

[**BFAD MEMORANDUM CIRCULAR NO. 19-A S.
1992, July 30, 1992**]

SPECIFIC STANDARDS AND REQUIREMENTS

Pursuant to Administrative Order 150 s. 1971 which provides that a cosmetic specialty shall be distributed only after having been officially registered with the Bureau of Food and Drugs, and to facilitate registration as well as to ensure a uniform application of the standards and requirements for registration, the following specific standards and requirements for the registration of cosmetic product are hereby established and/or confirmed, for the information of all parties concerned.

For purposes of registration and this Circular, cosmetics (or cosmetic specialty) means (1) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) article intended for use as a component of such article except that such term shall not include soap.

SECTION 1. Labelling Requirements for Cosmetic Products

1. Definition of Terms

a. **Label** means a display of written, printed, or graphic matter upon any article or any of its containers or wrappers or attached to or accompanying such articles.

b. **Principal display panel** means the part of the label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. This shall be large enough to accommodate all the mandatory label information required to be placed thereon with clarity and consciousness and without obscuring designs, vignettes, or crowding.

c. **Immediate container** means any form of packaging materials which enclose the article.

d. **Labelling** means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such articles.

e. **Inner Label** means the label on or affixed to an immediate container.

f. **Outer label** means the label on or affixed to the outside package of an article. This is often described as the carton label.

g. **Packaging material** means all items used or attached to bind, enclose, or contain the preparation in the final form for market presentation of the product.

2. All words, statements, and other information required to appear on the label shall be presented in the English or Filipino language. In case of articles distributed solely in a territory where the predominant language is one other than English or Filipino, the predominant language may be used.

3. *General Labelling Requirements for Cosmetic Products* — The labels of all cosmetic products shall bear or contain the following information:

- a. name of the product
- b. Name and address of the manufacturer, importer, distributor or repacker presented conspicuously as one phrase on the principal display panel of the inner and outer label and qualified by the phrase "Manufactured by" or words that express the fact, e.g. "Made by", "Produced by", etc.; provided that when the product is imported, the name of the importer must likewise be printed qualified by the words "Imported By". When these information cannot be printed on the inner label because of justifiable reason(s), the same may be printed on the outer label only.
- c. Net content expressed in standard metric sizes
- d. Registration number
- e. Ingredients known or suspected to cause untoward reaction to some individuals
- f. Directions for use and/or warnings, if any.

4. *Labelling Requirements for Specific products* — In addition to the information generally required for all cosmetic products, the following specific products shall comply with the corresponding specific labelling guidelines or requirements provided hereunder.

A. Cosmetic products packaged in a self-pressurized container and intended to be expelled from the package under pressure shall bear the following:

- a. Directions for use
- b. Warning: "Avoid spraying towards eyes or towards an open flame". Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 48oC. Keep out of reach of children.
 - b.1 For products intended to be used by children, the phrase "except under adult supervision" may be added at the end of the last sentence of the warning.
 - b.2 For products packaged in glass containers the work "break" may be substituted for the word "puncture" in the warning.
 - b.3 For products not expelled as a spray the words "avoid spraying towards eyes" may be deleted from the warning.
 - b.4 For products packaged in a self-pressurized container, the label shall

bear the following additional warning:

"Use only as directed, intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal."

The additional warning statements above are not required for the following products:

1. Products expelled in the form of a foam or cream, which contains less than 10% propellant in the container.
2. Products in a container with a physical barrier that prevents escape of the propellant at the time of use.
3. Products with a net quantity of contents less than 30 g. that are designed to release a measured amount of product with each valve actuation.
4. Products with a net quantity of contents less than 8 g.

B. Hair dyes shall bear the following:

- a. Direction for skin patch test
- b. Direction for use
- c. Warning: "This product contains ingredients which may cause skin irritation to some individuals. Preliminary tests according to the accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness."

When the space on the principal display panel of the immediate container is limited, the above warning may be contained in the carton/outer label.

Direction for skin patch tests and direction for use may be contained in a package insert.

