Burlington

STANDARD OPERATING PROCEDURE

COSMETIC LABELING REGULATIONS

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Department: Legal

Cosmetic Definition

The FD&C Act defines cosmetics by their intended use, as "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" (FD&C Act, sec. 201(i)). Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, and deodorants, as well as any substance intended for use as a component of a cosmetic product. It does not include soap

A product that suggests that it is intended to prevent, cure, treat, or mitigate disease or to affect a structure or function of the body comes within the definition of a drug in section 201(g) (1)

FDA approval of cosmetics

Under the law, cosmetic products and ingredients do not need FDA pre-market approval, with the exception of color additives. Companies and individuals who manufacture or market cosmetics have a legal responsibility to ensure the safety of their products. Neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients. The law also does not require cosmetic companies to share their safety information with FDA.
FDA may take regulatory action if there is reliable information indicating that a cosmetic is adulterated or misbranded.

Adulterated or Misbranded Cosmetics

“Adulteration” refer to any product contains

- any poisonous or deleterious substance which may render it injurious to users
- it consists in whole or in part of any filthy, putrid, or decomposed substance
- its container is composed, in whole or part, of any poisonous or deleterious substance which may render the contents injurious to health

“Misbranded” refer to any product contains

- Its label does not include all required information.
- the required information is not adequately prominent and conspicuous
- color additive does not conform to applicable regulations
- missing direction of safe use and warning statement

Prohibited & Restricted Ingredients

Although it’s against the law to use any ingredient that makes a cosmetic harmful when used as intended, FDA has regulations that specifically prohibit or restrict the use of the following ingredients in cosmetics:

- **Bithionol.** The use of Bithionol is prohibited because it may cause photo contact sensitization (21 CFR 700.11).
- **Chlorofluorocarbon propellants.** The use of chlorofluorocarbon propellants in cosmetic aerosol products intended for domestic consumption is prohibited (21 CFR 700.23).
- **Chloroform.** The use of chloroform in cosmetic products is prohibited because it causes cancer in animals and is likely to be harmful to human health too. (21 CFR 700.18).
- **Halogenated salicylanilides (di-, tri-, metabromsalan and tetrachlorosalicylanilide).** These are prohibited in cosmetic products because they may cause serious skin disorders. (21 CFR 700.15).
- **Hexachlorophene.** Because of its toxic effect and ability to penetrate human skin, hexachlorophene (HCP) may be used only when no other preservative has been shown to be as effective. The HCP concentration in a cosmetic may not exceed 0.1 percent, and it may not be used in cosmetics that are applied to mucous membranes, such as the lips (21 CFR 250.250).

- **Mercury compounds.** Mercury compounds are readily absorbed through the skin on topical application and tend to accumulate in the body. They may cause allergic reactions, skin irritation, or neurotoxic problems. The use of mercury compounds in cosmetics is limited to eye area products at no more than 65 parts per million (0.0065 percent) of mercury calculated as the metal and is permitted only if no other effective and safe preservative is available. All other cosmetics containing mercury are adulterated and subject to regulatory action unless it occurs in a trace amount of less than 1 part per million (0.0001 percent) calculated as the metal and its presence is unavoidable under conditions of good manufacturing practice (21 CFR 700.13).
- **Methylene chloride.** It causes cancer in animals and is likely to be harmful to human health, too (21 CFR 700.19).
- **Prohibited cattle materials.** To protect against bovine spongiform encephalopathy (BSE), also known as "mad cow disease," cosmetics may not be manufactured from, processed with, or otherwise contain, prohibited cattle materials. These materials include specified risk materials, material from non-ambulatory cattle, material from cattle not inspected and passed, or mechanically separated beef. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives, and hides and hide-derived products, and milk and milk products (21 CFR 700.27).
- **Sunscreens in cosmetics.** Use of the term "sunscreen" or similar sun protection wording in a product's labeling generally causes the product to be subject to regulation as a drug or a drug/cosmetic, depending on the claims. However, sunscreen ingredients may also be used in some cosmetic products to protect the product color. The labelling must also state why the sunscreen ingredient is used, for example, "Contains a sunscreen to protect product color." If this explanation isn't present, the product may be subject to regulation as a drug (21 CFR 700.35).
- **Vinyl chloride.** The use of vinyl chloride is prohibited as an ingredient of aerosol products, because it causes cancer and other health problems (21 CFR 700.14).
- **Zirconium-containing complexes.** The use of zirconium-containing complexes in aerosol cosmetic products is prohibited because of their toxic effect on lungs of animals, as well as the formation of granulomas in human skin (21 CFR 700.16).
- **Color additives** are permitted in cosmetics only if FDA has approved them for the intended use. In addition, some may be used only if they are from batches that FDA has tested and certified.

