Advertising Standards Canada to Preclear Natural Health Product Advertising

The Natural Health Products Regulations (“NHP Regulations”) under the Food and Drugs Act (Canada) came into force on January 1, 2004. This summer, Advertising Standards Canada (“ASC”) received authority to review and preclear consumer-directed broadcast and mass print advertising of natural health products to help ensure that advertising complies with the NHP Regulations. Approved advertising copy will be assigned a 9-digit ASC approval number signifying that the advertising complies with regulatory requirements. It is anticipated that advertising guidelines for marketed health products will be completed by early 2005.

Warning Labels for Electric Shock Gag Novelty Products

Health Canada issued a policy statement in August, 2004 asking importers, manufacturers and distributors of electric shock gag novelty products (those that may be mistaken for other commonly used products such as pens, lighters, calculators) to apply warning labels to the product as the shock emitted from these products may be harmful to young children. Specifically, the outside label should have indelibly printed on it or otherwise permanently affixed to it, in both official languages, the following warning statements: “This product is not a toy”; “Please keep out of the reach of children”; and “This product emits an electrical shock”.

Proposed Schedule F Ingredients

The Therapeutic Products Directorate (“TPD”) intends to update Part I of Schedule F to the Food and Drug Regulations (“FDR”) under the Food and Drugs Act (Canada). Part I of Schedule F lists medicinal ingredients that require a prescription for both human and veterinary use. It is proposed that the following ingredients be added to Part I: Adefovir and its salts and its derivatives, Almotriptan and its salts, Cetrorelix and its salts, Ketanserin and its salts, Phenylpropanolamine and its salts and its derivatives for veterinary use, Tadalafil and its salts and Teflubenzuron. Interested persons may make representations to the TPD by September 30, 2004.

Canadian Food Inspection Agency Sends Reminders and Letters Regarding Labelling Matters

No Carbohydrate Claims under the New Regulations

The Canadian Food Inspection Agency (“CFIA”) has published an information letter regarding carbohydrate related claims on foods. Amendments made to the Food and Drug Regulations (“FDR”) under the Food and Drugs Act (Canada) (“FDA”) on January 1, 2003 make nutrition labelling mandatory on most prepackaged foods. Food labels and advertisements must comply with the new FDR by December 12, 2005. Smaller companies meeting certain requirements have until December 12, 2007 to comply. During the transition period, food labels and advertisements may comply with either the former or the new FDR but may not use a combination of both.

Under the former FDR, foods for special dietary use are permitted to use carbohydrate-reduced claims in instances where the food meets the following criteria: (a) prior to carbohydrate reduction, the food must obtain 25% or more of its calories from its carbohydrate content; and (b) when ready to serve there must be a reduction of at least 50% of the available carbohydrate normally found in the product when not carbohydrate reduced and no more calories are provided than if it were not carbohydrate reduced. Under the former FDR, the label must carry the statement “carbohydrate reduced” in close proximity to and of the same type size as the common name. A core nutrition list must appear on the label and the label must state that the food is recommended for “carbohydrate-reduced diets”. The former Guide to Food Labelling and Advertising (“GFLA”) recognizes the use of a “low carbohydrate” claim if the food has 10% or less of available carbohydrates and 2 g or less of available carbohydrates per serving. The former GFLA recognizes the use of a “source of complex carbohydrate” claim if the food contains 10 g or more of starch per serving.

Under the new FDR, carbohydrate claims are not permitted. A limited number of claims may be made for the presence or absence of sugars and for the level of fibre contained in a food. Other express or implied representations (including the use of brand names and trade-marks) about the amount of carbohydrate in a food are also prohibited under the new FDR, unless specifically provided for. Quantitative statements about the amount of a nutrient in a food are permitted under specific conditions (e.g., carbohydrates may be expressed as the number of grams per serving of stated size or as a percentage of the daily value per serving of stated size). No word sets may be used around this type of statement.
Certain rules apply under either regime. For example, the abbreviation “carb” may be used in the context of nutrient content claims or as part of a quantitative statement but may not be used in the nutrition information/Nutrition Facts table. Wording used in brand names and trade-marks must comply with the provisions of the FDR. The terms “net carbohydrate”, “net impact carbohydrate”, “net effective carbohydrate”, “effective carbohydrate” and “digestible carbs” are not accepted. Statements regarding the glycemic index of a food and related claims (e.g., “does not raise blood sugar”) are also not acceptable. Statements or claims implying that a food is for weight reduction are limited to certain foods listed in the FDR.

Compliance and Enforcement Strategy

The CFIA has published an information letter explaining its compliance and enforcement strategy with respect to the FDA and FDR as they relate to food, including the recent amendments to the FDR concerning nutrition labelling, nutrient content claims and diet-related health claims. The CFIA compliance approach is based on risk. It, therefore, will initially focus its efforts on ensuring compliance of those nutrients of greater public health significance (e.g., trans fatty acids, saturated fatty acids and sodium). The CFIA inspection efforts will initially target the company where the food is manufactured or imported. The CFIA intends to principally focus on helping industry implement the new regulations through education. Appropriate enforcement action will be taken in situations where foods are mislabelled such as to cause potential health and safety risks. The CFIA will apply a staged compliance approach, initially focussing on the availability of the Nutrition Facts table, where required, the provision of mandatory information and the appropriate use of claims and eventually moving to more specific measures to verify nutrition values. The CFIA has published the Nutrition Labelling Compliance Test and the 2003 Guide to Food Labelling and Advertising to assist the industry in implementing the new regulations. Health Canada has developed templates to assist in the design of new labels that comply with the FDR.

Accompanying Documentation for Nutrition Labelling

The new FDR requires that written nutrition information accompany each delivery of prepackaged foods exclusively for use as (1) ingredients for further manufacture of other prepackaged products destined for sale at retail to consumers or as (2) ingredients in the preparation of food by a commercial or industrial enterprise or institution, and (3) prepackaged multi-serving ready-to-serve foods intended solely to be served in a commercial or industrial enterprise or institution respectively. The CFIA has published an information letter prescribing situations where nutrition information may be provided through means other than physically accompanying the product when it is delivered. Where foods are shipped on a continual basis, with no change in formulation, the CFIA will allow documentation to be provided to the purchaser with the first shipment provided the purchaser gives written consent. Note, however, that any change to the nutrition information would have to accompany the modified product with its first delivery after the change occurred.

New Names for Retail Pork Cuts

The CFIA has announced changes to the retail pork cut nomenclature system. The changes in the common name will not require any change in cutting methods. For example, the new name for “Loin Tenderloin Portion” or “Loin Tenderloin End” will be “Sirloin”. The CFIA has issued an information letter, which provides a chart outlining the new names to assist with an early transition to the full use of the new names.

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