Product Responsibility Best Practices

SUBJECT

FDA Personal Care Labels

LAST UPDATE

July 2018

APPLIES TO

- Suppliers
- Distributors

FOCUS ON

Federal registration and labeling regulations for personal care products in the promotional products industry.

QUICK LINKS

- PPAI Corporate Responsibility: http://www.ppai.org/corporate-responsibility
- UL: http://industries.ul.com/premiums-promotional-and-licensed-goods
- Consumer Product Safety Commission: www.cpsc.gov

Intended for beginner compliance programs

Italic grey text indicates a hyperlink listed in the Online Resources section of this document.

Introduction

In the promotional products industry, the term "personal care products" often refers to the variety of items that we commonly find at retail in the health and beauty departments. The *Food and Drug Administration (FDA)* notes that "these products may fall into a number of different categories under the law." These categories are defined by the *Federal Food Drug and Safety Act (FD&C Act)* as cosmetics or drugs.

Cosmetic products are "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance." Cosmetics do not claim to treat or prevent anything. These products and their ingredients are generally not subject to FDA premarket approval with some exceptions.

Examples of cosmetics include skin moisturizers, perfumes, lipsticks, fingernail polishes, cleaning shampoos, and hair colors.

Drug products are "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" including products that affect how a person looks. Typically, the FDA must provide premarket approval for new drugs. Over-the-counter (OTC) drugs must include an FDA monograph. The monograph lists acceptable limits of ingredients that have been shown to be "generally regarded as safe" (GRAS). These products do not need pre-market approval from the FDA. In the case of nonprescription drugs, conformance to special regulations is required. Drugs make claims to treat or prevent.

Examples of products considered by the FDA to be drugs include sunscreen products, lip balms, antiseptics, dandruff shampoo, acne treatments, antiperspirants, and diaper ointments.

Some products fall into both the cosmetic and drug category and must meet requirements for both.

Examples include moisturizers and makeup with SPF (sun protection factor) numbers.

Other categories include medical devices, dietary supplements and some consumer products.

Examples include hair removal devices, dietary supplements, and manicure sets.

How To Tell The Difference Between A Cosmetic And A Drug

The intended use, marketing claims, ingredients, and consumer perception all impact the determination of whether an item must be labeled a cosmetic, drug, or combination of both. Some products meet the definitions of both cosmetics and drugs when it has two intended uses. For example, a shampoo is a cosmetic because its intended use is to cleanse the hair. An antidandruff treatment is a drug because its intended use is to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug. Among other cosmetic/drug combinations are toothpastes that contain fluoride, deodorants that are also antiperspirants, and moisturizers and makeup marketed with sun-protection claims. Such products must comply with the requirements for both cosmetics and drugs.

Intended Use

Each of these product categories is regulated differently, and if a product has characteristics of more than one category, it must meet the requirements of each category. The intended use of the product determines whether a product is classified as a cosmetic or a drug, and there are a number of ways this can be accomplished.

Statements or marketing claims in advertising or on the label itself could result in a cosmetics being subject to drug regulations based on those claims made by marketing, advertising, and promotional efforts. Additionally, consumer perception may

influence the category as a result of the "product's reputation" and typically perceived outcomes from using the product. When a product contains ingredients known to the public and industry to have therapeutic use, the item will likely be considered a drug.

An example would be essentials oils. These oils are fragrances considered to have healing and aromatic benefits. The fragrance would cause the product to be classified as a cosmetic and the aromatherapy claim would result in the drug classification.

Registration

Drug Approval and Registration

The *FD&C Act, sec. 510; 21 CFR 207* states that it is mandatory for drug firms to register their companies and list their drug products with the FDA. Registration must be renewed bi-annually and is accessible through the *Drug Listing and Registration System (DRLS and eDRLS)*. This process requires a specially registered computer with the FDA, along with security certificates held by the FDA through their submission portal. The *FDA's Center for Drug Evaluation and Research (CDER)* establishes monographs and ensures the safety and effectiveness of prescription and nonprescription or *over-the-counter (OTC)* drugs marketed in the United States. The company seeking to market a new drug is responsible for testing it and submitting evidence to the CDER that the drug is safe and effective.

As stated above, an FDA monograph consists of specific labeling requirements and testing provisions for a drug class and lists the acceptable ingredients, doses, and formulations.

