsection*{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 \textit{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.

\subsection*{1.4 Definitions}

\textit{Brand Name}\textsuperscript{2} (or proprietary drug name) - C.01.001 (1) of the \textit{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:

\begin{itemize}
\item a. that is assigned to the drug by its manufacturer,
\item b. under which the drug is sold or advertised, and
\end{itemize}

\textsuperscript{1} Due to the regulatory mock-up requirements under the \textit{Regulations Amending the Food and Drug Regulations (Labelling, Packaging and Brand Names of Drugs for Human Use)}, manufacturers of prescription products and those administered or obtained through a health professional 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.

\textsuperscript{2} For the purpose of this guidance document, brand name and product name are interchangeable.
c. that is used to distinguish the drug.

Division 1 drug - a drug that was submitted to Health Canada as a Drug Identification Number application and authorized pursuant to the requirements of Division 1 in Part C of the Food and Drug Regulations.

Division 8 drug - a drug that was submitted to Health Canada as a New Drug Submission and authorized pursuant to the requirements of Division 8 in Part C of the Food and Drug Regulations.

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; route of administration.

Cross-licensed product - is a drug product (for which a licensee is seeking market authorization) for which 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. For a cross-licensed product to be eligible for administrative processing, the licensor’s product must have undergone a full review and received authorization from Health Canada; it must be marketed in Canada and market notified with Health Canada [C.01.014.3 of the Regulations] at the time of the licensee’s filing.

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, 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.

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3 Note that 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 PM.
**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.

**Change in Product Ownership** - when a manufacturer transfers the possession and responsibility for a product to another manufacturer.

### 1.5 Background

The 1998 *Change in Manufacturer’s / 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 draft guidance document addresses certain policy gaps that were identified throughout the years.


### 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. These include:
   - Changes in Product Ownership (i.e., Change in DIN Holder)
   - Mergers and Buyouts

2. Additional Product Names.

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4 Certain product names cannot be processed administratively. Refer to section 2.6 on Labelling.
3. Licensing Agreements between two manufacturers. These include:
   - Post-Authorization Labelling Changes, including Revised/Updated Product
     Monographs or Prescribing Information
   - Post-Authorization Chemistry and Manufacturing Updates (CMC) [Only for products
     regulated under Schedules C and D of the Regulations]

**Health Canada will not process administratively drug submissions and applications that**
reference only certain aspects of the licensor’s submission or application for the 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 - Revised / Updated Product Monograph

### 2.2 Roles and Responsibilities of Manufacturers

All manufacturers (which comprises licensees) filing submissions and applications under the
administrative pathway must meet the same regulatory standards as the original manufacturers.
These include, but are not limited to:

- Adhering to filing requirements, if the information supporting the DIN application is no
  longer correct [sections C.01.014.4 (b), C.01.014.5 and C.08.003 (1) of the Regulations].
  This applies equally to DIN assigned drugs under Division 1 and drugs with an NOC
  under Division 8.

- Complying with the labelling requirements governed by sections 3, 9, and 10 of the
  *Food and Drugs Act* and by sections contained in Parts A, C, D, G, and J of the
  Regulations.

- 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 label updates and 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).

 Applying for, and obtaining, a Drug Establishment License (DEL) C.01A.001, as part of the regulatory requirements associated with selling a drug.

 Assuming responsibility for the drug product such as complying with Good Manufacturing Practices (GMP) requirements under Division 2 of Part C of the Regulations and post-authorization requirements.

 Complying with all other provisions of the Food and Drugs Act and the Regulations, which include having systems in place to handle complaints, report and monitor the safety and efficacy of drugs (i.e., pharmacovigilance activities), and manage recalls.

 Notifying Health Canada of any recalls of their drug product C.01.051.

 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.

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. This policy does not apply to secondary licensing agreements between licensees and third-parties.

 Licensors are expected to provide their licensees 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, ensure

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6 Except for low-level disinfectants which are exempt from these Regulations.

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.

- Licensees are expected to update their product labels consistently with those of the licensor. 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.

### 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 Changes - 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 are identical, except for manufacturer name and/or product name;

- a completed Drug Submission Application (3011) Form;

- all proposed labels, including mock-ups as applicable;

- a Mock-Up 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;

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9 Refer to section 1.4 Definitions.

10 For non-prescription products, these requirements will come into effect in 2017. For prescription products and products administered or obtained through a health professional for human use, refer to the Guidance Document Questions and Answers: Plain Language Labelling Regulations.
● a completed Submission Fee Application Form and the relevant fee (not applicable to PDCs and NCs);

● a Letter of Authorization (LoA); 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, 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, 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.

