

When a risk issue is identified for a product, Health Canada works with the company to address the risk through voluntary action whenever possible. We focus on situations that pose risks to the health and safety of Canadians, such as poor manufacturing, adulteration (e.g. addition of prescription and non-prescription drugs to NHPs), and products making claims not substantiated by evidence.

In order for a NHP to be approved for use in Canada, companies must provide Health Canada with evidence regarding its safety, quality and efficacy. Nattokinase, a protein made from fermented soybeans, is claimed to break down blood clots and act as a blood thinner. This enzyme is not approved in Canada as a natural health product (NHP) as sufficient evidence regarding its safety, quality and efficacy as a blood thinner has not been provided to Health Canada. NHPs are not sold pursuant to a prescription. Health professional intervention is required to diagnose the need for blood thinners.

Since blood thinners carry a risk of internal bleeding, the Department requires data supporting their safe use. In Canada, companies wishing to sell products containing nattokinase did not include sufficient evidence to support this ingredient in their original applications. Therefore, the Department contacted these companies and gave them another opportunity to demonstrate that the benefits of nattokinase outweigh the risks, and that the product(s) can be used safely. To date, the Department has not received enough evidence to support the safe use of this ingredient as a NHP.

Companies wanting to sell NHPs always have the option of providing information in support of their product, even after an application has been refused. When they do so, Health Canada reviews that information and reconsiders whether the product can be licensed. If the industry can provide the Department with evidence that their product can be used safely, it will reassess its decision based on the new evidence. For additional information, please refer to Health Canada's Notice to Stakeholders, available on the Department's website at: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/nattokinase-eng.php>.

Moving forward, Health Canada remains committed to ensuring that the regulation of NHPs balances the protection of health and safety with freedom of choice, with the aim of empowering Canadians to continue to make informed decisions about their health.

Thank you for sharing your concerns. I appreciate having had this opportunity to respond.

Sincerely,



Adam Gibson  
Director General  
Natural and Non-prescription Health Products Directorate

cc: Mr. Mark Adler, M.P., York Centre