Color Additives

Color additives are subject to a strict system of approval under U.S. law [Federal Food, Drug, and Cosmetic Act] (FD&C Act). Failure to meet U.S. color additive requirements causes a cosmetic to be adulterated with the exception of coal-tar hair dyes. Color additive violations are a common reason for detaining imported cosmetic products offered for entry into this country.

The FD&C Act Section 721(c) [21 U.S. C. 379e(c)] and color additive regulations [21 CFR Parts 70 and 80] separate approved color additives into two main categories: those subject to certification (sometimes called "certifiable") and those exempt from certification.

C.I. (Color Index) numbers are not acceptable on product labeling unless they are preceded by the color additive names accepted in the U.S. followed by the C.I. number in parentheses.

21 CFR Part 73, Subpart C: Color additives exempt from batch certification

These color additives in the below table are obtained primarily from mineral, plant, or animal sources. They are not subject to batch certification requirements.

Color Additives Approved for Use in Cosmetics

21 CFR Section	Straight Color	Year Approved	Uses and Restrictions
§73.2030	Annatto	1977	Cosmetics generally including eye area use.
§73.2085	Caramel	1981	Cosmetics generally including eye area use.
§73.2087	Carmine	1977	Cosmetics generally including eye area use.
§73.2095	ß-Carotene	1977	Cosmetics generally including eye area use.
§73.2110	Bismuth citrate	1978	Cosmetics intended for coloring hair on the scalp only NTE 0.5 percent.
		2010	Cosmetics intended for coloring hair on the scalp only NTE 2.0 percent.
§73.2120	Disodium EDTA-copper	1974	Coloring of shampoos that are cosmetics.
§73.2125	Potassium sodium copper chlorophyllin (chlorophyllin copper-complex)	1969	Coloring dentifrices that are cosmetics NTE 0.1% in combination with a list of substances.
§73.2150	Dihydroxyacetone	1973	Externally applied cosmetics intended solely or in part to impart color to the human body.
§73.2162	Bismuth oxychloride	1977	Cosmetics generally including eye area use.
§73.2180	Guaiazulene	1977	Externally applied cosmetics.
§73.2190	Henna	1965	Coloring hair but not eyelashes, eyebrows, or eye area.
§73.2250	Iron oxides	1977	Cosmetics generally including eye area use.
§73.2298	Ferric ammonium ferrocyanide	1977	Externally applied cosmetics including eye area use.
§73.2299	Ferric ferrocyanide	1978	Externally applied cosmetics including eye area use.
§73.2326	Chromium hydroxide green	1977	Externally applied cosmetics including eye area use.
§73.2327	Chromium oxide greens	1977	Externally applied cosmetics including eye area use.
§73.2329	Guanine	1977	Cosmetics generally including eye area use.
§73.2396	Lead acetate	1981	Cosmetics intended for coloring hair on the scalp only,

			NTE 0.6 percent Pb (weight/volume).
§73.2400	Pyrophyllite	1973	Externally applied cosmetics.
§73.2496	Mica	1977	Cosmetics generally including eye area use.
§73.2500	Silver	1979	Coloring fingernail polish NTE 1% of final product.
§73.2575	Titanium dioxide	1973	Cosmetics including eye area use.
§73.2645	Aluminum powder	1977	Externally applied cosmetics including eye area use.
§73.2646	Bronze powder	1977	Cosmetics generally including eye area use.
§73.2647	Copper powder	1977	Cosmetics generally including eye area use.
§73.2725	Ultramarines	1976	Externally applied cosmetics including eye area use.
§73.2775	Manganese violet	1976	Cosmetics generally including eye area use.
§73.2991	Zinc oxide	1977	Cosmetics including eye area use.
§73.2995	Luminescent zinc sulfide	2000	Nail polish and externally applied facial makeup NTE 10% of final product for limited, occasional use.

21 CFR Part 74, Subpart C: Colors Subject to FDA Certification.

These color additives are derived primarily from petroleum and are sometimes known as "coal-tar dyes" or "synthetic-organic" colors. These colors must not be used unless FDA has certified that the batch in question has passed analysis of its composition and purity in FDA's own labs. If the batch is not FDA-certified, don't use it. These certified colors generally have three-part names. The names include a prefix FD&C, D&C, or External D&C; a color; and a number. An example is "FD&C Yellow No. 5." Certified colors also may be identified in cosmetic ingredient declarations by color and number alone, without a prefix (such as "Yellow 5").

