From: http://www.handmadebeauty.com/members/inci.asp

The Background*

As you know, the US Food & Drug Administration (FDA) requires that all cosmetics be labeled with, among other things, the ingredients contained in the product. Though there are exceptions, in the great majority of cases, these ingredients must be listed in descending order of predominance in the product.

Though the FDA rarely establishes a name for a specific cosmetic ingredient, if it has done so, that name can be found in the US Code of Federal Regulations at 21 C.F.R. § 701.30, and that name must be used to identify the ingredient on the product label. If the law does not specify the name to be used, the FDA has specified in 21 C.F.R. § 701.3 that the first source to consult after § 701.30 is the Cosmetic, Toiletry & Fragrance Association (CTFA) Cosmetic Ingredient Dictionary**, which contains the required International Nomenclature Cosmetic Ingredient (INCI) labeling names.

*The information provided here is informational only and is not intended to be legal advice. If you require legal advice about labeling your products, please consult with an attorney who can address your individual product labeling needs.

**Secondary sources include the United States Pharmacopeia and the National Formulary.

From: http://www.soapnuts.com/cosmeticlabeling.html

Labeling Cosmetics

Important!-Before you go further~
This page is meant only as a helpful guide on your path to safely manufacturing and selling your cosmetic products. Confusion abounds in the matter of the selling of homemade cosmetics and is one of the most asked about areas on mailing lists. The topic often causes much debate, concern, arguments and general mayhem, as well it should. Quite often soapmakers branch out from just making soap and create homemade toiletries such as lip balms, lotions, lotion bars, etc. and sometimes they offer them for sale at craft shows, web sites, etc. You may choose to enjoy creating these products just for family and friend use, but if you decide to take the path of selling these items to the general public, then you must do all you can to obey the law. By not doing so, you cast a shadow over the entire home-business industry and open yourself up to much harm. The following information was put here to help you:
a) Find the correct information
b) To help you make the right decisions, and
c) To open up the door to further education in this area
Please explore the laws and regulations fully before selling your products, this guide is meant as a 'helper' if you will and you should explore this area on your own time by visiting the FDA site below and/or calling your state for further information, laws vary by state and some states must purchase a license for making cosmetics in their home-

FDA Cosmetic Labeling Manual
http://vm.cfsan.fda.gov/~dms/cos-lab1.html

FDA Cosmetic Handbook
http://vm.cfsan.fda.gov/~dms/cos-hdbk.html

FDA Fact Sheet on "SOAPS"
http://vm.cfsan.fda.gov/~dms/cos-215.html

Definition of a cosmetic-

*The FD&C Act defines cosmetics as articles intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions. Included in this definition are products such as skin creams, lotions, perfumes, lipsticks, fingernail polishes, eye and facial make-up preparations, shampoos, permanent waves, hair colors, toothpastes, deodorants, and any material intended for use as a component of a cosmetic product. Soap products consisting primarily of an alkali salt of fatty acid and making no label claim other than cleansing of the human body are not considered cosmetics under the law.

Cosmetic Safety

Although the FD&C Act does not require that cosmetic manufacturers or marketers test their products for safety, the FDA strongly urges cosmetic manufacturers to conduct whatever toxicological or other tests are appropriate to substantiate the safety of their cosmetics. If the safety of a cosmetic is not adequately substantiated, the product may be considered misbranded and may be subject to regulatory action unless the label bears the following statement: "Warning - The safety of this product has not been determined."

With the exception of color additives and a few prohibited ingredients, a cosmetic manufacturer may, on his own responsibility, use essentially any raw material as a cosmetic ingredient and market the product without approval. The law requires that color additives used in food, drugs and cosmetics must be tested for safety and approved by the FDA for their intended uses. A cosmetic containing an unlisted color additive; i.e., a color additive which has not been approved by the FDA for it's intended use, is considered adulterated and subject to regulatory action. The color additives approved for use in cosmetics are listed at 21 CFR 73, 74 and 82.

