

Health Canada
4595 Canada Way, Suite 400
Burnaby, BC
V5G 1J9

Date: April 9th, 2015

Re. The Importation of Health Products and Cosmetics for Trade Shows and Similar

Dear Sir/Madame,

Health products and cosmetics in Canada are subject to specific import and sale regulations as described in the *Food and Drugs Act (FDA)*, *Food and Drug Regulations (FDR)*, *Natural Health Products Regulations (NHPR)*, *Medical Devices Regulations (MDR)* and the *Cosmetic Regulations (CR)* (please see References below for full details and product definitions).

Please be aware that “sell” (sale) is defined in the *FDA* as including “offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration”.

Medical Devices

Medical Devices imported into Canada are subject to the *FDA* and *MDR*. Medical Devices are divided into four classifications (class I-IV) based on risk, with class IV Medical Devices having the highest risk. Medical Devices (class II-IV), imported for sale in Canada or use on individuals, are required to have medical device licences. Importers and distributors of medical devices require a medical device establishment licence (some exceptions apply – for more detail, see References below).

At this time however, Health Canada does not object to companies importing unlicensed medical devices for display at a trade show or demonstrating to physicians under the following conditions:

- There is no intention to sell the device (including taking orders for the device).
- The device will not be used on an individual.
- The device is labelled with a clear and visible warning that the device is not licensed in accordance with Canadian law.
- The device must be shipped out of Canada after the trade show or demonstration is over.
- At all times during the Canadian trade show or during a demonstration, the medical device is under direct and continuous control of the company.

It is suggested that these medical device imports for tradeshow, be labelled accordingly (as described above) and a letter identifying the device as for tradeshow purposes when imported. This will help to avoid any undue delays in the medical device’s review at the border.

Drugs and Natural Health Products

Drugs and Natural Health Products commercially imported into Canada must meet all applicable requirements of the *FDA*, *FDR* and *NHPR*, including, but not limited to:

- Labelling
- Marketing authorization requirements and Establishment Licence, Site Licence or Establishment Registration requirements; and
- GMP requirements

For more information on what is considered a commercial importation by Health Canada, please refer to section 5.0 of the *Guidance Document on the Import Requirements for Health Products under the Food and Drugs Act and its Regulation* at http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/gui-0084_biu-uif-eng.php

Cosmetics

Cosmetic products commercially imported into Canada are subject to the *FDA* and the *CR*. A cosmetic includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth and includes deodorants and perfumes.

All cosmetic products sold in Canada must be safe to use and must not pose any health risk. The sale of a product includes not only the acceptance of payment, but also accepting orders for the non-compliant product, distribution of samples, and the application of the product on an individual.

Products for sale must meet the requirements of the *FDA* and *CR*. The requirements include, but are not limited to notification, ingredient labelling, presence of warning statements and ensuring that the requirements outlined in the Cosmetic Ingredient Hotlist have been met. For more information on cosmetic requirements, please refer to Health Canada website at <http://www.healthcanada.gc.ca/cosmetics>

For further information please do not hesitate to contact the undersigned.



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References:

Food and Drugs Act: <http://laws-lois.justice.gc.ca/eng/acts/F-27/>

Food and Drug Regulations: http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-1.html#docCont

Natural Health Products Regulations: <http://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/>

Medical Devices Regulations: <http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/page-1.html#docCont>

Cosmetic Regulations: <http://www.hc-sc.gc.ca/cps-spc/cosmet-person/index-eng.php>

Guidance Document on the Import Requirements for Health Products under the Food and Drugs Act and its Regulations: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/gui-0084_biu-uif-eng.php

Import and Export Policy for Health Products under the Foods and Drugs Act and its Regulations: http://www.hc-sc.gc.ca/dhp-mps/compli-conform/import-export/pol-0060_biu-uif-eng.php