FDA RULES & REGULATIONS

Please use this as regulatory guidance only

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Registrar Corp

Regulatory Guidance Only

REGULATORY GUIDANCE ONLY

This guide is intended for educational purposes only. To ensure the highest level of accuracy and expertise, we've partnered with Registrar Corp, the world's leading authority in MoCRA regulatory compliance. Their deep expertise helps navigate the complexities of MoCRA with confidence and accuracy.

To aid your transition into MoCRA compliance, **Registrar Corp is offering a 10% discount exclusively to Jansy clients. Simply mention discount code "Berlin10"** when reaching out to them (valid for new Registrar Corp clients only; certain other terms and conditions may apply; ability to use such discount code may vary).

As a friendly reminder, this summary is not a substitute for a review of current applicable MoCRA regulations or other standards specific to your business operations and should not be construed as legal advice or legal opinion.

As always, we encourage you to consult with a regulatory compliance specialist or an attorney to determine applicable legal requirements. Updated FDA guidelines can always be found on the FDA website at any time.

FDA Labeling 101

Primary Package

A Primary Package is the main container that directly holds the product, such as a bottle, jar, or tube. If placed inside another container (the “secondary package,” such as a carton) then it is subject to modified labeling requirements. However, if placed inside a transparent outer container it will become the "secondary package" and must meet those labeling requirements. If it does not have any secondary packaging, then it must meet the “secondary package” labeling requirements.

Front

The front side of a primary package / inner container is required to have the following:

- Name of product
- Statement of Identity (optional but prudent)

Information Panels

Generally, the side and back panels of the package are considered “information panels” and must bear the following:

- Net Quantity of Contents
- Directions
- Warnings
- Name and Place of Business for the Manufacturer, Packer, or Distributor
- Adverse Event Reporting Contact
- UPC (Not needed here if using secondary packaging)

Secondary Package

A Secondary Package is additional packaging that houses the primary packaging, such as an outer carton, sleeve, or wrapper. It is subject to specific labeling requirements, shown below. If a primary package does not have a secondary package, the primary package must meet the labeling requirements for a secondary package.

Principal Display Panel (PDP)

The PDP is the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The PDP may also be a tear- away tag, tape, or display card, especially for decorative containers or those smaller than ¼ ounce. The PDP is required to have the following:

- Name of product
- Statement of Identity
- Net Quantity of Contents

Information Panels

Generally, the side and back panels of the package (but not the bottom of cartons/boxes) are considered “information panels” and must bear the following:

- Directions
- Warnings
- Ingredients
- Name and Place of Business for the Manufacturer, Packer, or Distributor
- Adverse Event Reporting Contact
- Country of Origin (or may appear on PDP)
- UPC