Voluntary Cosmetic Registration Program (VCRP)

In contrast to required drug listings, the "FD&C Act does not require cosmetic firms to register their establishments or list their product formulations with FDA." The FDA does have a *Voluntary Cosmetic Registration Program (VCRP)* for use by manufacturers, packers, and distributors of cosmetic products to voluntarily list their products. This program only applies to cosmetic products being sold to consumers. *Title 21, Code of Federal Regulations (CFR), part 710.9* states that "it does not apply to products that are not for sale such as hotel samples, free gifts, or cosmetic products you make in your home to give to your friends."

Cosmetic companies have a legal responsibility for the safety of their products and ingredients, and the FD&C Act prohibits the marketing and sale of "adulterated or misbranded cosmetics." Proper labeling is imperative for FDA compliance.

Labeling

The labeling requirements for over the counter drug products used as promotional products is the same as those drug products which are offered for sale to the public, and there are specific content boxes required on the product labeling.

Principle Display Panel

The Principle Display Panel *(PDP)* is the part of the label that is "most likely to be displayed, presented, shown, or examined under customary conditions of display for retail." It must be large enough to accommodate all mandatory information in a clear and reasonable manner (Figure 1).

There are type-size requirements based on the size of the PDP in square inches. For irregular or cylindrical shaped items such as a lip balm, type size must be 40 percent of the total surface.

The **Statement of Identity** must be prominent, conspicuous, and in bold type. It cannot be misleading or falsely represent the product (Figure 1).

The **Declaration of Net Quantity** must also be prominent and distinct and spaced away from other printed material but must be located in the lower 30% of the PDP (Figure 1).

Figure 1

Over-the-Counter (OTC) Product Labeling

The FDA provides guidance intended to help small businesses understand and comply with labeling and testing regulations for certain over-the-counter (OTC) drug products. For our purposes, we will use sunscreen drug products.

Sunscreen Products

All sunscreen drug products must bear the "sunscreen" statement of identity. There are specific terms that cannot be used for sunscreen products. The use of any of these terms will cause the product to be misbranded:

- Sunblock
- Sweatproof
- Waterproof
- All day or extended wear
- Instant protection

"Water Resistant" statements may appear on the front panel, provided the product has passed required testing; however, it must have a specified time (40 minutes or 80 minutes) noted in parentheses. If only the words "water resistant" appear without

either the specified effectiveness time, this will cause the product to be considered misbranded.

Effectiveness claims may be used, provided the product has passed the specific required testing. The effectiveness claim of the product must be prominently displayed and follow the "broad spectrum" claim when applicable as SPF (sun protection factor) and then the number (Figure 2). If no "broad spectrum" testing was done, then only the SPF word followed by the number determined in testing would follow. The requirements are the same for font style, color, size and background.

Figure 2

The **Drug Facts** box contains active ingredients, purpose, uses, warnings, directions, inactive ingredients, other information and questions. The font color must be black with a contrasting white background (Figure 2).
The word **Drug Facts** is left justified, bold, italic and the first letter of each word is uppercase. The type size is the largest in the entire box (Figure 3).

Active Ingredients box – The first letter of each word of the established active ingredient name is uppercase, each is listed in alphabetical order, and the dosage amount follows the name. When a dosage does not apply as in the example here, it is the proportion or concentration rather than the dosage amount (Figure 3).

The font is italic and bold for each of these headings.

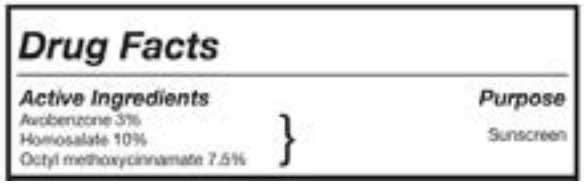

Figure 3

The **Purpose** must be right justified, italic and bold. When the OTC drug monograph contains a statement of identity, it shall also be stated as the purpose of the active Ingredient. If no monograph exists, the principal pharmacological category or the principal intended action of the ingredient can be used. If several active Ingredients are listed and they all have the same purpose, the purpose can be listed one time or it may listed after each ingredient (Figure 3).

Use(s) refers to the specific indication(s) or approved use(s) for the drug product. For drug-cosmetic products, only the drug-related indications can be included in the Use(s) section.
Bullets are geometric symbols that precede each statement in a list of statements. The same type of bullet must be used throughout the label and there are specific spacing requirements for bullets depending on where they are placed (Figure 4).

