



## **FOOD AND DRUGS AUTHORITY**

# **REQUIREMENTS FOR LABELLING OF PRODUCTS**

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## 1. SCOPE

In pursuance of Section 148 of the Public Health Act 2012, (Act 851), these Guidelines are hereby made to ensure the proper labeling of all cosmetics and household chemical substances

## 2. DEFINITIONS OF TERMS

In these Guidelines, unless the context otherwise states -

- a) "**Authority**" means the Food and Drugs Authority established under Section 80 of the Public Health Act 2012, (Act 851).
- b) "**Product**" means a cosmetics and household chemical substance
- c) "**Container labelling**" Means all information that appears on any part of a container, including that on any outer packaging such as a carton.
- d) "**Container**" includes bottle, jar, box, sachet, polyethylene, aluminium or any other receptacle which contains or is to contain a product regulated under this Law and which is in direct contact with the product to be administered but does not include a capsule.
- e) "**Label**" includes a legend, tag, brand, work or mark, pictorial or any other descriptive matter written, printed, stenciled, marked, embossed or impressed on or attached to a container of a product regulated under this Act.
- f) "**Carton**" means a large cardboard container or box in which goods are packed in smaller containers.
- g) "**Brand name**" means the proprietary name of the product
- h) "**INN**" means International Non-proprietary Name
- i) "**Generic**" means a finished product based on an active substance that is off-patent and which may be marketed under a different name from that of the original branded product or with the INN.
- j) "**IUPAC**" means International Union of Pure and Applied Chemistry
- k) "**INCI**" means International Nomenclature of Cosmetic Ingredients

### **3. REQUIREMENTS**

#### **3.1 General Requirements**

3.1.1 Labelling shall be informative and accurate.

3.1.2 Product labels shall be printed. The print shall be in a clear font and legible. The print shall be indelible and not fade when exposed to sunlight.

3.1.3 The information on a label shall include, but not be limited to, the following:

- (a) The name of the product, and the generic or INN/INCI
- (b) A list of the active ingredients using INN/INCI or IUPAC system, where applicable, showing the amount of each present in a dosage unit.
- (c) The net content of the container
- (d) The batch number
- (e) Date of manufacture and best before/expiry date
- (f) Directions for use, and any warnings or precautions that may be necessary
- (g) Any special storage conditions or handling precautions that may be necessary
- (h) Indications, frequency, route and conditions of use where applicable
- (i) The names of any excipients known to be a safety concern
- (j) Name, postal address and premises address of the manufacturer and Distributor
- (k) Country of origin.

3.1.4 The product name, package or label shall not bear close resemblance to a previously Registered product.

3.1.5 If the original label is in a local or foreign language, the product information shall be in English or a translation thereof.

3.1.6 All products that are not recommended for use in or by children, the statement "not to be taken/used by children" shall be included.

- 3.1.7 All products shall bear the statement "keep out of the reach of children"
- 3.1.8 Products meant for external use shall bear the statement "for external use only"
- 3.1.9 In addition, the name of product shall not be offensive, unethical, socially or traditionally unacceptable, superstitious, magical etc
- 3.1.10 All dosages should be stated in words.
- 3.1.11 For products meant for children, the age ranges shall be specified for each dosage Regimen.
- 3.1.12 The list of indications shall correspond to the known activity of active ingredients declared.
- 3.1.13 Product locally manufactured shall bear FDA registration number

## **3.2 Specific Requirements**

### **3.2.1 Cosmetics**

In addition to clauses a- k (above), claims on cosmetics shall not imply actions that are normally considered therapeutic in nature.

### **3.2.3 Household Chemical Substances**

In addition to clauses a-k (above), household chemical substances shall be required to provide:

- (a) Mode or method of dilution
- (b) Method of application and protection required
- (c) For insecticide aerosols, re-entry periods shall be specified
- (d) Precautions and treatment of accidental ingestion and poisoning
- (e) Appropriate conditions for disposal of the container
- (f) Hazard symbols