
This compliance and enforcement policy is broader in scope than the previous policy and covers such areas as product licensing, site licensing, Good Manufacturing Practices, labeling and advertising.

We are currently in an education and compliance promotion phase.

Products can continue to be marketed with a Submission Number and a valid Site License Number until March 1, 2011.

Full implementation of the policy will begin March 1, 2011.

As of March 1, 2011 all natural health products offered for sale in Canada will require a Natural Health Product Number (NPN or DIN-HM) or Exemption Number (EN) or they may face compliance action.

The following is excerpted from recent (December 3, 2010) Health Canada correspondence to the Canadian Health Food Association. Health Canada is expected to release an official document to all stakeholders shortly.

1. “Leading up to March 1, 2011, product license applicants should prepare to cease the supply of their NHPs without an NPN, DIN HM or EN to their importers, distributors and/or retailers.

2. As of March 1, 2011, manufacturers, packagers and labellers of NHPs without an NPN, DIN HM or EN should stop any further sale and/or importation.

3. Any product that has already been distributed or imported prior to March 1, 2011 would be considered a lower priority for compliance and enforcement for a reasonable period of time (i.e. 6 months), unless a risk to health is identified.

4. A product recall would be expected in cases that may pose a risk to health.”

The letter further discusses Health Canada’s focus with respect to compliance and enforcement “on those products that may pose a risk to health or those that have not made efforts to come into compliance with the requirements of the Natural Health Products Regulations or the Natural Health Products (Unprocessed Product License Applications)
Regulations. The department plans to publish a guideline that will outline how they will proceed with compliance and enforcement starting March 2011 and what the expectations are for industry.

It is imperative that industry apply for licenses as soon as possible for any products on the market that do not currently have an EN, NPN or DIN-HM. Complete applications attesting solely to precleared information should be able to receive a license within 60 days of their receipt by the Natural Health Products Directorate. For more information on licensing requirements please contact dicentra.