

A Brief Overview of the Canadian Natural Health Products Regulation

By Dr. Y. Bai, July 2006

Before the new Natural Health Products Regulations came into force on January 1, 2004, Natural Health Products (NHPs) were sold as either drugs or foods in Canada under the Food and Drugs Act and Regulations because there was not a special category for NHPs.

In the past most NHPs marketed in Canada were regulated as foods and made no claims. When classified as drugs, NHPs had to comply with the rigorous pharmaceutical drug review process, including proof of safety and efficacy through clinical trials, and receive a Drug Identification Number (DIN) to be sold.

As more and more Canadians discovered the potential health benefits of NHPs and started using NHPs, it became apparent to the Canadian health authorities that neither the drug regulations nor the food regulations were appropriate for the category of NHPs. As a result, a new policy was developed for NHPs and Health Canada published the Natural Health Products Regulations in the Canada Gazette, Part II on June 18, 2003.

The new regulations require all business entities conducting manufacturing, packaging, labelling and importing of NHPs activities to possess site licenses and all natural health products, including the products currently being sold on the market and any new products that are planning to enter to the market, possess product licenses issued by the Natural Health Product Directorate of Health Canada. The compliance process of the new regulations definitely poses a challenge to small to medium size companies.

At Wellgenex, our professional regulatory experts have long time pharmaceutical working experiences under fully GMP compliance environments and as well as have many years' natural health products research experiences.

Product License Application Services:

We will file the Product License Application on behalf of the client by:

- 1) Conducting an initial assessment of the product qualification
- 2) Providing a list of information that the client should submit to the consultant
- 3) Performing a thorough literature search of each medicinal ingredient of the product
- 4) Compiling "Evidence Summary Report", "Safety Summary Report", and "Quality Summary Report"
- 5) Completing the "Natural Health Product License Application Form" and finalize the submission
- 6) Communicating with the NHPD of Health Canada during the entire "Assessment Process" to collaborate with the Client in responding to any further NHPD requirements in a timely manner.

Site License Application Services:

We will file the Site License Application on behalf of the client by:

- 1) Assessing the current operations of the site, identifying deficiencies, and providing corrective action advice
- 2) Developing and implementing a GMP compliance operation system for the client if required, such as Quality Control and Quality Assurance System, Standard Operation Procedures, Recall Reporting System, Sanitation Program, Log Books, Tracking Record, and etc.
- 3) Preparing a set of GMP compliance documentations accordingly
- 4) Providing GMP training session at the site for client's employee and setting up staff training record system
- 5) Compiling "Quality Assurance Report" for the client's operation site
- 6) Completing the "Site License Application Form" and finalize the submission
- 7) Communicating with the NHPD during the entire "Assessment Process" to collaborate with the client in responding to any further NHPD requirements in a timely manner.