ANEXO 11

CAPITULO 5

5.1 Guía De Etiquetado Para Cosméticos De La FDA

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Cosmetics and Colors
October 1991

COSMETIC LABELING GUIDE

CONTENTS

The cosmetics marketed in the United States, whether they are manufactured here or are imported from abroad, must comply with the labeling requirements of the Federal Food, Drug, and Cosmetic (FD&C) Act, the Fair Packaging and Labeling (FP&L) Act, and the regulations published by the Food and Drug Administration under the Authority of these two laws.
The FD&C Act was enacted by Congress to protect consumers from unsafe or deceptively labeled or packaged products by prohibiting the movement in interstate commerce of adulterated or misbranded food, drug devices and cosmetics.

FEDERAL FOOD, DRUG, AND COSMETIC ACT OF 1938, AS AMENDED
TO PROTECT CONSUMERS FROM UNSAFE OR DECEPTIVELY LABELED OR PACKAGED PRODUCTS BY PROHIBITING THE MOVEMENT IN INTERSTATE COMMERCE OF ADULTERATED OR MISBRANDED FOOD, DRUG, DEVICES AND COSMETICS.
21 U.S.C. 321-392

The FP&L Act was passed by Congress to ensure that packages and their labels provide consumers with accurate information about the quantity of contents and facilitate value comparisons.

FAIR PACKAGING AND LABELING ACT
TO ENSURE THAT PACKAGES AND THEIR LABELS PROVIDE CONSUMERS WITH ACCURATE INFORMATION ABOUT THE QUANTITY OF CONTENTS AND FACILITATE VALUE COMPARISONS.
15 U.S.C. 1451-1460

The FD&C Act prohibits the marketing of cosmetics that are adulterated or misbranded as well as their adulteration or misbranding while in interstate commerce.

FEDERAL FOOD, DRUG AND COSMETIC ACT
THE FD&C ACT PROHIBITS THE MARKETING OF COSMETICS THAT ARE ADULTERATED OR MISBRANDED AS WELL AS THEIR ADULTERATION OR MISBRANDING WHILE IN INTERSTATE COMMERCE.
Sec. 301, FD&C Act

Essentially, the "package" is the outer container of a product as, for example, a box or folding carton. However, the "package" can also be the immediate container, e.g., bottle, jar or aerosol can that holds the product if the immediate container is not displayed in a box or folding carton.

PACKAGE
A CONTAINER OR WRAPPING, OTHER THAN A SHIPPING CONTAINER OR WRAPPING, IN WHICH A CONSUMER COMMODITY IS DELIVERED OR DISPLAYED TO RETAIL PURCHASERS.
Sec. 10(b), FP&L Act
21 CFR 1.20

The term "label" is defined in the FD&C Act and the FP&L Act. The definitions differ in that under the FD&C Act definition a label is "a display of written, printed or graphic matter upon the immediate container," and under the FP&L Act definition "written, printed or graphic matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity."

One may say that the term "label" applies in the first instance to the information appearing directly on the immediate container and in the second instance to information attached to the immediate container and directly on or attached to the outer container if so packaged.
The FD&C Act, however, requires in sec 201(k) that any information required to appear on the label of the immediate container shall also appear on the outside container of the retail package or is legible through the outside container.

LABEL
A WRITTEN, PRINTED OR GRAPHIC DISPLAY OF INFORMATION ....

- **ON THE CONTAINER OF A COSMETIC.**

Sec. 201(k), FD&C Act.

- **AFFIXED TO OR APPEARING ON A PACKAGE CONTAINING A CONSUMER COMMODITY.**

Sec. 10(c), FP&L Act
21 CFR 1.3(b)

The FD&C Act defines in sec. 201(m) "labeling" to mean "all labels and other written, printed or graphic matter on or accompanying such article."
This includes labels, inserts, risers, display packs, leaflets, promotional literature or any other written or printed information distributed with a product.

LABELING
ALL LABELS AND OTHER WRITTEN, PRINTED OR GRAPHIC MATERIAL *ON OR ACCOMPANYING* A PRODUCT IN INTERSTATE COMMERCE OR HELD FOR SALE.
Sec. 201(m), FD&C Act
21 CFR 1.3(a)

A label may consist of more than one panel. It may consist of a front panel, side panels and a back panel. Back and side panels are generally called information panels.
The FP&L Act also defines for consumer commodities, or packages containing a consumer commodity, the term "principal display panel," otherwise known for short as PDP.
The "principal display panel" is that part of a panel that is most likely to be shown or examined under customary conditions of display for retail sale. Usually, it is the front panel of the label of the outer package.

PRINCIPAL DISPLAY PANEL
THE PART OF A LABEL THAT THE CONSUMER SEES OR EXAMINES WHEN DISPLAYED FOR RETAIL SALE.
Sec. 10(t), FP&L Act
21 CFR 701.10

As mentioned before, the PDP is that part of the label that is most likely to be shown or examined under customary conditions for retail sale.
Regulations [21 CFR 701.10] published by the FDA require that the PDP be large enough to accommodate all required label information with clarity and conspicuousness.
If a package bears more than one PDP, the information required to be placed on the PDP must be duplicated on all PDPs.