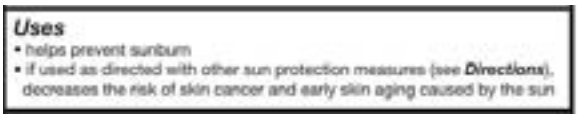

Figure 4

Warnings provide details about the side effects that could occur and substances or activities to avoid.

These are examples of modified labeling formats where each warning is separated by line rather than a bullet which is acceptable (Figure 5).

The following would be bold for sunscreen:

- **For external use only**
- **Do not use …**
- **When using this product …**
- **Stop use and ask a doctor …**
- **Keep out of reach of children …**

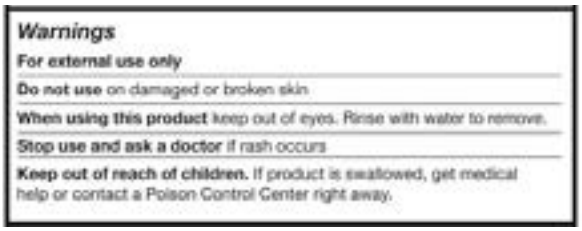

Figure 5

If not using a modified format, each statement would be followed by a bullet. If the product is broad spectrum but with an SPF of at least 2 but less than 15, the first statement under warning is:

- "Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging."

Directions may have some requirements or options listed in the specific monograph. "The directions for the product may

not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and may not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient." Note the time intervals and age limitations for administration of the individual ingredients (Figure 6).

For sunscreens it may state "For sunscreen use"; "liberally" may be replaced with "generously"; an option may be to state "apply to all skin exposed to the sun."

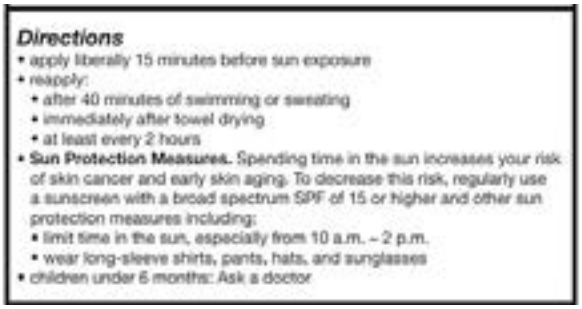
Directions
- apply liberally 15 minutes before sun exposure
- reapply:
  - after 40 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
  - limit time in the sun, especially from 10 a.m. – 2 p.m.
  - wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Figure 6

Other Information addresses information which is required by or is made optional under an appropriate OTC drug monograph, other OTC drug regulation or is included in the labeling of an approved drug application.

For sunscreen, the actual requirement is: protect the product in this container from excessive heat and direct sun (Figure 7).


Other information
- protect this product from excessive heat and direct sun

Figure 7

Inactive Ingredients provides a listing of the established name of each inactive ingredient. The inactive ingredients are listed in alphabetical order (Figure 8).

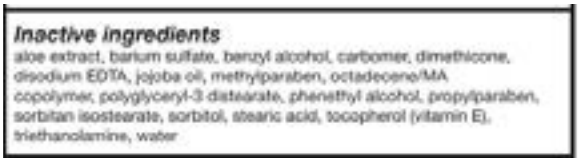
Inactive ingredients
aloe extract, barium sulfate, benzyl alcohol, carbomer, dimethicone, disodium EDTA, jojoba oil, methylparaben, octadecene/MA copolymer, polyglyceryl-3 distearate, phenethyl alcohol, propylparaben, sorbitan isostearate, sorbitol, stearic acid, tocopherol (vitamin E), triethanolamine, water

Figure 8

Sometimes "other information" follows "inactive ingredients" rather than coming before it.

Questions must provide sufficient information about how to contact the manufacturer with questions about the product or to report adverse conditions. This includes a telephone number of a source to answer questions about the product. It is recommended that the days of the week and times of the day when a person is available to respond to questions also be included. Figure 9 only has the phone number which is not in compliance.

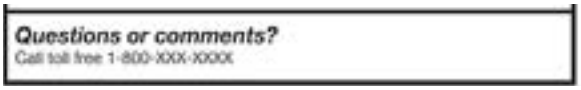
Questions or comments?
Call toll free 1-800-XXX-XXXX

Figure 9

Country of Origin and Distributed by must be on the label. Country of origin and distributor information are not part of the facts box but must be part of the label (Figure 10).


