



Health  
Canada

Santé  
Canada

### **Health Canada Regulatory Requirements for Natural Health Products**

The upcoming enforcement period for natural health products (aka dietary supplements) in Canada is approaching, and here are some important points:

- On **December 1<sup>st</sup>**, Health Canada will begin strictly enforcing a highly regulated new set of rules that govern the manufacturing, importation and distribution of Natural Health Products (NHPs) in the Canadian marketplace.
- Strict enforcement will happen at the importation and manufacturing level. NHPs will be expected to have final approval licenses (NPNs) in place as well as adhere to the rules governing formulation and labeling.
- Manufacturers, packagers, labellers, and importers of NHPs must hold a valid site license, issued by Health Canada.
- All natural health products shipped to Canada must be imported by a fully licensed and compliant Health Canada Site facility, or they will be refused entry into Canada.
- Failure to comply is seen as putting the health of Canadians at risk, and is a very serious offense. Health Canada will have the right to:
  - Immediately enforce a stop sale and suspension of product
  - Immediately suspend the site license of manufacturers producing unlicensed NHPs.
  - Insist on immediate recall of all distributed products from consumers
  - Post an Import Alert – refusal of products entering Canada
- Enforcement measures beyond the above could include fines & penalties, ban on future importation of other products, postings to other official agencies including the FDA. In some instances, criminal charges may be imposed.