POLICY

Changes in Manufacturer’s Name and/or Product Name

Please note: with the coming into force of the *Regulations Amending the Food and Drug Regulations (Labelling, Packaging and Brand Names of Drugs for Human Use)* on June 13, 2015 for human prescription drug products and products administered or obtained through a health professional and on June 13, 2017 for human non-prescription drug products including contact lens disinfectants the following changes to the Change in Manufacturer/Product Name (CMPN) policy take effect for these products:

- all sponsors are required to file mock-ups of their inner and outer labels and packaging as part of their CMPN package at the time of submission.
- 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* (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), submissions should be filed as Labelling Only class and should include evidence supporting the product name(s) submitted along with the appropriate fee.
- sponsors will still be required to certify that all aspects of their product remain the same as was previously approved 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). Sponsors who wish to change the location and/or size of text and/graphics are required to file a Labelling Only class submission with the appropriate fees and indicate clearly that a name change is also required.
- sponsors are also required to file a mock-up labels and packages certification form with their submission package which includes an attestation to the accuracy of translation.

1. PURPOSE

The purpose of this policy is to define the conditions and procedures for the administrative processing of drug submissions pertaining to a change in manufacturer’s name and/or product name following a merger, buy-out or other corporate restructuring or as a result of a licensing agreement.

2. BACKGROUND

If a manufacturer's name for a drug product and/or the product name changes subsequent to a merger, buy-out or other corporate restructuring or as a result of a licensing agreement, Section C.01.014.1 of the Food and Drug Regulations requires that a submission for a Drug Identification Number (DIN) be submitted. For new drugs, a New Drug Submission (NDS) is required. Section C.01.014.3 of the Regulations, requires manufacturers to notify the Health Canada within 30 days of the commencement of sale of a drug product.

New data requirements for DIN submissions were first issued by the Therapeutic Products Program (TPP) in September 1994. The gap between these and former DIN submission requirements is considered to be bridged by the knowledge gained from Canadian market experience for products that received a DIN and were marketed (notified) prior to September 1994. This same knowledge and experience has not been gained on drug products for which DINs were issued but were not notified for sale before this date.

All manufacturers holding a DIN issued prior to September 1994 for a product that has not been notified must submit to Health Canada for review, the data necessary to meet current requirements under the Guideline on Preparation of DIN Submissions (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/preparation-drug-identification-number-submissions.html) should they wish to make any changes to the product and/or begin to market the product. Manufacturers must not market the product until they are advised of the outcome of the review. Health Canada will advise the manufacturer upon the completion of the review if the DIN for that product remains valid. If the DIN remains valid, the manufacturer may then market the product and notify the product for sale with Health Canada within 30 days.

3. SCOPE

This policy applies to eligible drug submissions submitted to Health Canada for administrative processing as a result of a change in the manufacturer’s name and/or product name subsequent to a merger, buy-out or other corporate restructuring or the establishment of a licensing agreement.
This policy replaces the current policy: Therapeutic Products Directorate Policy Issues: Changes in Manufacturer’s Name, January 18, 1996.

4. DEFINITIONS

Licensing Agreement: an agreement between two firms whereby one firm supplies a drug product to another firm for sale under the second firm’s name.

5. POLICY STATEMENT

If a manufacturer's name changes1 and/or the product name for a drug product changes, a DIN Submission for each affected drug product must be submitted to Health Canada. For new drugs, a New Drug Submission is required to be submitted.

All aspects of the drug product, including the conditions of manufacture and sale must be identical to those previously authorized for that product except for:

   a) the manufacturer’s name, and/ or
   b) the product name

In the case of a product name change, the submission for the proposed name change must not make a claim that conflicts with the conditions of the previously issued DIN or Notice of Compliance (NOC).

The New Drug Submission must be cross-referenced to the previous submission for that drug product for which a NOC was issued.

The DIN Submission must be cross-referenced to the previous submission for that drug product. The product must be currently marketed (notified) in Canada.2

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1 Only substantive changes to the manufacturer’s name are required to comply with the requirements stated in this policy. Notice of non-substantive name changes, e.g., the addition of “a Division of...”, “Inc” or “Ltd” following a manufacturer’s name, should be submitted in writing to the Office of Submissions and Intellectual Property of the Therapeutic Products Directorate.

2 DIN Submissions which cross-reference a previous submission for a drug product which is not marketed (not notified) will be subject to a full review.
6. **RESPONSIBILITIES & PROCEDURES**

a) Manufacturers must submit to the Office of Submissions and Intellectual Property (OSIP) of the Therapeutic Products Directorate (TPD) the following documentation:

- a signed Certification Form (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/forms.html) for each drug product, certifying that all aspects of the product and labelling material will remain the same except for the name change(s) in the labelling material and/or Product Monograph;

- for human prescription drug products and those obtained or administered by a health professional and for human non-prescription drug products including contact lens disinfectants,

  a) a further certification that the label and packaging material are similar to the original product with respect to size and placement of graphics, logos and font;
  b) mock-ups of the new labels and packaging;

- a completed Drug Submission Application form(https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodpharma/appllic-demande/form/hc3011_sc3011-eng.pdf);

- labelling material bearing the new name of the manufacturer and/or product name;

- a completed Submission Fee Application Form (https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodpharma/appllic-demande/form/feef_fraisf-2017-eng.pdf); and

- **for new drugs only**, a copy of the Product Monograph is also required.

b) **Merger/Buy-out**

In addition to the documentation listed in 6 a), manufacturers must:

- provide written confirmation of the changed business circumstance from the original DIN owner with authorization to access the cross-referenced submission; and

- provide written notification concerning whether they prefer to have the current DIN
for that drug product reassigned to the new manufacturer name and/or product name or whether they wish to have a new DIN assigned to that product.

- **Licensing Agreement**

  In addition to the documentation listed in 6 a), manufacturers must:

  - provide written authorization from the original DIN owner to access the cross-referenced submission and indicate whether or not the original DIN owner intends to continue to market the product; and
  
  - if the original DIN owner is ceasing to market the product, provide written notification concerning whether they prefer to have the current DIN for that drug product reassigned to the new licensed manufacturer’s name or whether they wish to have a new DIN assigned to that product.


Manufacturers applying for a DIN for a drug product as a result of a licensing agreement will be assigned a new DIN under the licensed manufacturer’s name/product name in cases where the original DIN owner company intends to continue to market the product under its own name.

d) Manufacturers must notify Health Canada within 30 days of the commencement of sale of the drug product under the new manufacturer's name and/or product name.

e) Manufacturers must inform Health Canada when the drug product marketed under the manufacturer's former name is no longer sold. Manufacturers are responsible for the drug product even if the DIN has been discontinued but continues to be available in the marketplace.

7. **FEES**

For information on issues related to Fees for the Review of Drug Submissions and Applications and annual Fees for the Right to Sell Drugs, please refer respectively to current versions of the

8. EFFECTIVE DATE

This policy is effective as of June 13, 2017.