Mandatory Declarations

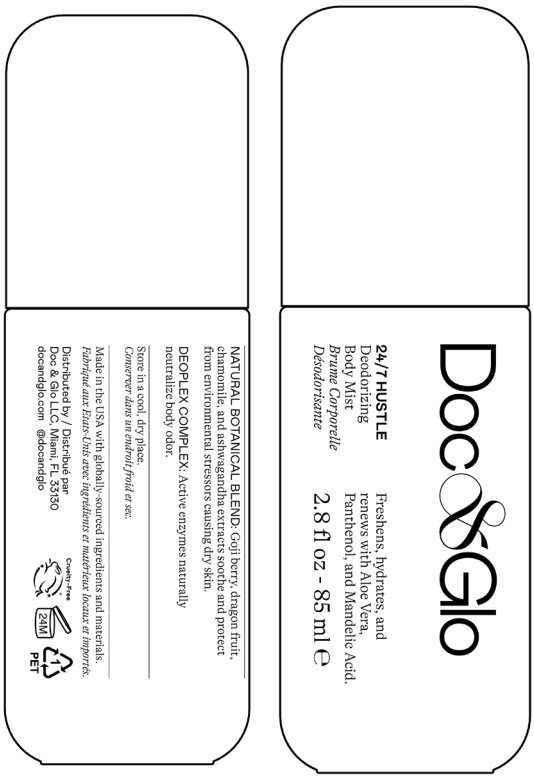
Statement of Identity

The package should declare the identity of the commodity in terms of 1) the common or usual name, or 2) an appropriately descriptive name, or 3) fanciful name when the nature of the product is obvious, or 4) appropriate illustration depicting its use. The statement of identity must be in bold type on the PDP of the outer container in a size reasonably related to the most prominent statements on the label, and parallel to the base of the package.

Net Quantity of Contents

The net quantity of contents is declared in terms of weight, volume, numerical count, or a combination of numerical count and weight or measure. Generally, solid/semisolid/viscous products are declared by weight and liquid products by volume, but FDA allows flexibility (e.g., semisolid declared by volume) if it is a firmly established trade custom.

The net quantity appears on the PDP, in bold, clearly contrasting with the background and in the bottom 30% of the panel parallel to the base of the package. The placement requirement is waived if the PDP is ≤ 5 sq. in. Primary packages are also waived from this placement requirement. Cosmetics in packages containing less than 1/4 av. oz. or 1/8 fl. oz. are exempt from the net quantity of contents declaration if affixed to a properly labeled display card or sold at retail in a properly labeled outer container.



The statement must include imperial (e.g., oz, fl oz) and metric (e.g., g, mL) values. If ≥ 1lb, then the amount in lb should be included in parentheses after the amount in ounces. If ≥ 1 pint or 1 quart, then these amounts should be included in parentheses after the amount in fluid ounces. If declared by weight, must be preceded by “Net Weight” or “Net Wt.” “Net” or “Net Contents” is optional for declarations by volume. The spacing around the text must be at least the height of the lettering used and at least twice the width of the letter “N.”

The type size is determined by the area of the PDP. The aspect ratio should not exceed 3:1. Letter heights refer to uppercase letters. When upper and lowercase or all lowercase letters are used, it is the lowercase letter “o” or its equivalent that shall meet the minimum standards. Type size 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.
- 1/4 in. if PDP area > 100 sq. in.

Mandatory Declarations

Directions and Warnings

Labels must clearly state directions and warnings necessary for safe use of the product. Certain products will require special warnings as mandated by FDA:

- Cosmetics in self pressurized containers
- Feminine deodorant sprays
- Foaming detergent bath products
- Coal tar hair dyes
- Suntanning preparations

Liquid oral hygiene products and cosmetic vaginal products must be packaged in tamper resistant packaging with an indicator or barrier to entry which if breached or missing, alerts a consumer that tampering has occurred.

Ingredients

Each ingredient must be declared on the product label, except that "flavor" and "fragrance" ingredients may be named as such. FDA has a hierarchy for determining the manner which you must declare the name of each ingredient here. Must be declared in descending order of predominance by weight or grouped as follows:

(1) Ingredients, other than color additives, present at a concentration greater than 1 percent, in descending order of predominance; followed by

(2) Ingredients, other than color additives, present at a concentration of not more than 1 percent, without respect to order of predominance; followed by

(3) Color additives, without respect to order of predominance.

For certain shaded product lines, the same ingredient list may be used, with all color additives declared at the end following the phrase "may contain."

MoCRA also mandates that FDA publish a list of fragrance allergens that must be declared on the label. At the time of publication of this guide, FDA has not issued a list of fragrance allergens.

Manufacturer/Packer/Distributor

The label must include a declaration of the manufacturer, packer, or distributor. Any one of the three will meet the requirement, but note that that entity is considered the "responsible person" under MoCRA and must be prepared to meet those requirements. The declaration must include the actual corporate name and full address. The street address may be omitted if found in a local directory. If the entity is not the manufacturer, then it must be clarified with a phrase such as "manufactured for" or "distributed by."