903083 97
DISTRIBUTED BY: GREENBRIER INTERNATIONAL, INC.
CHESAPEAKE, VA 23320
MADE IN CHINA

Figure 10

Additional Products

Consumer Antiseptics

The purpose of antiseptics is to prevent infections. Because antiseptics are used on humans and make claims to "treat or prevent" they are considered a drug and are regulated by the FDA. Antiseptics are classified into three categories based on proposed use: consumer antiseptics, food handler antiseptics, and healthcare antiseptics. Consumer antiseptics are also referred to as antiseptic handwashes, typically marketed as antibacterial soaps. Food handler antiseptics are intended for handwashing in food handling facilities. Healthcare antiseptics are for use in healthcare facilities.

All of these categories include antiseptic products intended for use without water that are marketed as hand sanitizers. The promotional products industry generally deals in consumer antiseptics. "Consumer antiseptics are considered OTC drugs and are currently evaluated under the Healthcare Antiseptic rulemaking."

Examples include antibacterial soaps, hand sanitizers, and antibacterial wipes.

Additional Information About Sunscreens

Even though there is a list of product forms not currently covered by the monograph, it doesn't mean that a manufacturer cannot submit an NDA for that product to the FDA. The sunscreen monograph currently covers oils, lotions, creams, gels, butters, pastes, ointments, sticks and sprays. It does not cover wipes, towelettes, powders, body washes, and shampoos.

Labeling Content: 21 CFR 201.66 (abbreviated)

Description of Paragraph	Comments
Drug Facts, Drug Facts (continued)	The title to be used is **Drug Facts** (on subsequent panels use **Drug Facts** (continued)).
Active ingredient(s) (established name, strength/concentration)	For drug-cosmetic products, the drug ingredients are considered the active ingredients, and the cosmetic ingredients are considered the inactive ingredients.
Purpose(s)	If there is no statement of identity or no applicable OTC drug monograph, the ingredient purpose is stated based on its general pharmacological category(ies) or the principal intended action(s) of the drug product.
Use(s)	The use(s) are the specific indication(s) or approved use(s) for the drug product. For drug-cosmetic products, the use in the Drug Facts labeling is attributed only to the drug component.
Warning(s)	Warning information appears in a specific order, under the heading **Warnings**, as applicable. Most warnings follow specific subheadings.
Directions	Described in an applicable OTC drug monograph or approved drug application.
Other information and additional information not included.	The subheading used for additional information that is not included under the other subheadings, but which is required or is made optional under an OTC drug monograph(s), other OTC drug regulation(s), approved drug application, statute, or OTC drug guidance.
Additional information	For example: storage conditions, tamper-evident statement.
Inactive ingredients	A list of each inactive ingredient, using its established name.
Questions? (or Questions or Comments?)	Optional heading used to provide a telephone number of a source to answer questions about the drug product or to receive reports of adverse events associated with the use of the drug product.

Antiseptic target market and intended use for each category.

Summary of Currently Available Antiseptic Products			
Product	**Target Population**	**Marketed Use(s)**	**Use Setting**
Consumer antiseptics: Consumer antiseptic handwash Consumer antiseptic bodywash Consumer hand sanitizer	General population	To reduce bacteria on the hands To reduce body odor To prevent infection	Homes, day care centers
Food handler antiseptics: Food handler handwash Food handler hand sanitizer	Commercial food handlers	To reduce the risk of food-borne disease	Commercial food establishments, e.g., restaurants, food processing plants
Healthcare antiseptics: Healthcare personnel handwash Patient preoperative skin preparation Surgical hand scrub Healthcare hand sanitizer	Healthcare professionals and patients	To reduce bacteria on the skin prior to patient care or surgery	Hospitals, clinics, doctor's offices, outpatient settings, nursing homes

Lip Moisturizer/Balm

A lip protectant, often referred to as "lip balm," is considered a drug because it temporarily prevents dryness and helps relieve chapping of the exposed surfaces of the lips.