For the purpose of assuring uniform type size for declaring a product's net quantity of contents, the size of the surface area bearing the PDP, and not the size of the PDP itself, is the determining factor. The area of the PDP is for a:
Rectangular package: One entire side.
Cylindrical package: 40% of height x circumference.
Any other shape of container: 40% of total container surface, excluding top, bottom, neck, shoulder, flanges.

PLACEMENT AND SIZE OF PRINCIPAL DISPLAY PANEL
LOCATION
SIZE
MULTIPLE PDP'S
EXCEPTIONS
DECORATIVE CONTAINERS
COMPACTS OR PENCILS
CONTAINERS OF 1/4 AV.OZ. OR 1/8 FL.OZ. CAPACITY
DISPLAY CARDS
21 CFR 701.10 and 701.13(e)

The following information must appear on the label of the outer container which usually is a box, folding carton, wrapper etc. holding the inner (immediate) container. The immediate container holding the cosmetic product also is the outer container if it is not displayed in a box, folding carton etc.
Please note that only the label of an outer container has a PDP.
Statement of the brand name of the product is not a regulatory requirement under the FD&C or FP&L Act.

PLACEMENT OF INFORMATION ON LABELS
OUTER CONTAINER
(OR LABEL OF SINGLE CONTAINER PRODUCT)

PRINCIPAL DISPLAY PANEL	INFORMATION PANELS
Name of Product Identity § 740.10 Warning Net Quantity of Contents	Directions for Safe Use Warnings Name and Place of Business Ingredient Declaration Any Other Required Information

The following information must appear on the label of the inner (immediate) container holding the cosmetic product. The inner container is packaged and displayed in a non-transparent box, folding carton etc. If the outer container is removed and the product displayed for sale without it, the label of the immediate container becomes a label of an outer container.

PLACEMENT OF INFORMATION ON LABELS
INNER CONTAINER
(IF PACKAGED IN AN OUTER CONTAINER)

FRONT PANEL	INFORMATION PANELS
Name of Product	Directions for Safe use Warnings Name and Place of Business Net Quantity of Contents Any Other Required Information

LANGUAGE

- **ENGLISH LANGUAGE STATEMENTS**
- **FOREIGN LANGUAGE STATEMENTS**

21 CFR 701.2(b)

Ingredient Declaration: Generally, in letters not less than 1/16" in height [21 CFR 701.3(b)]. If surface area available to bear label (excludes surfaces with decorative relief, sculptured surfaces) is less than 12 square inches, letter height may be not less than 1/32" [21 CFR 701.3(p)].
Net Contents Declaration on PDP: Minimum letter height determined by the area of the PDP. In the case of "boudoir-type" containers, including decorative cosmetic containers of the cartridge, pill box, compact or pencil type, and cosmetics of 1/4 oz. or less capacity, the type size is determined by the total dimensions of the container. If the container is mounted on a display card, the display panel determines the letter height [21 CFR 701.13(e) and (i)].
Warning Statements: Type size no less than 1/16" unless smaller size established by regulation [21 CFR 740.2].
Letter Height: The lower case letter "o" or equivalent when upper and lower case letters are used [21 CFR 701.13(h)].

TYPE SIZE

INGREDIENTS:	**1/16"** **1/32" (Labeling Surface, Less Than 12 Sq. In.)**
NET CONTENTS:	**1/16" (PDP Less Than 5 Sq. In.)** **1/8" (PDP 5-25 Sq.In.)** **3/16" (PDP 25-100 Sq.In.)**
WARNING:	**1/16"**
ALL OTHERS:	**REASONABLY RELATED TO PANEL SIZE**

21 CFR 701.2(a) (b), 701.3(b), 701.11(c), 701.13(i), 740.2(b)

The name and business address appearing on the label may be those of the manufacturer, packer or distributor.
If the name and address is not that of the manufacturer, the name must be preceded by phrases such as "Manufactured for ...", "Distributed by ...", or other appropriate wording.
The name of the firm must be the corporate name, and the address may be that of the principal place of business. Stating also the name of a corporation's particular division is optional.

NAME AND PLACE OF BUSINESS
CORPORATE NAME
MANUFACTURED FOR ...
DISTRIBUTED BY ...
ADDRESS
PRINCIPAL PLACE OF BUSINESS
21 CFR 701.12

Location: If the cosmetic is sold at retail in an outer container, the net contents statement must appear (1) within the bottom 30% of the PDP of the outer container, generally parallel in line to the base on which the package rests, and (2) on an information panel of the inner container. The bottom location requirement is waived for PDPs of 5 square inches or less.

The PDP may be a tear-away tag or tape affixed to a decorative container or to a container of less than 1/4 oz., or it may be the panel of a display card to which the container is affixed.
Prominence: The declaration must be a distinct item, separated from other printed matter by a space equal to at least the height of the lettering used in the declaration and twice the width of the letter "N".
Conspicuousness: The print must be easily legible bold face type in distinct contract to background and other matter on the package. The letter height must be at least that of the lower case letter "o", and the aspect ratio of height to width must not exceed 3:1.
The type size, as determined by the area of the PDP must be at least 1/16 in. if PDP area ≤ 5 sq. in., 1/8 in. if PDP area > 5 to ≤ 25 sq. In., 3/16 in. if PDP area > 25 to ≤ 100 sq. in., and 1/4 in. if PDP area > 100 sq. in.

