Archived Content

Informing You About Natural Health Products

Information Sheet #1 - for Retailers - Informing Yourself

Protecting and promoting the health and safety of Canadians, their families and communities is of paramount importance to the Government of Canada. The Government is committed to ensuring that regulation of natural health products balances the protection of consumers' health and safety with the freedom to choose complementary and alternative products.

What types of products are regulated as "natural health products?"

Natural health product (or NHP) is a term used in Canada to refer to a group of health products including: vitamin and mineral supplements, herbal remedies and other plant-based health products, traditional medicines (such as traditional Chinese medicines and Ayurvedic [East Indian] medicines), homeopathic medicines, fatty acids (such as omega 3, 6 and 9), probiotics and some personal care products such as antiperspirants, medicated shampoos and mouthwashes.

Why were the Natural Health Products Regulations adopted?

The *Natural Health Products Regulations*, which have been in force since January 1, 2004, were put in place after extensive public consultations to help assure that Canadians have access to NHPs that are safe, effective in delivering the health benefits claimed and of high quality. They do so by setting out requirements for the manufacture, packaging, labelling and importation of NHPs for sale in Canada. The Regulations have allowed for the sale in Canada of natural health products which otherwise could not receive market authorization under the *Food and Drug Regulations* that applied to these products prior to 2004. The Regulations outline requirements for detailed label information about NHPs because this was identified by consumers as an important element in helping them to make informed choices.

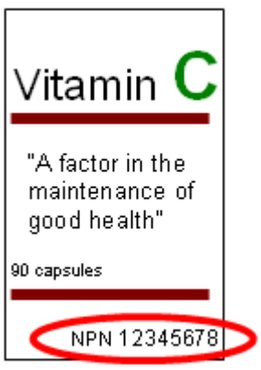
The *Natural Health Products Regulations* are available online at:
http://gazette.gc.ca/archives/p2/2003/2003-06-18/html/sor-dors196-eng.html

How does Health Canada decide which NHPs will be authorized for sale?

Health Canada assesses NHPs for their safety, efficacy and quality before they are authorized for sale in Canada. In assessing NHPs, Health Canada looks at the information provided by the applicant to determine whether the product formula is safe and the health benefit claims are reasonable for the proposed ingredients and dosage amounts. Health Canada assesses any risks which the product may pose, for example, when combining the NHP with other NHPs, prescription drugs or foods, or when the product is used by certain consumers such as pregnant or breast feeding women. Health Canada's assessment assures that appropriate warnings and cautions appear on the product label so that consumers can make informed choices. Health Canada also examines the practices and controls which are applied in the manufacture and processing of the NHPs to ensure that the products are of high quality (e.g. controls to prevent product contamination or a mistake involving use of an incorrect ingredient).

How can I tell which natural health products have been authorized for sale in Canada?

Natural health products that have been authorized for sale by Health Canada will bear a Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) on the product label. The NPN or DIN-HM on the label means that the product has been assessed by Health Canada and is considered safe, of high quality and does what it claims to do.



Further information on NHPs that have been authorized for sale in Canada is available online in the **Licensed Natural Health Products Database (LNHPD):**
www.healthcanada.gc.ca/lnhpd

Can I sell NHPs that do not have a NPN or DIN-HM on the label?

To be sold in Canada, NHPs must meet the requirements of the *Natural Health Products Regulations*.

Prior to the adoption of the *Natural Health Products Regulations* in 2004, some products (e.g. vitamins and minerals) were assessed by Health Canada and issued a Drug Identification Number (DIN). As with a NPN or DIN-HM, a DIN is a valid licence to sell a natural health product in Canada. The use of a DIN for NHPs is being phased out beginning January 1, 2010. Therefore, some NHPs may still be found on store shelves with a DIN on the label and not a NPN or DIN-HM. After a NPN is issued for a product that once had a DIN, the older label stock (bearing the DIN) may still be used and found on the labels of NHPs on the market for a period of time.

Over 19,000 natural health product licences (representing some 25,000 products) have been issued and other products are currently under review and assessment for a licence. In order to allow access to safe NHPs while the review process is being completed for product licence applications currently with Health Canada, Health Canada has adopted a risk-based approach to compliance and enforcement of these unlicensed products.

Under this approach, action is taken (e.g. requesting NHPs be relabelled or be removed from store shelves) specifically when an unacceptable risk to health is identified; when the unlicensed product does not currently have a product licence application under assessment at Health Canada; and/or when the unlicensed product is manufactured, packaged, labelled or imported by Canadian sites that do not hold valid site licences.

This approach allows Health Canada to target those NHPs which present a risk to health without restricting access to other lower-risk NHPs that are awaiting the assessment of their licence application. This explains why unlicensed NHPs without a NPN or DIN-HM or DIN can be found on store shelves.

How long can I continue to sell NHPs that are under review and assessment for a NPN or DIN-HM?

Health Canada has set March 31, 2010 as the target date for completion of the review and assessment of a collection of product licence applications currently under review and assessment. This date is not set out in law or regulations – it is simply an internal date adopted by Health Canada. It is not a date for the removal of products from store shelves that have not yet been authorized for sale.

In keeping with the current approach to compliance and enforcement actions, Health Canada is developing a plan to increase compliance awareness (e.g. the need for a NPN or DIN-HM before products are sold in Canada) and understanding of compliance and enforcement activities (e.g. requests for the removal of NHPs from store shelves or the relabeling of NHPs). Health Canada is working with Industry and other stakeholders to develop an updated compliance and enforcement plan that is appropriate for NHPs now that over 25,000 products have been licensed for sale.

It is anticipated that this compliance and enforcement initiative for NHPs will be in place and implemented sometime in the fall of 2010.

Further information on the compliance and enforcement related to NHPs is available online at:
http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/prodnatur/index-eng.php

Information regarding product advisories, warnings and recalls is available online at:
http://www.hc-sc.gc.ca/dhp-mps/advisories-avis/index-eng.php