Color Additives Subject to FDA Certification

21 CFR	Straight Color	Year Approved	Uses and Restrictions
§74.2052	D&C Black No. 2	2004	Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel.
§74.2053	D&C Black No. 3	2007	Eyeliner, eye shadow, mascara, and face powder.
§74.2101	FD&C Blue No. 1	1982	Cosmetics generally.
		1993	Allows MnO_2 in manufacture.

		1994	Eye area use (includes lake).
§74.2104	D&C Blue No. 4	1977	Externally applied cosmetics.
§74.2151	D&C Brown No. 1	1976	Externally applied cosmetics.
§74.2203	FD&C Green No. 3	1982	Cosmetics generally.
§74.2205	D&C Green No. 5	1982	Cosmetics generally.
		1994	Eye area use.
§74.2206	D&C Green No. 6	1982	Externally applied cosmetics.
§74.2208	D&C Green No. 8	1976	Externally applied cosmetics (NTE 0.01% (by wt.) of finished cosmetic product).
§74.2254	D&C Orange No. 4	1977	Externally applied cosmetics.
§74.2255	D&C Orange No. 5	1984	Externally applied cosmetics.
		1982	Mouthwashes, dentifrices, lipsticks, and other lip cosmetics NTE 5 percent.
§74.2260	D&C Orange No. 10	1981	Externally applied cosmetics.
§74.2261	D&C Orange No. 11	1981	Externally applied cosmetics.
§74.2304	FD&C Red No. 4	1976	Externally applied cosmetics.
§74.2306	D&C Red No. 6	1983	Cosmetics generally.
		2012	Ether-soluble matter specification changed to 1-[(4-methylphenyl)azo]-2-naphthalenol, not more than 0.015 percent.
§74.2307	D&C Red No. 7	1983	Cosmetics generally.
		2012	Ether-soluble matter specification changed to 1-[(4-methylphenyl)azo]-2-naphthalenol, not more than 0.015 percent.
§74.2317	D&C Red No. 17	1976	Externally applied cosmetics.
§74.2321	D&C Red No. 21	1982	Cosmetics generally.
§74.2322	D&C Red No. 22	1982	Cosmetics generally.

§74.2327	D&C Red No. 27	1982	Cosmetics generally.
§74.2328	D&C Red No. 28	1982	Cosmetics generally.
§74.2330	D&C Red No. 30	1982	Cosmetics generally.
§74.2331	D&C Red No. 31	1976	Externally applied cosmetics.
§74.2333	D&C Red No. 33	1988	Externally applied cosmetics; mouthwashes, dentifrices; cosmetic lip products (NTE 3% (by wt.) of finished cosmetic product).
§74.2334	D&C Red No. 34	1976	Externally applied cosmetics.
§74.2336	D&C Red No. 36	1988	Externally applied cosmetics; cosmetic lip products (NTE 3% (by wt.) of finished cosmetic product).
§74.2340	FD&C Red No. 40	1975	Cosmetics generally.
		1994	Eye area use (includes Al lake). No oxidizing or reducing agents that may affect integrity.
§74.2602	D&C Violet No. 2	1976	Externally applied cosmetics.
§74.2602a	Ext. D&C Violet No. 2	1976	Externally applied cosmetics.
§74.2705	FD&C Yellow No. 5	1985	Cosmetics generally.
		1994	Eye area use (includes Al lake).
§74.2706	FD&C Yellow No. 6	1986	Cosmetics generally.
§74.2707	D&C Yellow No. 7	1976	Externally applied cosmetics.
§74.2707a	Ext. D&C Yellow No. 7	1976	Externally applied cosmetics.
§74.2708	D&C Yellow No. 8	1976	Externally applied cosmetics.
§74.2710	D&C Yellow No. 10	1983	Cosmetics generally.
		1984	Modification of uses and restrictions.
§74.2711	D&C Yellow No. 11	1976	Externally applied cosmetics.

