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## Natural Health Products (Unprocessed Product Licence Applications)

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The *Natural Health Products (Unprocessed Product Licence Applications) Regulations* came into effect on August 4, 2010.

These Regulations provide a temporary solution for Product Licence Applications that have been waiting for a licensing decision for longer than 180 days. An exemption may be obtained for qualified applications that would allow their legal sale prior to obtaining a Natural Health Product licence.

There is a 60-day opt-in period after a product licence application becomes eligible for exemption. If an application for exemption has not been received within this 60-day period, Health Canada will assume that the exemption is not required.

Please note that these Regulations do not apply to products that have a higher risk potential, such as products for children under 12 years of age, for pregnant and breastfeeding women, sterile products for ophthalmic use, products that make Schedule A claims and products that contain a prohibited ingredient or an ingredient that has been under recall or stop sale.

The Regulations will be repealed in 30 months after coming into force, by which time Health Canada expects to process the existing backlog of Product Licence Applications and meet target review times for NHPs.

More information on the Application for Exemption process may be found here:

[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/acts-lois/gazette1/fiche\\_info\\_sheet-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/acts-lois/gazette1/fiche_info_sheet-eng.php)

The formal Regulations including information on eligibility criteria may be accessed via this link:

<http://www.gazette.gc.ca/rp-pr/p1/2010/2010-05-08/html/reg16-eng.html>

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**Dell Tech can assist you with these new regulations by contacting: [cutredtape@delltech.com](mailto:cutredtape@delltech.com)**