• CANADA TO CHANGE THE REGULATION OF “FOOD-LIKE” NATURAL HEALTH PRODUCTS •

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On April 17, 2012, Health Canada announced that it will classify and transition all “food-like” natural health products (“NHPs”) to the regulatory framework that governs the sale of food products in Canada. Health Canada’s Natural Health Product Directorate will no longer accept NHP applications for products that are represented, packaged and sold as foods.
Background

Products with added vitamins, minerals or amino acids that appear to be foods, as well as foods advertised with certain health claims, have up to now been marketed as NHPs under the Natural Health Products Regulations ("NHP Regulations"). Some examples of these food-like NHPs are caffeinated energy drinks; juices and waters fortified with vitamins and minerals; yogurts and bars with specific health claims; and granulated and powdered products added to food or drinks.

After almost a decade of regulating these products as NHPs, Health Canada is now of the view that consumers have not been able to distinguish a food-like NHP from a food product—creating confusing and safety concerns.

Health Canada officially began the transition process with its announcement in 2011 that it would regulate caffeinated energy drinks as foods. Health Canada has, however, now expanded the products subject to this transition to include all food-like NHPs.

Practical Implications

Any product that has been regulated as an NHP and that has "food-like qualities" will now be regulated as a food. These products will be subject to the prescribed nutrition, ingredient and allergen labelling requirements of the Food and Drug Regulations ("FD Regulations"), because they will be regulated as foods. In particular, the label for each product must display a nutrition facts panel, which provides consumers with information regarding the nutrient and caloric content of the food.

Further, only nutritional, general health and risk-reduction claims as prescribed in the FD Regulations will be permitted for food-like NHPs; therapeutic-use claims will not be permitted.

A number of food-like NHPs make claims or contain products that contravene the FD Regulations—for example, non-prescribed vitamins, amino acids or minerals. It is anticipated that the FD Regulations will be amended so that these products can continue to be marketed.

Recognizing the potential challenge in transitioning label claims from NHPs to food products, Health Canada’s Food Directorate has indicated that it is willing to work with interested companies to ensure that claims used on their food labels are compliant with the Food and Drugs Act¹ and its regulations.

Transitional Arrangements

Health Canada has a transition process in place for both new and existing NHPs on the market (i.e., NHPs that have been issued either a Natural Product Number or an Exemption Number, or that are considered subject to an "application in progress").

For existing products that could not be legally sold as a food without a change to the FD Regulations, Health Canada will transition these NHPs to foods through the issuance of Temporary Marketing Authorization Letters ("TMA Letters") and/or Interim Marketing Authorizations (subject to the conditions set out in the TMA Letters).

Products that can transition from NHPs to foods "as is" and require no regulatory amendment to accommodate their market access will only need to comply with the mandatory food and allergen labelling requirements under the FD Regulations. Health Canada has suggested that compliance is expected by December 2012, and it has stated that it intends to release submission standards and processing timelines with respect to TMA submissions in July 2012.

For an updated list of foods transitioned from NHP Regulations to the FD Regulations through a TMA Letter, please see the link below.²

Timing

The transition process is expected to be completed by December 2012 to coincide with the repealing of the Natural Health Products (Unprocessed Product Licence Application) Regulations, which is scheduled for February 4, 2013.
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