S. I. of 2005

DRUGS AND RELATED PRODUCTS (REGISTRATION, ETC) ACT 1999 (AS AMENDED)

Cosmetics Products (Labelling) Regulations 2005

Commencement:

In exercise of the powers conferred on it by Section 8 of the Drugs and Related Products (Registration etc) Act 1999 (as amended) and of all the powers enabling it in that behalf, the GOVERNING COUNCIL OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL with the approval of the Honourable Minister of Health hereby makes the following Regulations:-

1. Prohibition.

No person shall manufacture, import, export, distribute, advertise, display for sale or sell a cosmetic, unless a label has been affixed thereto with the information required by these Regulations appearing on both the inner and outer container (as applicable).

2. Cosmetics not to be described or labelled.

A cosmetic shall not be described or presented on any label -

(a) in a manner which is false, misleading, deceptive or is likely to create an erroneous impression regarding its character, quality, quantity and origin;

(b) by words, pictorial or other means which refer to any other product or suggests either directly or indirectly, that the cosmetics is connected with such other product.


(1) The outer and inner labels of a cosmetic shall be required to bear the name of the cosmetic product which shall indicate the accurate nature of the cosmetic.

(2) Where a class name has been established for the cosmetic, it shall be used in conjunction with the brand name of the cosmetic product.

(3) Where no class name exists for a cosmetic product, an appropriate descriptive name shall be affixed thereto.

(4) Where a coined or fanciful name is used for the cosmetic product, the name shall not be misleading and shall be accompanied by an appropriate descriptive term.

4. List of ingredients.

(1) A complete list of ingredients used in preparing the cosmetic product shall be declared on the outer label and inner label where appropriate in decreasing order of predominance, except that fragrance, colour or flavour may be listed in any order after the other ingredients as fragrance, colour or flavour and an ingredient that is a fragrance, colour and flavour shall be designated by each of the functions it performs, unless such ingredient is identified by name.
(2) Where there is no outer packaging, the list of ingredients shall appear on the inner label.

(3) Ingredients in concentrations of less than 1% may be listed in any order after those concentrations of 1% or more.

(4) For decorative cosmetics, marketed in several colour shades, all colouring agents may be listed, preceded by the words “may contain”.

(5) Where the ingredients of a cosmetic product have more than one component the name of the components shall be included in the list of ingredients.

(6) The declaration of ingredients shall appear with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase.

(7) Where a cosmetic product is also an over-the-counter drug product, the declaration of ingredients shall declare the active drug ingredients as set forth in the Drug Labeling Regulations.

(8) Where the ingredients of a cosmetic product is known to cause hypersensitivity, such shall be declared on the label.

(9) Where multi-packs are involved the following shall apply - where the ingredient labeling is on the outer packaging, the ingredients for each product may be separately listed or combined into one list;

(a) where labeling on the outer packaging is impossible for practical reasons or impracticable for reasons of size or shape, the list shall be given on a leaflet, label, tag, tape or card enclosed with the product and the consumer shall be referred to the text either by abbreviated information or by a special symbol;

(b) if the products within the multi-pack have containers which are individually labeled or printed with an ingredient list, there is no need for a separate leaflet, label, tape, tag or card; and

(c) in the case of transparent packaging, where the ingredient labeling of the products is clearly visible, separate labeling is not required.

(10) For the purposes of labeling, the following shall not be regarded as cosmetic ingredient and need not be shown on the label:

(a) impurities of the raw materials;

(b) subsidiary technical materials used in the preparation of the cosmetic product but not present in the final product; and

(c) materials used in strictly necessary quantities as solvents or as carriers for perfumes and aromatic compositions.

(11) Where the information specified in regulation 4 is impracticable for reasons of size or shape, the information shall be given on a label, tag, tape or card attached to the product and the consumer shall be referred to it, either by abbreviated information or a special symbol on the outer packing.
5. **Net content of cosmetic.**

   (1) The average net content of every cosmetic product shall be declared on the inner and outer label in the metric system.

   (2) Products that have only an inner label shall meet the same requirements as those for the outer labels of products having both an outer and inner label.

   (3) The declaration of the average net content of the cosmetic product shall be required to be made in the case of:
      
      (a) liquid cosmetic in volume;
      
      (b) solid cosmetic by weight and number or count (where applicable); and
      
      (c) semi-solid or viscous cosmetic by weight or volume.