Mandatory Declarations

Adverse Event Reporting Contact

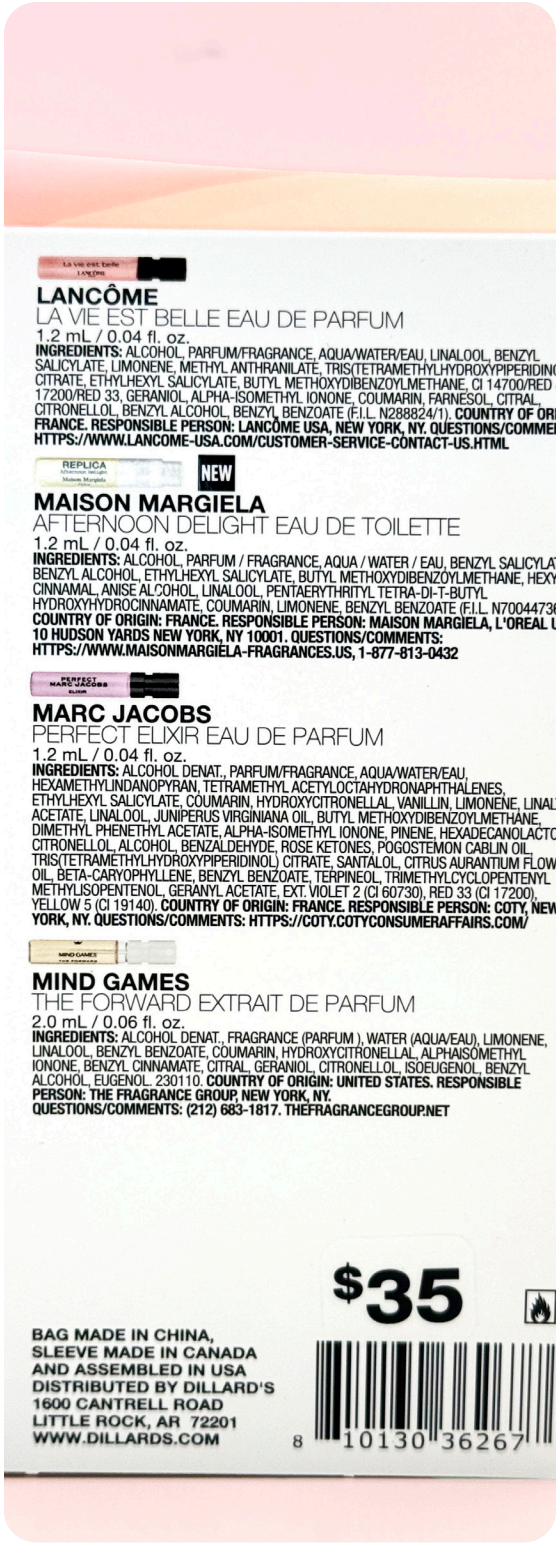
MoCRA requires that cosmetic labels bear a domestic U.S. phone number, mailing address, or electronic contact (which may include a website) to which a consumer can report, and the responsible person can receive a report of an adverse event. Serious adverse events must be reported to FDA within 15 business days.