Voluntary Registration

Although the FD&C Act does not require cosmetic firms to register

manufacturing establishments or formulations with the FDA or make available safety data or other information before a product is marketed in the United States, manufacturers or distributors of cosmetics may submit this information to the agency voluntarily. Voluntary registration and assignment of a registration number by the agency does not denote approval of a firm or product by the FDA. Any use of a registration number in labeling must be accompanied by a conspicuous disclaimer phrase as prescribed by regulation. See 21 CFR 710, 720 and 730.

Cosmetic Labeling

The cosmetics distributed in the United States must comply with the labeling regulations published by the FDA under the authority of the FD&C Act and the FPLA. Labeling means all labels and other written, printed or graphic matter on or accompanying a product. The label statements required under the authority of the FD&C Act must appear on the inside as well as any outside container or wrapper. FPLA requirements, e.g., ingredient labeling and statement of the net quantity of contents on the principal display panel, only apply to the label of the outer container. The labeling requirements are codified at 21 CFR 701 and 740. Cosmetics bearing false or misleading label statements or otherwise not labeled in accordance with the codified requirements may be considered misbranded and may be subject to regulatory action.

The principal display panel, i.e., the part of the label most likely displayed or examined under customary conditions of display for sale (21 CFR 701.10) and generally bearing the name of the product. It must 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.

The net quantity of contents statement of a solid, semi-solid or viscous cosmetic must be in terms of the avoirdupois pound and ounce, and a statement of liquid measure must be in terms of the U.S. gallon of 231 cubic inches and the quart, pint, and fluid ounce subdivisions thereof. If the net quantity of contents exceeds one pound or one pint, it must be expressed in ounces, followed in parenthesis ( ) by a declaration of the largest whole units (i.e., pounds and ounces or quarts and pints and ounces). The net quantity of contents may additionally be stated in terms of the metric system of weights or measures.

The name and place of business of the firm marketing the product must be stated on an information panel of the label (21 CFR 701.12). The address must state the street address, city, state, and zip code. If a firm is listed in a current city or telephone directory, the street address may be

omitted. If the distributor is not the manufacturer or packer, this fact must be stated on the label by the qualifying phrase "Manufactured for ..." or "Distributed by ..." or similar, appropriate wording.

The Tariff Act of 1930 (19 U.S.C. 1304) requires that all imported articles state on the label the English name of the country of origin. See also 19 CFR 134.

All label statements required by regulation must be in the English language and must be placed on the label or labeling with such prominence and conspicuousness that they are readily noticed and understood by consumers under customary conditions of purchase (21 CFR 701.2).

Declaration of Ingredients

The ingredient declaration must be conspicuous so that it is likely to be read at the time of purchase. It may appear on any information panel of the outer con-tainer, i.e., an information panel of the folding carton, box or wrapping if the immediate container is so pack-aged or, if not packaged in an outer container, an information panel of the jar, tube or bottle containing the product. The ingredient declaration may also appear on a tag, tape or card that is firmly affixed to the outer container. The letters must not be less than 1/16 of an inch in height (21 CFR 701.3(b)). If the total package surface available to bear labeling is less than 12 square inches, the letters must not be less than 1/32 of an inch in height (21 CFR 701.3(p)). Off-package ingredient labeling is permitted if the cosmetic is held in tightly compartmented trays or racks, it is not enclosed in a folding carton, and the package surface area is less than 12 square inches (21 CFR 701.3(i)).

The ingredients must be declared in descending order of predominance. Color additives (21 CFR 701.3(f)(3)) and ingredients present at one percent or less (21 CFR 701.3(f)(2)) may be declared after the ingredients present at concentrations exceeding one percent without regard for predominance. The ingredients must be identified by the names established or adopted by regulation (21 CFR 701.3(c)); those accepted by the FDA as exempt from public disclosure may be stated as "and other ingredients" (21 CFR 701.3(a)). -ingredients at 1% or less in your formula, may be listed in any order.

From: http://www.soapnuts.com/cosmeticlabeling.html

Label Warnings

Cosmetics which may be hazardous to consumers when misused must bear appropriate label warnings and adequate directions for safe use. The statements must be prominent and conspicuous. Some cosmetics must bear label warnings or cautions prescribed by regulation (21 CFR 740). Cosmetics in self-pressurized containers (aerosol products), feminine deodorant sprays and, children's bubble bath products are examples of products

requiring such statements.