   (4) The declaration shall accurately reveal the quantity of cosmetic in a package exclusive of wrappers and other material packed therewith, provided that:
      
      (a) in the case of cosmetics packed in containers designed to deliver the cosmetic under pressure, the declaration shall state the net quantity of the contents that will be expelled when the instructions for use as shown on the container are followed and the propellant is included in the net quantity declaration;
      
      (b) in the case of a package which contains the integral components making up a complete kit, and which is designed to deliver the components in the manner of an application, the declaration may state the net quantity of the contents in non-deceptive terms of the number of applications available in the kit when the instructions for use as shown on the container are followed; and
      
      (c) the declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package and reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized along with variations from stated quantity of contents which shall not be unreasonably large.

6. **Name, Address and country of manufacture, etc. to be declared.**

   (1) The name and full location address of the manufacturer, packer, distributor, importer, exporter or vendor of a cosmetic shall be specified on both the inner and outer label (where present) in such a manner that is easily readable.

   (2) When a cosmetic product undergoes any processing which affects its contents in another country, such a country shall be considered as the country of manufacture for the purpose of labeling.

7. **Clear, prominent statements, etc.**

   (1) Any statement required to appear on the label of a cosmetic product shall be clear, prominent and legible to the consumer and be of contrasting colour to that of the background.

   (2) No information shall be obscured by design or by other written, printed or graphic matter contained on the label.
3. The letters of the name of the cosmetic product and the net content shall be of a size reasonably related to the predominant character on the label.

4. Where a cosmetic container is covered by a wrapper, the label shall be readily legible through the outer wrapper and not be obscured by it.

5. Where the wrapper carries the required information, it shall be affixed in a manner that is not removable from the cosmetic container.

6. Any extraordinary claims on the cosmetic product shall be substantiated.

8. **Batch number.**

   The batch number shall be indicated on both the inner and outer labels (where present) of all Cosmetic products and where it is impossible, for reasons of size, for details of the batch number to appear on both the primary container and outer packaging, the details shall be given on the outer packaging.

9. **Date marking instructions.**

   1. Unless otherwise specified for a cosmetic product, the day, month and year of manufacture and expiry shall be stated on both the inner and outer labels (where present).
   
   2. The batch number and date markings shall not be pre-printed on the label.

10. **Storage condition.**

    The required special storage conditions shall be specified on both the inner and outer labels (where present).

11. **Trade mark.**

    1. The trade mark shall be displayed on the label such that the trade mark shall not give a wrong impression of the nature, quality or substance of the cosmetic product.

    2. The trade mark registration shall be territorial.

    3. Where the trade mark registration is in conflict with any regulations or requirements of the Agency, the latter shall supersede and prevail.

12. **Registration number.**

    Every cosmetic product shall bear on its label its Registration Number issued on Registration in such a manner as prescribed by the Agency.

13. **Language.**

    Any declaration required to be made under these Regulations shall be in English Language, in addition to any other language(s).

14. **Directions for use.**

    Directions for use, including reconstitution, where applicable, shall be included on the label to ensure correct utilization of the cosmetic product.

15. **Warnings, cautions etc.**

    1. The outer label and inner label of every cosmetic product shall carry clear and adequate warning to prevent any danger in the use of the product.
(2) The following specific requirements shall apply to under-mentioned classes of products –

(a) **Hair Dyes:** Hair dyes containing para-phenylenediamnes or other coal tar dye intermediates, shall bear the following on its outer and inner labels:

   "CAUTION": This product contains ingredients that may cause skin irritation on certain individuals and preliminary test according to accompanying directions should first be made and this product must not be used for dyeing the eye lashes or eyebrows as to do so may lead to blindness".

Instructions similar to the following shall describe how to conduct a preliminary test:

   (i) using either soap and water or alcohol, clean a small area of skin behind the ear or on the inner surface of the forearm,

   (ii) apply a small quantity of the hair dye, as prepared to the area and allow it to dry,

   (iii) after 24 hours, gently wash the area with soap and water, and

   (iv) if no irritation or inflammation is apparent, it may be assumed that no hypersentivity to the dye exists and the test, however should be carried out before each application;

(b) **Pressurized Genital Deodorants:** A deodorant for use in the genital area that is sold in a pressurized container shall carry the following information on its outer and inner labels:

   "Directions: For external use only. Use sparingly and not more than once daily. Spray external skin surface while holding nozzle at least 8 inches from the skin".