Certain product names cannot be processed administratively.

2.4.3 Changes in Product Ownership

For changes in product ownership, 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 following must be provided:

1. A written attestation (Refer to Appendix 2) from the acquiring manufacturer attesting that:

   ● It assumes all responsibility for the drug product and no changes are taking place within the drug submission or application including, but not limited to, all clinical, chemistry and manufacturing data, product formulation, strength, route of
administration and dosage forms, authorized indication(s) and condition(s) of use as well as all product labels¹, except for the manufacturer name and/or product name.

- Once the drug product is marketed under the name of the acquiring manufacturer, it will notify Health Canada within 30 days of the sale of its product [C.01.014.3] and submit copies of labels, if applicable. Health Canada expects that there is a 6 month phase-in period to replace the original product labels with the new product labelling.

2. A LoA (Refer to Appendix 3) from the divesting manufacturer 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 buyouts¹¹, 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, 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 following must be provided:

1. A written confirmation from the original manufacturer 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. A written attestation (Refer to Appendix 4) from the new manufacturer stating that:

- It assumes all responsibility for the drug product and no changes are taking place within this drug submission or application including, but not limited to, all clinical, chemistry and manufacturing data, product formulation, strength, route of administration and dosage forms, authorized indication(s) and condition(s) of use as well as all product labels¹, except for the manufacturer name and/or product name.
Once the drug product is marketed under the name of the new manufacturer, it will notify Health Canada within 30 days of the sale of its product [C.01.014.3] and submit copies of labels, if applicable. Health Canada expects that there is a 6 month phase-in period to replace the original product labels with the new product labels.

### 2.4.5 Licensing Agreements

For licensing agreements\(^\text{11}\), 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:

1. A LoA (Refer to Appendix 5) 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. For Schedules C and D products, refer to section 2.4.5.3 Post-Authorization Chemistry and Manufacturing Updates (CMC).

2. A statement of commitment (Refer to Appendix 6) from the licensee confirming that it will:
   - Comply with the regulatory requirements associated with selling a drug and maintain safety and efficacy information updates within 30 days of the licensor; and,
• Remain consistent with the licensor’s post-authorization chemistry and manufacturing updates and product formulation updates\(^\text{11}\). For Schedules C and D products, refer to section 2.4.5.3 Post-Authorization Chemistry and Manufacturing Updates (CMC).

2.4.5.1 Post-Authorization Labelling Changes, including Revised/Updated Product Monographs or Prescribing Information

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 provide 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 a PDC. For Division 8 drugs, the manufacturer must file a supplement to an EUNDS, NDS, ANDS, AEUNDS or an NC. Authorization from Health Canada must be obtained before any changes are made to labels.


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 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

\(^{11}\) To exercise due diligence, Health Canada may request an attestation of product identicality from the licensee at any time during the products’ life-cycle.
supporting data. The cross-licensed product would no longer be eligible for any future filings under the administrative pathway as the aspects of the authorization would no longer be considered identical to the licensor.

2.4.5.3 Post-Authorization Chemistry and Manufacturing Updates (CMC) [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 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.

2.5 Drug Identification Number (DIN) Issuance

2.5.1 Changes in Product Ownership including Mergers and Buyouts

When the appropriate regulatory steps are taken, Health Canada will reissue the same DINs, for all changes in product ownership including mergers or buyouts.

These business arrangements may involve:

- an approved product which is not marketed (DIN with an approved or dormant status):
  
  If the acquiring manufacturer or new manufacturer markets its drug product, it must notify Health Canada within 30 days of the sale of the product [C.01.014.3].

  If, at any time after the transfer is approved, the acquiring manufacturer or new manufacturer discontinues the sale of its drug product [C.01.014.7], this will result in DIN cancellation [C.01.014.6 (1)(a)].
• an approved product which is marketed:

If the acquiring manufacturer or new manufacturer continues to market its drug product, they must notify Health Canada within 30 days of the sale of the product [C.01.014.3].

❖ Health Canada expects that there is a 6 month phase-in period to replace the original product labels with the new product labels.

The acquiring manufacturer or new manufacturer must notify Health Canada within 30 days when a drug product has not been sold for a period of 12 months [C.01.014.12 (2) of the Regulations Amending the Food and Drug Regulations (Shortages of Drugs and Discontinuation of Sale of Drugs)]. This will result in a change to the status of the product in the Drug Product Database (DPD) from ‘marketed’ to ‘dormant’.

