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What'll it Be?

A whole lot of choices going on

One little understood but important area of food law relates to the issue of whether something you consume is a food or a drug. The regulatory systems are completely different and there has always been major confusion when a product can be both, as, in the case of natural health products. Generally, in the past (with, of course, many exceptions) if a health claim is made, the product is a drug, if not, it's food.

However, the new Nutrition Regulations now allow five diet-related health claims for food. And we also have detailed proposed new regulations that provide a whole new regulatory framework for natural health products, and Health Canada (HC) has also proposed to allow for product specific health claims for food.

The proposed *Natural Health Products Regulations* were published in December, 2001, and should come into effect by this June. They contain provisions for the regulation of the manufacture, packaging, labelling, storage, importation, distribution and sale of Natural Health Products (NHP's). They mandate adverse event reporting and regulatory oversight of the clinical trial process. In short, while many details are still to be determined, they are to be regulated as a subset of drugs.

With the new diet-related health claims now legal, we will see foods being widely advertised as risk reduction for certain diseases while many NHP's will be limited to using the confusing and limiting criteria presently allowed for direct-to-consumer advertising for drugs. At the same time, the *NHP Regulations* permit an NHP to carry on its label or in its advertising structure/function, risk reduction and therapeutic claims, while foods (but for the five diet related health claims) will not. As there is no limitation within the *NHP Regulations* as to dosage form, it's likely that NHPs may have the same look and feel as those foods right next to them on the shelf, except that the NHP will have a permitted claim and the food will not.

The difference between the two products may also include the addition of several substances not permitted to be added to a food, but permitted to be added to an NHP, generally as an active ingredient. For example, orange juice, sold as a food where calcium supplementation is not permitted or orange juice supplemented with calcium, sold as an NHP where it is.

To further complicate matters, HC says it intends to implement a regulatory change permitting a manufacturer to make a product specific health claim for a food. From the manufacturer's perspective, the situation is problematic. Which process of review should be followed? Will the level of evidence be the same, what about the costs? These issues will promote regulatory approval forum shopping, which should not be the basis for deciding on how a product should be regulated.

There is no question that at the present time and into the foreseeable future, products consumed by Canadians that they think are foods will be regulated as a food, drug or NHP. This overlap of regulatory oversight will continue to lead to confusion both for the industry trying to bring the product to market, advertisers trying to decipher the regulatory environment to provide for the appropriate message, and the consumer who wants to make an informed choice. In addition, Canadians are inundated with information on similar products through magazines, television, the internet and catalogues from the U.S., where the regulations are completely different.

My partner Joel Taller has acted for manufacturers of drugs, foods and natural health products for many years. His conclusion: "Our clients have a real sense of uncertainty. Planning for bringing new products to market is actually more complex now. Do we want our product to be a food, food with claim, or NHP?" Well, that depends…

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