Exotic or Novel Color Additives

No matter how exotic or novel the color additive or its intended use, it is subject to the same regulations as the more everyday colors and products. The following items are a sampling of some out-of-the-

ordinary color additives. This list is not exhaustive. Rather, it is intended to show how the regulations apply to such colors:

- **Color-changing pigments:** Colors that change in response to such factors as change in pH or exposure to oxygen or temperature are subject to the same regulations as all other color additives.
- **Composite pigments:** Color additives used in combination to achieve variable effects, such as those found in pearlescent products, are subject to the same regulations as all other color additives. Some color additives, when used in combination, may form new pigments, which may not be approved for the intended use. An example is a "holographic" glitter, consisting of aluminum, an approved color additive, bonded to an etched plastic film.
- **Fluorescent colors:** Only the following fluorescent colors are approved for use in cosmetics, and there are limits on their intended uses: D&C Orange No. 5, No. 10, and No. 11; and D&C Red No. 21, No. 22, No. 27, and No. 28 [21 CFR 74.2254, 74.2260, 74.2261, 74.2321, 74.2322, 74.2327, and 74.2328].
- **Glow-in-the-dark colors:** Luminescent zinc sulfide is the only approved glow-in-the-dark color additive [21 CFR 73.2995].
- **Halloween makeup:** These products are considered cosmetics [FD&C Act, sec. 201(i); 21 U.S.C. 321(i)] and are therefore subject to the same regulations as other cosmetics, including the same restrictions on color additives.
- **Liquid crystal colors:** These additives, which produce color motifs in a product through diffraction, are unapproved color additives. Their use in cosmetics is therefore illegal [FD&C Act, sec. 601(e); 21 U.S.C. 361(e)].
- **Tattoo pigments:** As noted above, no color additives are approved for injection into the skin, as in tattoos and permanent makeup.
- **Theatrical makeup:** Like Halloween makeup, these products are considered cosmetics [FD&C Act, sec. 201(i); 21 U.S.C. 321(i)] and are therefore subject to the same regulations as other cosmetics, including the same restrictions on color additives.

Cosmetic Labeling Components

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. Below are discussed the various labeling components in details.

Principal Display Panel & Information Panel

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. Back and side panels are generally called information panels

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

The area of the PDP 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.

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.

Outer Container (Or Label of Single Container Product)

Principal Display Panel	Information Panels
Name of product	**Directions for safe use**
Identity	**Warnings**
§ 740.10 warning*	**Name and place of business**
Net quantity of contents	**Ingredient declaration**
	Any other required information

*§740.10 - Labeling of cosmetic products or its ingredient for which adequate substantiation of safety has not been obtained prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

Warning — The safety of this product has not been determined.

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. Since the information must be prominent and conspicuous, the bottom of the package is generally not acceptable for placement of required information, such as the cosmetic ingredient declaration.

Inner Container (If Packaged in an Outer Container)

Front Panel	Information Panels
	Directions for safe use
	Warnings
Name of Product	Name and Place of Business
	Net Quantity of Contents
	Any Other Required Information

The information above must appear on the label of the inner (immediate) container holding the cosmetic product. 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.
The contrast must be sufficient to make the required label statements conspicuous and easily readable
The required statements must not be obscured by vignettes or other designs or by crowding with other printed or graphic matter.

Language

All labels or labeling statements required by law or regulation must be in the English language. Products distributed solely in Puerto Rico or a Territory where the predominant language is one other than English, may state the required label information in the predominant language in place of English

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

Identity Labeling

The identity of the commodity may be expressed in terms of the common or usual name of the cosmetic, a descriptive name, or when the nature of the cosmetic is obvious, a fanciful name.
The identity statement must be in bold type and in a size reasonably related to the most prominent printed matter, which is usually the name of the cosmetic
It must be in lines generally parallel to the base on which the product rests when displayed at retail.

Name and Place of Business

The name and business address must appear on the label. 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 business address must include the street address, name of the city and state, and the ZIP code. The street address may be omitted if the firm is listed in a current city or telephone directory

The Tariff Act of 1930 requires that imported products state on the label the English name of the country of origin

Net Quantity of Contents Declaration

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 print must be easily legible bold face type in distinct contract to background and other matter on the package.

Cosmetic Warning Statements

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" A cosmetic not bearing a necessary warning statement may be considered misbranded. The lettering must be in bold type on contrasting background and may in no case be less than 1/16 inch in height.

Cosmetic Aerosols:

The label of a cosmetic packaged in a self-pressurized container and intended to be expelled from the package under pressure must bear the warning stated below.

***Warning*--Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F. Keep out of reach of children.**

The words "Avoid spraying in eyes" may be omitted if the product is not expelled as a spray. Example: Aerosol shave cream.