QUANTITY OF CONTENTS

LOCATION ON PACKAGE ON PDP ON INFORMATION PANEL	**§ 701.13 (e) and (f)(2)**
PROMINENCE PLACEMENT SPACING	**§ 701.13 (f) and (f)(1)**
CONSPICUOUSNESS CONTRACT LETTER HEIGHT ASPECT RATIO TYPE SIZE	**§ 701.13 (h) and (i)**

Economy Size: Representations of this type are permitted if the firm offers at least one other packaged size of the same brand, only one is labeled "economy size," and the unit price of the package so labeled is substantially (at least 5%) reduced compared to that of the other package.
Giant Pint, Full Quart: Supplemental statements describing the net quantity of contents are permitted on panels other than the PDP. However, these statements must not be deceptive or exaggerate the amount present in the package.
Six Applications: Declarations by numerical count or linear or area measure may be augmented by statements of weight or size of individual units or total weight or measure to give accurate information. These are not regarded as separate statements and must appear on the PDP.
Cosmetic Kit: If a package contains the integral components making up a kit and delivers the components in the manner of an application as, for example, a home permanent wave kit, the net contents declaration may be stated in terms of the number of applications as per given instructions [21 CFR 701.13 (g) (2)].
Regulations require that "[the label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product" [21 CFR 740(1)]. A cosmetic not bearing a necessary warning statement may be considered misbranded under sec. 602(a) of the FD&C Act because it fails to reveal a fact "material ... with respect to consequences which may result from the use of the article" [sec 201(n), FD&C Act].
Prominence: A warning statement must appear on the label prominently and conspicuously as compared to other words, statements or designs so that it is likely to be read by ordinary consumers at the time of purchase and use.
Conspicuousness: The lettering must be in bold type on contrasting background and may in no case be less than 1/16 inch in height.

COSMETIC WARNING STATEMENTS
GENERAL REQUIREMENT

PROMINENCE
PLACEMENT
SPACING
CONSPICUOUSNESS
CONTRAST
TYPE SIZE
21 CFR 740 (1) and (2)

The ingredients must be listed in descending order of predominance. However, there are a few exceptions to this requirement.

1. If the cosmetic is also a drug, section 502(c) of the FD&C Act requires that the active drug ingredient(s) be declared before declaration of the cosmetic ingredients. A declaration, thus, would read as follows: "Active Ingredient: ... (Name of drug ingredient). Other (or Cosmetic) Ingredients: ... (Names of cosmetic ingredients in descending order)." [§ 701.3(d)]
2. Ingredients present at a concentration not exceeding 1% may be listed in any order after the listing of the ingredients present at more than 1% in descending order of predominance. [§ 701.3(f)(2)]
3. Color additives of any concentration may be listed in any order after the listing of the ingredients which are not color additives [§ 701.3(f)(3)].
4. The name of an ingredient accepted by FDA in accordance with the procedure established in § 720.8 as a trade secret need not be disclosed on the label. In lieu of declaring the name of that ingredient, the phrase "and other ingredients" may be used at the end of the ingredient declaration [§ 701.3(a)].

The declaration of ingredients in labeling accompanying a cosmetic, i.e., off-package ingredient labeling, requires that:

(1)The product is not enclosed in an outer container,
(2)The total package surface area is less than 12 square inches, and
(3)The products are held for sale in tightly compartmented trays or racks.

Among the various conditions described in §§ 701.3(j) and (k) that must be met if off-package ingredient labeling is utilized as an alternative to the declaration of ingredients on an information panel, the following deserve particular attention:

1. The display unit or chart must bear the statement "Federal law requires ingredient lists to be displayed here" in letters not less than 3/16 of an inch in height. This statement becomes conspicuous when the last ingredient list has been taken or may also be shown at all times adjacent to the holder of labeling bearing the ingredient declaration(s).

OFF-PACKAGE INGREDIENT LABELING
HOLDER OF LABELING
1. MUST BEAR THE FOLLOWING STATEMENT VISIBLE AFTER LAST LIST HAS BEEN TAKEN...
"FEDERAL LAW REQUIRES INGREDIENT LIST TO BE DISPLAYED HERE."
21.CFR 701.3(j)

2. The holder of off-package cosmetic ingredient labeling, e.g., padded sheets or leaflets, must be attached to the display unit or chart so that the labeling is in front of the display unit or chart and can be read in full by a purchaser facing the display under customary conditions of retail sale.

As an alternative to full display of off-package ingredient labeling, the labeling may also be on the side of the display unit or chart, but not at the top, back or bottom, in which case it must be accompanied by a conspicuous notice in 3/16 of an inch lettering on the front of the display unit, describing the location of the off-package labeling and stating "Federal law requires ingredient lists to be displayed here."