**ADMINISTRATIVE CHANGES[[1]](#footnote-1) - CERTIFICATION FORM**

**(For Human and/or Disinfectant Drug Submissions and Applications)**

**Section A - Reason for Filing (Please select one of the following):**

|  |  |  |
| --- | --- | --- |
|  | Manufacturer Name Change | For these changes, the same[[2]](#footnote-2) DIN(s) will be issued. Please include DIN(s) below.DIN(s) …………… …………… …………… …………… |
|  | Product Name Change[[3]](#footnote-3) |
|  | Manufacturer and Product Name Change3 |
|  | Change in Product Ownership |
|  | Merger/Buyout |
|  | Labelling Update (to match Licensor) |
|  | Chemistry and Manufacturing Update[[4]](#footnote-4) (to match Licensor) |
|  |  |  |
|  | Licensing Agreement between two manufacturers |  New[[5]](#footnote-5) DIN(s) will be issued, **or**  Same[[6]](#footnote-6) DIN(s) may be issued. If Same6 DIN(s), please include DIN(s) below.DIN(s) …………… …………… …………… …………… |
|  |  |  |
|  | Additional product name3 | New5 DIN(s) will be issued |

**Section B - Certification**

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name of manufacturer submitting the application), certify that all aspects of the drug submission or application pertaining to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (proposed brand name), are identical to the cross-referenced product \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (cross-referenced product brand name), that is manufactured by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (manufacturer name), with the following DIN(s) \_\_\_\_\_\_\_\_\_\_\_; \_\_\_\_\_\_\_\_\_\_\_; \_\_\_\_\_\_\_\_\_\_\_, except for a change in the manufacturer name and/or product name and that the proposed product will be manufactured in the same location(s) with identical specifications and procedures.

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| --- |
| 1. **For human prescription drug products, products obtained or administered through a health professional and non-prescription drug products, I certify one of the following**:
* the location and size of graphics, text and logos on the inner and outer labels and packaging are **similar** to the cross-referenced product outlined above; and all other labelling materials (e.g. the product monograph, package insert etc.) **are identical** to the cross-referenced product; and the proposed brand name is acceptable under the administrative pathway.
* the location and size of graphics, text and logos on the inner and outer labels and packaging **are not similar** to the cross-referenced product outlined above; and/or other labelling materials (e.g. the product monograph, package insert etc.) **are not identical** to the cross-referenced product; and/or the proposed brand name is not acceptable under the administrative pathway. A labelling only or labelling standard submission is being filed with a clear indication in the cover letter as to the nature of the change.
* the location and size of graphics, text and logos on the inner and outer labels and packaging **are not similar** to the cross-referenced product outlined above; and/or other labelling materials (e.g. the product monograph, package insert etc.) **are not identical** to the cross-referenced product; and/or a brand name assessment was previously required outside of the administrative pathway. However, these deviations were filed in a submission ***prior to March 1, 2018*** and were approved. No further deviations and/or additional changes (e.g. to labelling, new licensing agreements etc.) other than those to match the cross-referenced product are proposed.
1. **For human non-prescription drugs, I further certify one of the following:**
* that a **standard** Canadian Drug Facts Table (CDFT) or a CDFT with **tailored** flexibilities for Category IV products, mouthwash and toothpaste is used on the outer packaging of the proposed product outlined above, or
* that a CDFT with **identical** **graduated** flexibilities to those of the cross-referenced product is used on the outer packaging of the proposed product outlined above, or
* that a CDFT with **graduated flexibilities** is used on the outer packaging of the proposed product outlined above, but the cross-referenced product either has: a) different graduated flexibilities; b) a standard CDFT, or; c) does not have a CDFT. A labelling only or labelling standard submission is being filed with a clear indication in the cover letter of the nature of the change.
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Name of Authorized Signing Official

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Title of Authorized Signing Official

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Manufacturer Name

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Authorized Signature

……………………………………………………………………………………....

Date

1. For more information on administrative changes, please consult the Guidance Document: Administrative Processing of Submissions and Applications Involving Human or Disinfectant Drugs. [↑](#footnote-ref-1)
2. The same sequence of numbers as the original Drug Identification Number (DIN) will be issued. [↑](#footnote-ref-2)
3. Submissions which include a product name change or an additional product name where a brand name or Look Alike Sound Alike name assessment is required will be ineligible for filing under the administrative pathway. For Division-8 products, these types of changes should be filed as Labelling Only submissions. For Divison-1 products, these types of changes should be filed as Category IV Monograph Drug Identification Number Application/Drug Identification Number Application (DINF/DINA) Labelling Standard, or Labelling Only submissions (depending on the original submission class for the product). [↑](#footnote-ref-3)
4. For schedule C and D products. [↑](#footnote-ref-4)
5. A new sequence of numbers will be issued. [↑](#footnote-ref-5)
6. The same sequence of numbers as the original DIN may be issued if deemed acceptable. [↑](#footnote-ref-6)