*FDA/Industry Activities Staff Booklet: 1992

Links to other pertinent info on FDA site-

21 CFR FDA Regulations
21 CFR 172 - Food additives permitted for direct addition to food for human consumption
21 CFR 181 - Prior-sanctioned food ingredients
21 CFR 182 - Substances generally recognized as safe
21 CFR 184 - Direct food substances affirmed as generally recognized as safe
21 CFR 70 Color Additives
21 CFR 701 - Cosmetic Labeling
21 CFR 701.1 - Misbranding
21 CFR 701.10 - Principal display panel
21 CFR 701.11 - Identity labeling
21 CFR 701.12 - Name and place of business of manufacturer, packer, or distributor
21 CFR 701.13 - Declaration of net quantity of contents
21 CFR 701.2 - Form of stating labeling requirements
21 CFR 701.20 - Detergent substances, other than soap, intended for use in cleansing the body
21 CFR 701.3 - Designation of ingredients
21 CFR 701.30 - Ingredient names established for cosmetic ingredient labeling
21 CFR 701.9 - Exemptions from labeling requirements
21 CFR 73 - Listing of color additives exempt from certification
21 CFR 74 - Listing of color additives subject to certification
21 CFR 740.10 - Labeling of cosmetic products for which adequate substantiation of safety has not been obtained
21 CFR 740.11 - Cosmetics in self-pressurized containers
21 CFR 740.17 - Foaming detergent bath products - Warning Label
21 CFR 740.19 - Suntanning preparations - Warning Label
21 CFR 81 General Specifications and General Restrictions for Provisional Color Additives
21 CFR 82 Listing of Certified Provisionally Listed Colors and Specifications
27 CFR PART 21 BATF Formulas for Denatured Alcohol and Rum

Examples

Here are some example ingredient labels-The FDA specifies the International Cosmetic Ingredient Dictionary
published by the Cosmetic, Toiletry, and Fragrance Association (CTFA) as the primary source for INCI names.please visit INCI to view other ingredients-

LIP BALM-Ricinus communis (castor oil), Simmondsia Chinensis (Jojoba) Seed Oil, Cera Alba (beeswax), fragrance.

BODY LOTION- Water, Aloe Barbadensis (Aloe) Leaf Juice, Citric Acid, Butyrospermum parkii (shea butter), Stearic Acid, Cera Alba (beeswax), fragrance.

BATH FIZZY-Ingredients: Sodium Bicarbonate, Citric Acid, Corn Starch, Prunus Dulcis (Almond) Oil, Fragrance, Water, Sodium Borate, Blue #1

From: FDA/CFR website

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN
SERVICES (CONTINUED)

PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE--Table of Contents

Subpart B--Listing of Specific Substances Affirmed as GRAS

Sec. 184.1702 Sheanut oil.

(a) Sheanut oil is produced from sheanuts derived from the Shea tree Butyrospermum parkii and is composed principally of triglycerides containing an oleic acid moiety at the 2-position and saturated fatty acids, usually stearic or palmitic acids, at the 1- and 3-positions.

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(b) The ingredient meets the following specifications when tested using any appropriate validated methodology:
(1) Saponification value of 185 to 195,
(2) Iodine value of 28 to 43,
(3) Unsaponifiable matter not to exceed 1.5 percent,
(4) Free fatty acids not more than 0.1 percent as oleic acid,
(5) Peroxide value not more than 10 milliequivalents/equivalent (meq/eq),
(6) Lead not more than 0.1 part per million (ppm),
(7) Copper not more than 0.1 ppm.
(c) In accordance with Sec. 184.1(b)(3), the ingredient is used in the following food categories at levels not to exceed current good manufacturing practice, except that the ingredient may not be used in a standardized food unless permitted by the standard of identity: Confections and frostings as defined in Sec. 170.3(n)(9) of this chapter, coatings of soft candy as defined in Sec. 170.3(n)(38) of this chapter, and sweet sauces and toppings as defined in Sec. 170.3(n)(43) of this chapter.

[63 FR 28895, May 27, 1998]