# 

# 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 product brand name) are identical to

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (cross-referenced product brand name), 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.

|  |
| --- |
| 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, or * 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. 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.  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. |
|  |

.............................................................................................................

Name of Authorized Signing Official

.............................................................................................................

Title of Authorized Signing Official

.............................................................................................................

Manufacturer Name

……………………………………………………………………………………….

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 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 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)