If, at any time after the transfer is approved, the acquiring manufacturer or new manufacturer discontinues the sale of its drug product [C.01.014.7], this will result in DIN cancellation [C.01.014.6 (1)(a)].

• a drug product with a cancelled DIN (Refer to section 2.5.4 Transfer of a Cancelled DIN).

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 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

Licensors are expected to keep their DINs active to allow licensees to maintain safety updates.

If the drug submission or application is authorized, Health Canada will issue new DINs 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 will be required to retain the same DIN(s).
In cases where changes in licensing agreements involve cross-licensing products authorized 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), licensees will not be permitted to retain the same DINs as this would be misleading to drug plan providers and patients.

2.5.4 Transfer of a Cancelled Drug Identification Number (DIN)

The transfer of a cancelled DIN will require a drug submission or application, which will result in the reissuance of the DIN upon approval. For more information, contact the DIN Division at the following address:

Office of Submissions and Intellectual Property
Finance Building #2
Tunney’s Pasture, Address Locator: #0201A1
Ottawa, Ontario
K1A 0K9

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

For additional information with respect to DIN cancellations, refer to Health Canada’s Draft 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 licensees 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 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 expects that there is a 6 month phase-in period to replace the original product labels with new product labels.

With the coming into force on June 13, 2015 of the Regulations Amending the Food and Drug Regulations (Labelling, Packaging and Brand Names of Drugs for Human Use), for prescription products and products administered or obtained through a health professional for human use, 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 requesting a product name change, unless the change fits the exemptions set out in the Frequently Asked Questions - Guidance document for Industry - Review of Drug Brand Names, the submission should be filed as a Labelling Only submission and should include evidence supporting the product name(s) submitted along with the appropriate fee.

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 initially 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/graphics are required to file a Labelling Only submission with the appropriate fees.

Manufacturers are also required to file the Mock-up 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 on Plain Language Labelling.

2.7 Fees

3. CONTACT INFORMATION

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

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

Email: OSIP-BPPI@hc-sc.gc.ca
Fax number: 613-946-5610 or 613-941-0825

4. REFERENCES

Submission/Application Related Documents:


• How to Pay Fees to the Health Products and Food Branch (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/costs-couts/crpay_rcfrais_for-eng.php)


• Right to Sell Drugs Fee Remission Request and Attestation Form (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/form/right_sell_form_droit_vendre-eng.php)


Labelling Related Guidances:


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)


5. APPENDICES

• Appendix 1: Administrative Changes - Certification Form

• Appendix 2: Sample - Attestation - Change in Product Ownership (Acquiring Manufacturer)

• Appendix 3: Sample - Letter of Authorization - Change in Product Ownership (Divesting Manufacturer)

• Appendix 4: Sample - Attestation - Merger / Buyout (New Manufacturer)

• Appendix 5: Sample - Letter of Authorization (Licensing Agreement)

• Appendix 6: Sample - Statement of Commitment (Licensing Agreement)
APPENDIX 1: ADMINISTRATIVE CHANGES - CERTIFICATION FORM

Administrative Changes - Certification Form for Human or Disinfectant Drugs

Reason for Submission:

- [ ] Manufacturer Name Change → Existing DIN(s) must be retained
- [ ] Product Name Change → Existing DIN(s) must be retained
- [ ] Manufacturer and Product Name Changes → Existing DIN(s) must be retained
- [ ] Changes in Product Ownership → Existing DIN(s) must be retained
- [ ] Additional Product name → New DIN(s) must be issued
- [ ] Merger/Buyout → Existing DIN(s) must be retained
- [ ] Licensing Agreement between two Manufacturers\(^{12}\) → New DIN(s) issued or Existing DIN(s) retained

Labelling Update (to match Licensor) → Existing DIN(s) must be retained

CMC Update (to match Licensor) → Existing DIN(s) must be retained

I, the undersigned, certify that all aspects of the drug submission or application pertaining to:

(Name of Product) submitted by:

(Name of Manufacturer) are identical to:

(Name of product, Name of Manufacturer) [Current DIN(s)]

except for name changes to the manufacturer and/or product, and that the product will be manufactured in the same location(s) with identical specifications and procedures.

\(^{12}\) If existing DINs are retained, please clearly list the DINs under this check box.
For prescription and products obtained or administered through a health professional for human use only:

Please certify below that the location and size of graphics, text and logos on the inner and outer labels and packaging are similar to the product outlined above. Changes to labels or packaging that fall outside of these elements will require the filing of a Labelling Only submission and a clear indication in the cover letter as to the nature of the administrative change.

