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Pharma in brief - Canada

Health Canada releases for consultation Draft Guidance Document – Administrative Processing of Submissions and Applications Involving Human or Disinfectant Drugs

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Summary

Health Canada recently released for consultation the Draft Guidance Document – Administrative Processing of Submissions and Applications Involving Human or Disinfectant Drugs. Stakeholders may provide comments on the draft guidance document by email to Policy_Bureau_Enquiries@hc-sc.gc.ca. The consultation period is open until **April 18, 2017.**

Overview

The draft guidance document outlines the conditions and procedures by which Health Canada administratively processes a change in manufacturer name and/or product name as a result of business circumstances (such as licensing arrangements or mergers/buyouts), when there are no deviations to the product.

One finalized, this guidance document will replace Health Canada's policy Change in Manufacturer's / Product Name Policy, which currently governs the administrative processing of drug submissions and applications.

The draft guidance document addresses current policy gaps that have been identified and provides clarity to industry on the requirements under this administrative pathway.

Generally, the types of applications that will be eligible for administrative processing include:

- manufacturer name change
- product name change
- product ownership change (i.e., change in DIN holder)
- merger or buyout
- additional product name
- licensing agreement between two manufacturers (this policy does not govern secondary licensing agreements between licensees and third parties)
- revised/updated product monograph

This draft guidance document provides additional information about the roles and responsibilities of manufacturers, licensors and licensees, as well as the types documentation and attestations required upon submission.

The draft also sets out some expectations on labelling considerations, including a six-month phased-in period to replace original product labels with new product labels for manufacturers transitioning their products under new business arrangements.

Link:

Draft Guidance Document: Administrative Processing of Submissions and Applications Involving Human or Disinfectant Drugs

For more information, please contact your IP/Life sciences or healthcare practice professional at Norton Rose Fulbright Canada LLP.

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