Claims

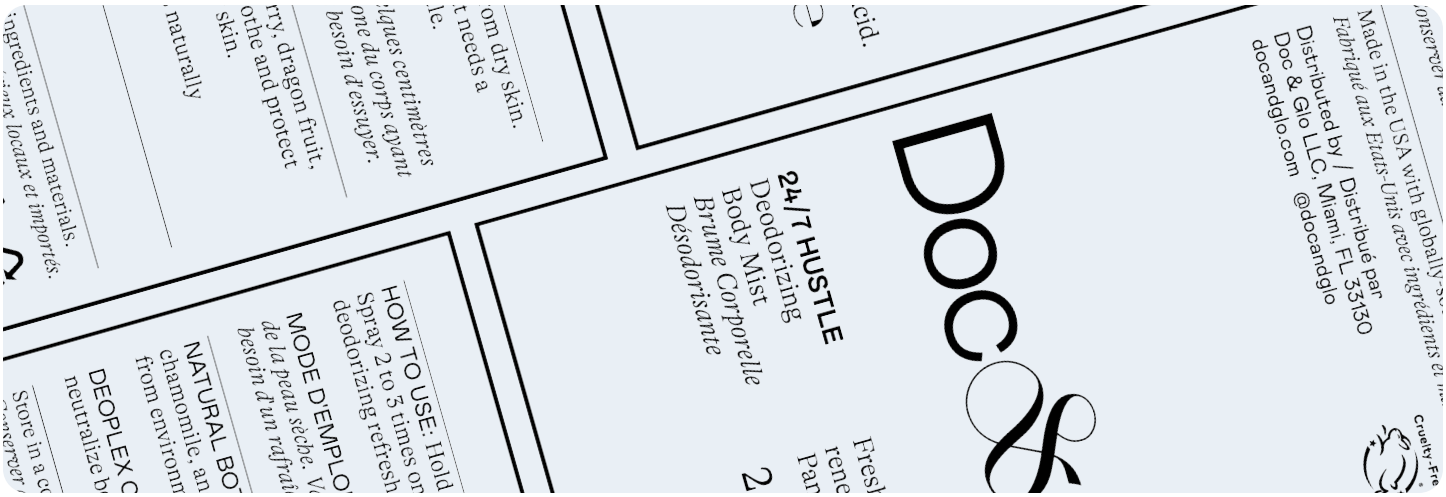
Claims are an integral part of cosmetic labeling but must be in compliance with FDA's policies regarding what is deemed appropriate. FDA classifies products based on their intended use. Cosmetics are defined by FDA as products intended to "cleanse, beautify, promote attractiveness, or alter the appearance." Drugs are defined (in part) as products intended to "affect the structure or any function of the body." Cosmetics should not make claims that could cause FDA to deem them drugs based upon claims that that exceed the definition of a cosmetic.

Type Size and Legibility

Ensure your packaging meets FDA regulations with clear, legible, and unobstructed labeling for consumer readability and compliance. Unless otherwise noted, FDA generally requires a minimum type size of 1/6th inch in height. The background must contrast with the text to ensure readability. High-contrast combinations, like black text on a white background, are preferred over low-contrast choices, such as pink text on red. No design elements, images, or packaging features should obscure mandatory labeling.



Primary Package Label



NAME OF PRODUCT

ADVERSE EVENT REPORTING CONTACT

STATEMENT OF IDENTITY

MANUFACTURER, PACKER, OR DISTRIBUTOR

NET QUANTITY OF CONTENTS

DIRECTIONS & WARNINGS

Bottom Labels

Minimum Info Needed

The bottom label should include the shade name, lot code, batch number, manufacturer/packer/distributor, net quantity, and country of origin.

SHADE NAME
Identifies the product's color.

LOT CODE / BATCH NUMBER
Tracks production for quality control.

MANUFACTURER, PACKER, OR DISTRIBUTOR

Additional Information

The bottom label should include key identifiers like shade name and lot code, along with essential distribution and manufacturing details.

MANUFACTURER, PACKER, OR DISTRIBUTOR

EXPIRATION OR PAO

COUNTRY OF ORIGIN

NET QUANTITY OF CONTENTS

NAME / COLOR
Clarifies product identity.

Secondary Package Label

STILL HAVE QUESTIONS?

For more information, please reach out to Registrar Corp or visit the FDA website for further instructions and guidance.

Registrar Corp

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- ✓ EU and UK Compliance
- ✓ Labeling & Ingredient Reviews
- ✓ Product Registration & Listing
- ✓ Adverse Event Management Software
- ✓ Product Formulation & GMP Software
- ✓ Online Compliance Training
- ✓ OTC Drug Compliance

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