(c) **Pressurized Metal Containers:** If the packaging of a pressurized metal container has only an inner label, the following items shall be provided:-

   (i) the explosive symbol shall appear on the display panel of the label,

   (ii) the word “CAUTION” shall appear on the display panel of the label and this signal word shall appear immediately below the symbol and must be printed in boldface type,

   (iii) the message “CONTAINER MAY EXPLODE IF HEATED” shall appear on the display panel of the label and this statement shall appear immediately below the signal word in boldface type,

   (iv) the following statement shall appear on any part on Panel of the label, except the bottom of the container:

      "Contents under pressure. Do not place in hot water or near radiators, stoves or other sources of heat and do not puncture or incinerate container or store at temperatures over 50 degrees Celsius".
(d) For pressurized metal containers having both an outer label and inner label, the following shall apply; if the net quantity of product is:

(i) more than 120ml/120g, the outer label and inner label shall comply with the requirements of regulation 15(2)(c) i-iv,

(ii) 120ml/120g or less but more than 60ml/60g, the outer label shall comply with the requirements of regulation 15(2)(c). i-iv and the inner label shall comply with paragraph 15(2)(c) i-iii but may also comply with paragraph 15(2)(c) iv,

(iii) 60ml/60g or less, the outer label shall comply with paragraph 15(2)(c) i-iv and the inner label shall comply with paragraph 15(2)(c) i and ii but may also comply with paragraph 15(2)(c) iii & iv.

(iv) where the information specified in this Paragraph 15 is impracticable for reasons of size or shape, the information shall be given on a label, tag, tape or card attached to the product and the consumer shall be referred to it, either by abbreviated information or a special symbol on both the primary container and outer packing.

16. Grade Designation.

Where a grade designation is used, it shall be appropriate and readily understandable and not be misleading or deceptive in anyway.

17. Drug related claims.

Where a cosmetic product is labeled to treat or prevent disease or otherwise affect the structure or functions of the human body, such claims establish the product as drug, even if the product is marketed as if it were a cosmetic and shall comply with the Drug labeling Regulations and other Provisions made under the Drug and Related Products Registration, etc) Act (as amended).

18. Soap

(1) Where soap is supplied in a container or wrapper, it shall comply with the labeling requirements set forth in these Regulations.

(2) Where soap is not supplied in a container or wrapper, the name and address of the manufacturer or supplier and the batch number shall be given on either:

(a) the soap itself; or

(b) the packaging in which it is exposed for supply; or

(c) the container in which it was packed before being exposed for supply.

(3) The remaining information, that is:-

(a) minimum durability date;

(b) warning statements and precautionary information;

(c) product function (where applicable); and

(d) ingredient listing,

shall be provided on a leaflet supplied with the soap.
19. **Display information etc. not in conflict with mandatory requirement.**

   (1) Any information required to be displayed on a label which misleads or deceives a consumer in anyway shall constitute an offence under these Regulations.

   (2) No person shall remove, add to, alter, deface or render, illegible any statement upon a label printed on or attached to a wrapper or container in pursuance of these Regulations.

20. **Penalty.**

   (1) A person who contravenes a provision of these Regulations is guilty of an offence and liable on conviction:-

   (a) in case of an individual to a fine not exceeding ₦50,000 or to imprisonment for a term not exceeding two years or to both fine and imprisonment; and

   (b) in the case of a body corporate to a fine not exceeding ₦100,000.

   (2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals -

   (a) every director, manager, secretary or other similar officer of the body corporate; or

   (b) every partner or officer of the firm; or

   (c) every trustee of the body concerned; or

   (d) every person concerned in the management of the affairs of the association; or

   (e) every person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

21. **Forfeiture.**

   In addition to the penalty specified in regulation 20 of these regulations, a person convicted of an offence under these regulations shall forfeit to the Agency the cosmetic products and whatsoever is used in connection with the commission of the offence.

22. **Interpretation**

   **“Container”** means any form of packaging of cosmetic for sale as a single item whether by completely or partially enclosing the cosmetic and includes wrappers;

   **“Ingredient”** includes all substances or mixture of substances used in the manufacture or preparation of cosmetic;

   **“Label”** includes any writing, printed or graphic matter relating to and accompanying the cosmetic product;

   **“Inner label”** means a label on or affixed to the immediate container of a cosmetic;

   **“Outer label”** means a label on or affixed to the outside package of a cosmetic;

   **“Principal display panel”** means the part of a package or label that is most likely to be displayed, presented, shown or examined under customary conditions of display for display for retail sale;
“Address” means where the business of manufacture or sale or distribution or storage or display of cosmetic product is carried out which includes the house number, plot number, street name, Town/City, State, Country, etc.

“Decorative cosmetics” means cosmetic products intended to modify the appearance of the area to which they are applied, usually by the use of colour.

23. Citation.

These Regulations may be cited as the Cosmetics Products (Labeling) Regulations 2005.

MADE at ABUJA this day of 2005.

DR. ANDEM NYONG ANDEM
Chairman Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)