

NEW TRANSITION PLAN FOR NATURAL HEALTH PRODUCTS

On February 4 2013, the 2010 Natural Health Products (Unprocessed Product License Applications) Regulations ("NHP-UPLAR") came to an end. Health Canada has introduced a new transition plan to help industry address the repeal of the NHP-UPLAR and to come into full compliance with the Natural Health Product Regulation ("NHP Regulation") under the *Food and Drugs Act*, R.S.C. 1985.

An 18 month transition period starts this **March 2013** to give companies time to adjust to the repeal of NHP-UPLAR and phase out non-compliant products.

History of NHP-UPLAR

Prior to 2004, natural health products ("NHPs") were regulated either as a food or a drug, often in an inconsistent manner. To address the inconsistencies, the federal government introduced a regulation under the *Food and Drugs Act* specific to NHPs in 2004. This regulation provided a two (2) year transition period for site licensing and a six (6) year transition period for product licensing.

The introduction of the NHP Regulation created an unforeseen amount of unprocessed product license applications, which Health Canada could not resolve by the end of the original six year transition period.

In an effort to deal with the backlog, the government enacted NHP-UPLAR - a

temporary solution for the large quantity of unprocessed applications. In effect, NHP-UPLAR permitted low risk natural health products which had not received a product license from Health Canada to be temporarily exempt from full compliance with the NHP Regulation. These products were given exemption numbers (ENs) and authorized for sale in Canada pending Health Canada's full processing of their corresponding product license application.

Impacts of New Approach for Industry

Going forward, the majority of license applications for NHPs are expected to be processed by Health Canada within 180 days. The government aims to have all NHPs in compliance with the NHP Regulation by **September 1, 2014**.

With the repeal of NHP-UPLAR, Health Canada is no longer issuing ENs. From now on, all NHPs sold in Canada will be required to have either a NHP number (NPN) or a Homeopathic Medicine Number (DIN-HM). This is particularly relevant to retail companies that may need to ensure that they eliminate leftover stock of products that had an EN, but which will not be receiving an NPN or DIN-HM from Health Canada.



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