Health Canada | Santé Canada
Health Products and Food Branch | Direction générale des produits de santé et des aliments

Natural and Non-prescription Health Products Directorate
250 Lanark Avenue
Ottawa, Ontario K1A 0K9

MAY 19 2017

To Whom It May Concern,

The Natural and Non-Prescription Health Products Directorate (NNHPD) is the regulating authority for natural health products (NHPs) for sale in Canada. Its role is to ensure that Canadians have ready access to NHPs that are safe, effective and of high quality, through the issuance of product and site licences. As of January 1, 2004, all NHPs must comply with the *Natural Health Products Regulations* (NHPR).

The NHPR requires that products meeting the definition of a NHP must, before being sold in Canada, meet the regulatory requirements for safety, efficacy, and quality. Evidence demonstrating these requirements must be submitted to Health Canada by means of a product licence application. In addition, any Canadian site where NHPs are manufactured, labelled, packaged and/or imported must have a site licence. Site licences are obtained by demonstrating that the above-mentioned activities are conducted in accordance with the requirements of the Canadian Good Manufacturing Practices (GMPs) for NHPs.

Recently, following compliance-driven action by the Regulatory Operations and Regions Branch (RORB), the NNHPD was made aware of questions regarding whether herbal concentrated granule products fall under the NHPR. The NNHPD would therefore like to take this opportunity to reiterate the position that any product meeting the definition of a NHP, which is imported in a finished dosage form, is not considered raw material.

In 2012, the NNHPD was made aware of compliance challenges with respect to Traditional Chinese Medicine (TCM) products, such as herbal extract granules, being imported into Canada as unlicensed NHPs. The NNHPD worked with the TCM industry to help facilitate the licensing of TCM products through the development of the TCM monograph and the "Pathway for Licensing of Traditional Medicines" guidance document. In addition, information was provided on the requirements of the NHPR as they relate to products found to be in finished dosage form (i.e. products that require no further processing and are ready to use or be administered). The NNHPD has further identified to the TCM industry areas where they could obtain further clarification in both the NHP Compounding Policy and the Natural Health Product Raw Material Policy.

Specifically, when determining whether a product meets the definition of a NHP, Health Canada does not look at a single criterion in isolation. It is the combination of the following that assist in making the determination of whether a material being imported is represented for use as a NHP in finished dosage form:

- Nature of the substance and whether it is inherently therapeutic
- Packaging
- Labelling (including claims)
- Accompanying information/advertising
- Form (e.g. in dosage form)
- Sender
- Recipient (e.g. retail outlet)
- Manner in which it is being sold (i.e. to consumers versus as part of the chain of manufacturing)

Meeting two or more of the criteria above will mean that the product is a finished NHP requiring a product licence.

The NNHPD has determined that herbal concentrated or extract granules and other products that are considered to be in finished dosage form, meet the definition of a NHP. Therefore, product and site licensing are required before they can be sold in Canada. Imported products claiming to be 'herbal teas' but are in fact herbal concentrated granules still meet the definition of a NHP. As such, they shall not be referred to as food products and must be licensed by Health Canada before their entry on the Canadian market. As a reminder, products may not need a claim to be a NHP.

Please note that the NNHPD works closely with the RORB to ensure compliance with the Regulations.

For more information on product licence application forms and templates, please refer to: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index-eng.php.

Site licensing and Quality Assurance Report application forms and templates can be found at: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-site-exploit/form/index-eng.php.

If you have any concerns or questions, please contact NNHPD_DPSNSO@hc-sc.gc.ca.

Sincerely,

Cecilia Lei
Director
Bureau of Policy, Risk Management and Stakeholder Engagement