The word "puncture" may be replaced by the word "break" if the product is packaged in a glass container.
If the product is intended for use by children, the phrase "except under adult supervision" may be added at the end of the last sentence of the warning.
If the propellant of a cosmetic packaged in a self-pressurized container consists in whole or in part of a halocarbon or hydrocarbon, the label must bear a second warning as stated below.

***Warning*-- Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.**

This second warning is not required for the following products:

1. Aerosol foam or cream products containing less than 10% propellant.
2. Products which do not expel the propellant at the time of use. Examples: products with built-in piston barrier or propellant bag.
3. Metered spray products of less than 2 oz. net contents.
4. Aerosol products of less than 1/2 oz. net contents.

Feminine Deodorant Sprays

A feminine deodorant spray which, for the purpose of this regulation, is defined as "any spray deodorant product whose labeling represents or suggests that the product is for use in the female genital area or for use all over the body" must bear the caution stated below.

***Caution*--For external use only. Spray at least 8 inches 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.**

If the expelled product does not contain a liquefied halocarbon or hydrocarbon propellant, the sentence "Spray at least 8 inches from skin" may be omitted.
The regulation further states that the use of the word "hygiene" or "hygienic" or similar words renders any such product misbranded.

Foaming Detergent Bath Products

A foaming detergent bath product--also known as bubble bath product--is, for the purpose of this regulation, defined as "any product intended to be added to a bath for the purpose of producing foam that contains a surface-active agent serving as a detergent or foaming ingredient."

***Caution*--Use only as directed. Excessive use of prolonged exposure may cause irritation to skin and urinary tract. Discontinue use if rash, redness or itching occurs. Consult your physician if irritation persists. Keep out of reach of children**

The caution stated above is required on the label of any foaming detergent bath product which is not clearly labeled as intended for use exclusively by adults. The following are two examples of label statements identifying a product as intended for use exclusively by adults: "Keep out of reach of children" and "For adult use only."
If the bubble bath product is intended for use by children, the phrase "Keep out of reach of children" may be expanded to further read "except under adult supervision."
The regulation further requires that the label "Shall bear adequate directions for safe use" of the product.

Cosmetic Ingredient Labeling

The label on each package of a cosmetic shall bear a declaration of the name of each ingredient in descending order of predominance, except that fragrance or flavor may be listed as fragrance or flavor. An ingredient which is both fragrance and flavor shall be designated by each of the functions it performs. Where one or more ingredients is accepted by the Food and Drug Administration as exempt from public disclosure pursuant to the procedure established in 720.8(a) of this chapter, in lieu of label declaration of identity the phrase "and other ingredients" may be used at the end of the ingredient declaration.
The declaration of ingredients shall appear with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase. The declaration shall appear on any appropriate information panel in letters not less than 1⁄16 of an inch in height and without obscuring design, vignettes, or crowding. In the absence of sufficient space for such declaration on the package, or where the manufacturer or distributor wishes to use a decorative container, the declaration may appear on a firmly affixed tag, tape, or card.
The provisions of this section do not require the declaration of incidental ingredients that are present in a cosmetic at insignificant levels and that have no technical or functional effect in the cosmetic. For the purpose of this paragraph, incidental ingredients are:

(1) Substances that have no technical or functional effect in the cosmetic but are present by reason of having been incorporated into the cosmetic as an ingredient of another cosmetic ingredient.
(2) Processing aids, which are as follows:

> (i) Substances that are added to a cosmetic during the processing of such cosmetic but are removed from the cosmetic in accordance with good manufacturing practices before it is packaged in its finished form.
> (ii) Substances that are added to a cosmetic during processing for their technical or functional effect in the processing, are converted to substances the same as constituents of declared ingredients, and do not significantly increase the concentration of those constituents.
> (iii) Substances that are added to a cosmetic during the processing of such cosmetic for their technical and functional effect in the processing but are present in the finished cosmetic at insignificant levels and do not have any technical or functional effect in that cosmetic.

Color Additives Added Sometimes for Color Matching

A color additive(s) that is added to a cosmetic during manufacture for the purpose of color matching may be declared on the label of each batch or lot even if not present in each.
The color additive sometimes added for color matching is listed after the declaration of other color additives, or at the end of the declaration, and after the phrase "May Contain."

