

**7. We manufacture health products and we are concerned about competing products being marketed in Canada that we believe to be unsafe. Should we report them to Health Canada?**

Health products are regulated in Canada under the *Food and Drugs Act* (“FDA”) and its specific regulations for food, drugs, cosmetics, medical devices and natural health products. The FDA and its regulations are administered by Health Canada and, for food, the Canadian Food Inspection Agency (“CFIA”). The FDA and the regulations prohibit the advertising and sale of food, drugs, cosmetics, devices, and natural health products that are unsafe. The specific licensing and overall regulatory requirements and the language of the prohibitions vary for food, drugs, cosmetics, devices and natural health products.

To provide support for your position that your competitor’s products are unsafe, you should consider the specific regulatory requirements (for licensing and otherwise) that apply to the competing product. You would provide that information to Health Canada or the CFIA and the applicable agency would determine whether enforcement action is required. The FDA and its regulations authorize Health Canada and the CFIA to take steps such as requiring the manufacturer or importer to obtain or update their licenses and in some cases, requiring the recall of a product.

If your research indicates that the competitor is complying with licensing and other requirements (e.g., good manufacturing practices), you may wish to consider whether the products are being marketed and advertised in a way that is contrary to the FDA and its regulations, or is misleading to consumers. The FDA prohibits direct-to-consumer advertising of most drugs, and the FDA and the *Competition Act* prohibit misleading representations. These prohibitions may apply to the competitor’s advertising and you may be able to interest either Health Canada or the Competition Bureau in investigating the matter.

Finally, you could consider the *Canadian Code of Advertising Standards*, administered by the self-regulatory body, Advertising Standards Canada (“ASC”). Under the *Code*, there are procedures for ASC to review consumer complaints and disputes between advertisers. In addition, for cosmetic products, the ASC administers *Guidelines for Cosmetic Advertising and Labelling Claims*, prepared with Health Canada. If the competing products are being advertised using claims that are unacceptable under these Guidelines, evidence of this contravention should be brought to the attention of Health Canada.

For additional information about the regulatory requirements that could apply to your situation, contact Carol Anne O’Brien at [caob@caobrienlaw.com](mailto:caob@caobrienlaw.com) or (416) 640-7270.