C. Feminine deodorant spray which is defined as spray deodorant product whose labelling represents or suggests that the product is for use in the female genital area, shall bear the following:

- a. Direction for use
- b. Warning: "For external use only. Spray at least 20 cm. away from skin. Do not apply to broken, irritated or itching skin. Persistent, unusual odor or discharge may indicate conditions for which a physician should be consulted. Discontinue use immediately if rash, irritation, or discomfort develops."

Products whose expelled contents do not contain a liquefied gas propellant such as hydrocarbon propellant need not include the sentence "Spray at least 20 cm. away from skin" in the warning.

The use of the word "hygiene" or "hygienic" or words which may represent or suggest that this product has medical usefulness will render this same product

misbranded.

D. Bubble bath products which are added to a bath for foaming effects and which contain surface active agents serving as detergent or foaming ingredients, shall bear the following:

- a. Direction for use.
- b. Warning: "Use only as directed. Excessive use or prolonged exposure may cause irritation to skin and urinary tract. Discontinue use if rash, redness, or itching occur. Consult your physician if irritation persists. Keep out of reach of children."

For products intended for use by children, the phrase "except under adult supervision" may be added at the last sentence of the warning.

E. Shampoos, Conditioners, and Rinses shall bear the direction for use.

F. Shampoos containing egg shall comply with the following guidelines in their labelling:

- a. Shampoos with less than one egg per shampoo should not be referred to as an "egg shampoo" and the word "egg" should not be used as part of the name of the article. The words "plus egg" may be used provided such words appear in subordinate position on the label.
- b. Shampoos containing less than 2% egg need not declare the presence of egg in the preparation.
- c. Shampoos designated as "egg shampoo" should contain one egg (or the equivalent amount of dried whole egg or 2% egg lecithin) in that quantity of product which would be used in one shampooing of the hair.

G. Cosmetics containing borax or boric acid should contain the warning: "For external use only. Do not apply to broken or raw skin, or large area of the body." However, if this cosmetic preparation is rinsed off immediately after its use, the same cosmetic may not contain the said warning.

H. Eyebrow pencils, eyeliners and other cosmetic preparations in pencil form which do not have bottom label need not print the cosmetic registration number on the product itself, provided, however, that the same registration number is printed on the carton or outer label.

I. Hair straighteners, depilatories, perming lotion, and neutralizers shall bear the following:

- a. Direction for use
- b. Warning: "Improper use of this product may cause serious skin irritation."

J. Cosmetics contained in small containers shall comply with the following specific guidelines in labelling:

- a. When the inner label of the cosmetic is too small to accommodate all the information required, a box/carton/outer label or package insert/outsert must be provided to contain all the necessary labelling requirements.
 - b. Cosmetics contained in small containers with bottom labels whose diameter does not exceed 20 mm. and where the other parts of the container are without graphics need not print the cosmetic registration number on the label of the immediate container, provided, however, that the said number is printed on the carton/outer label.
- K. Cosmetics containing flammable ingredients, *e.g.* nail polish, nail enamel, shall contain the warning: "Flammable. Keep away from flame, keep out of reach of children."
- L. Cosmetics intended for use by children shall bear the following:
- a. Direction for use
 - b. Warning: "Use only under adult supervision".
- M. Cosmetics used for controlling dandruff shall contain the warning: For external use only. Avoid contact with eyes. If this happens, rinse thoroughly with water. If condition worsens or does not improve after regular use of this product as directed, consult a doctor."
- N. Cosmetics containing anti-perspirant ingredients shall bear the following:
- a. Direction for use: Apply to underarm. Do not use generally over the body.
 - b. Warning: "Do not apply to broken skin. Some users will experience skin irritation. If irritation develops, discontinue use. Consult physician if necessary."
 - c. Active ingredient/s.
- O. Beauty masks and similar products shall bear the following:
- a. Direction for use
 - b. Warning: Do not apply around the area of the eye.
- P. Suntan products shall bear the following:
- a. Direction for use
 - b. Maximum safe sun exposure period under conditions of prescribed use.
 - c. Necessary warning statements to prevent health hazards.
- Q. Nail hardeners which contains no more than 5% formaldehyde shall bear the following:
- a. Direction for use