Regardless of the size of the container, it must be labeled properly. If you package a lip moisturizer in a lip balm tube that makes an SPF claim, it must be labeled as an OTC drug. Therefore, you must put all of the information on the label of the lip balm tube as with the sunscreen bottle. Refer to 21 CFR 201.66(d)(1) through (d)(9) for labeling formats. The chart on page 6 demonstrates **Standard Versus Modified Labeling: 21 CFR 201.66**

Format Labeling Element	Standard Format	Modified Format
Drug Facts box	Set off by barline	Barline may be omitted if color contrast used to set off from the rest of the labeling
Drug Facts	Larger than largest type size used in Drug Facts box or similar enclosure	Larger than largest type size used in the Drug Facts box or similar enclosure
	No smaller than 8-point type	No smaller than 7-point type
Headings	>8-point type, or 2-point type > point size of text	>7-point type, or 1-point type > point size of text
Subheadings	No smaller than 6-point type	No smaller than 6-point type
Bulleted text	No smaller than 6-point type	No smaller than 6-point type
Leading	Minimum 0.5-point type	Smaller than 0.5-point type can be used, provided the ascenders and descenders do not touch
Bullets	Minimum 5-point type Vertical alignment	Minimum 5-point type No alignment required

Cosmetic Labeling

Cosmetics, whether manufactured in the United States or imported, 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. Packages and their labels should provide consumers with accurate information as to the quantity of the contents, facilitate value comparisons, and protect consumers from unsafe or deceptively labeled or packaged products.

According to *21 CFR 701.10*, cosmetic labels "must state the name of the product, identify by descriptive name or illustration the nature or use of the product, and bear an accurate statement of the net quantity of contents of the cosmetic in the package in terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The declaration must be distinct, placed in the bottom area of the panel in line generally parallel to the base on which the package rests, and in a type size commensurate with the size of the container as prescribed by regulation." (Figure 11)

The information panel must contain the name and place of business for the organization marketing the product *21 CFR 701.12*. This would include the street address, city, state, and zip code. The address may be omitted if the organization is listed in a current city or telephone directory.

Regulations *21 CFR 740(1)* 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." A cosmetic may be considered misbranded if it does not contain a necessary warning statement regarding the consequences which may result from the use of the product.

Figure 11

Manufacturers, packers, and distributors should contact the following relevant offices for questions on whether a particular FDA requirement applies to their drug or drug-cosmetic product.

ONLINE RESOURCES

PPAI Product Responsibility: http://www.ppai.org/corporate-responsibility/product-responsibility

PPAI Code of Conduct: http://ppai.org/corporate-responsibility/ppai-code-of-conduct/

CDER Small Business and Industry Assistance (CDER SBIA):
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/default.htm

Addresses for Regulatory Submissions:
https://www.fda.gov/drugs/developmentapprovalprocess/default.htm

New Drug Development and Review Process: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm053131.htm

Drug Registration and Listing System (DRLS & eDRLS):
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm2007058.htm

Over-the-Counter (OTC) Drug Product Review Process:
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm052786.htm

Voluntary Cosmetic Registration Program (VCRP): http://www.fda.gov/cosmetics/registrationprogram/default.htm

Federal Register 21 CFR parts 201 and 310 Labeling and Effectiveness Testing; Sunscreen Drug Products for OTC Human Use – Final Rule: http://www.gpo.gov/fdsys/pkg/FR-2011-06-17/pdf/2011-14766.pdf

Federal Register 21 CFR 201.66 Format and content requirements for OTC drug product labeling (Drug Facts Label):
https://www.gpo.gov/fdsys/pkg/CFR-2012-title21-vol4/pdf/CFR-2012-title21-vol4-sec201-66.pdf

FDA Drug Safety Communication: FDA requests label changes and single-use packaging for some over-the-counter topical antiseptic products to decrease risk of infection: http://www.fda.gov/Drugs/DrugSafety/ucm374711.htm

Questions and Answers: FDA requests label changes and single-use packaging for some over-the-counter topical antiseptic products to decrease risk of infection: http://www.fda.gov/Drugs/DrugSafety/ucm374838.htm

CFR - Code of Federal Regulations 21 CFR 347: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=347&showFR=1

Federal Food, Drug, and Cosmetic Act (FD&C Act): http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/

FDA Authority Over Cosmetics: http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm

Office of Compliance (CDER): http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm081992.htm

Office of Nonprescription Products (CDER): www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm093452.htm

Office of Cosmetics and Colors (CFSAN): www.fda.gov/Cosmetics/

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