I further certify:

- that the location and size of graphics, text and logos on the inner and outer labels and packaging are similar to the product outlined above, or
- that the location and size of graphics, text and logos on the inner and outer labels and packaging are not similar to the product outlined above and this submission is being filed as a Labelling Only submission.

<table>
<thead>
<tr>
<th>Name of Authorized Signing Official and Title</th>
<th>Authorized Signature</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Manufacturer Name</th>
<th>Telephone Number</th>
</tr>
</thead>
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<table>
<thead>
<tr>
<th>Email</th>
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</thead>
</table>
APPENDIX 2: SAMPLE - ATTESTATION - CHANGE IN PRODUCT OWNERSHIP

(ACQUIRING MANUFACTURER)

Office of Submissions and Intellectual Property
Therapeutic Products Directorate
Finance Building, Address Locator: 0201A
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 is being transferred from (Divesting Manufacturer) and acknowledge that Health Canada will reissue the DINs to (Acquiring Manufacturer).

We assume all regulatory responsibilities for the product. We confirm that no changes are taking place within this drug submission or application including, but not limited to, all clinical data, chemistry and manufacturing data, product formulation, strength, route of administration and dosage forms, authorized indication(s) and condition(s) of use as well as all product labels¹, except for the manufacturer name and/or product name.

We will submit a market notification to Health Canada [C.01.014.3] within 30 days of the first day of sale of the product with accompanying labels, if applicable.

Yours sincerely,

(Authorized signature - Acquiring Manufacturer)

(Signee’s Name and Title)
APPENDIX 3: SAMPLE - LETTER OF AUTHORIZATION - CHANGE IN PRODUCT OWNERSHIP (DIVESTING MANUFACTURER)

Office of Submissions and Intellectual Property
Therapeutic Products Directorate
Finance Building, Address Locator 0201A
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 reissue the DINs 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 4: SAMPLE - ATTESTATION - MERGER / BUYOUT (NEW MANUFACTURER)

Office of Submissions and Intellectual Property
Therapeutic Products Directorate
Finance Building, Address Locator 0201A
101 Tunney’s Pasture Driveway
Ottawa, Ontario
K1A 0K9

Dear Sir or Madam:

RE: (Name of Product)

As a result of a (merger or buyout) between (Divesting Manufacturer) and (Acquiring Manufacturer or New Manufacturer), we acknowledge that Health Canada will reissue the DINs to (Acquiring Manufacturer or New Manufacturer).

We assume all regulatory responsibility for the product. We confirm that no changes are taking place within this drug submission or application including, but not limited to, all clinical, chemistry and manufacturing data, product formulation, strength, route of administration and dosage forms, authorized conditions of use as well as all product labels\(^1\), except for the manufacturer name and/or product name.

We will submit a market notification to Health Canada [C.01.014.3] within 30 days of the first day of sale of our product with accompanying labels, if applicable.

Yours sincerely,

(Authorized signature - New Manufacturer)
(Signee’s Name and Title)
APPENDIX 5: SAMPLE - LETTER OF AUTHORIZATION ( LICENSING AGREEMENT )

Office of Submissions and Intellectual Property
Therapeutic Products Directorate
Finance Building, Address Locator 0201A
101 Tunney’s Pasture Driveway
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 update product labels 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)
Office of Submissions and Intellectual Property
Therapeutic Products Directorate
Finance Building, Address Locator 0201A
101 Tunney’s Pasture Driveway
Ottawa, Ontario
K1A 0K9

Dear Sir or Madam:

RE: (Name of Product)

As a drug manufacturer under the Food and Drugs Act and its Regulations, we commit to:

- Comply with all regulatory requirements associated with selling a drug as listed in section 2.2 of the Guidance Document Administrative Processing of Drug Submissions and Applications Involving Human or Disinfectants Drugs.

- Remain identical in every way [i.e., all aspects of the authorization] to the licensor’s product throughout its life-cycle, with the exception of the manufacturer name and/or product name, including filing safety and labelling updates within 30 days of the licensor.

- File the appropriate chemistry and manufacturing updates for our Schedules C and D product(s) subsequent to the licensor's approved post authorization Chemistry and Manufacturing updates such that all aspects of the authorization remain identical to the licensor's product throughout its life-cycle, with the exception of the manufacturer name and/or product name.

Yours sincerely,

(Authorized signature - Licensee)

(Signee’s Name and Title)