Cosmetic Products Claims

Solid documentary evidence should be provided to substantiate any claims vendor wish to make for their products. The following is a guide to the regulation of claims for cosmetic products. Vendors are required to consult their own legal advisors if their claims are validated.
The FD&C Act defines cosmetics by their intended use, as "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" (FD&C Act, sec. 201(i)). Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, and deodorants, as well as any

substance intended for use as a component of a cosmetic product. It does not include soap. Typical cosmetic claims contain words such as clean, protect, cover, mask, perfume.

A medicinal product is defined as: (a) Any substance or combination of substances presented for treating or preventing disease in human beings and/or (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. Typical medicinal claims include words such as treat, restore, cure, rejuvenate, repair, lift, prevent, and fix.

REJECTED CLAIMS	ACCEPTABLE CLAIMS
HAIR PRODUCTS	
• Makes your hair stronger • Control (eliminate) dandruff • Dandruff (anti-dandruff) shampoo (formula) • Prevent (stop) (cure) hair loss, hair thinning (baldness) • Replace thinning hair • Restore hair cells • Stimulate hair follicles (growth)	• Removes (washes) (cleans) loose dandruff (flakes) from the hair • Add body to (color) (alter shape of) hair • Help make hair look thicker (fuller) • Revitalize appearance (look) of hair, restore beauty (luster) (sheen) to the hair • Promote luster
CLEANSERS, SOAP (FOR SKIN)	
• Purify • Antibacterial (antimicrobial) • Antiseptic / disinfectant (fungicide) (germicide) (virucide) • Reference to disease-causing organisms, kills pathogens • Anti-blemish cream • Cleans cuts (wounds) • Helps control (treat) infection (jock itch)	• Helps eliminate odor caused by bacteria • Cleanse oily skin · removes top layer of dead skin • Cleans all types of skin (not just oily) • Cleans skin • Clarify, purity
SKIN MOISTURIZERS	
• Chapped skin • Feel (look) young (youthful) • Desensitize (makes less sensitive) • Reduce (prevent) irritation • Prevent (protect) damage (drying) • Relieves (soothes) itching (due to dry skin)	• Moisten (hydrate) (lubricate) (soften) skin dried (chapped) by the elements • Long lasting protection • Promotes elasticity (suppleness) • Cools skin • Desensitize razor-burned skin (e.g. aftershave lotion) • Relieves (soothes)(softens) skin (dry skin) (lips) chapped (dried) by wind (cold) (elements) • Soothes skin, makes skin feel fresher, smoother • Firms top layer of skin (temporary effect only)
GENERAL	
TYPICAL MEDICINAL CLAIMS: Treat, Restore, Cure, Rejuvenate, Repair, Lift,	TYPICAL COSMETIC CLAIMS: Clean, Protect, Cover, Mask, Perfume, Help,

REJECTED CLAIMS	ACCEPTABLE CLAIMS
GENERAL	
Prevent, Fix	Promote, Feeling, Appears
• Reduce/remove/correct lines and wrinkles	• Reduce the appearance of lines and wrinkles • Lines and wrinkles appear diminished
• Prevent/reduce ageing/premature ageing	• Helps prevent/reduce the signs of ageing/premature ageing
• Permanently fills in wrinkles/ long lasting wrinkle filler	• Filling effect or Fill/ fills in wrinkles
• Nourishes your skin	• Nourishes your skin by replacing lost moisture • Nurture (take care of)
• Increases elasticity/suppleness	• Promotes elasticity/suppleness
• Permanent/long lasting plumping/firming of the skin	• Firm/plump up your skin
• Anti-wrinkle/anti-ageing effect	• Anti-wrinkle/anti-ageing product
• See results within 3 days/2 weeks	• Instant results
• Long lasting results	• Benefits last with continued/regular use
• Lifting effect/ combats sagging skin	• Tightens and tones/ temporary lifting effect/tighten
• Treat/remove/reduce spots	• Cover up/conceal spots
• Removes/Reduces/Treats dark circles/puffiness	• Reduces the appearance of dark circles/puffiness
• Vitamins/antioxidants/peptides/ ”exotic” ingredient reduce the appearance of lines and wrinkles	• Fortified with/containing vitamins/anti-oxidants/ peptides, this product reduces the appearance of lines and wrinkles
• Effect continue after you’ve stopped using the product	• See results as long as you are using the product
• Healthy (healthy tan) • Promotes (restores) health	• Healthy looking (healthy glowing) appearance • Feels healthy
• Revitalize (skin) (scalp) (hair) • Rejuvenate, revitalize living tissue (e.g. hair follicles), living cells	• Moisturize the skin so that complexion looks radiant • Revitalize the appearance (the look) of skin, hair, scalp, face