Course Instructions

NOTE: The following page contains a preview of the final exam. The final exam is identical to the final exam that your will take online **after you purchase the course.**

After you purchase the course online, you will be taken to a receipt page online which will have a link to take the final exam. You will then click on this link to begin taking the exam. The link will also be emailed to you.

3 Easy Step to Complete the Course:

1.) **Read the Course Below**

2.) **Purchase the Course Online & Take the Final Exam – see note above**

3.) **Print Out Your Certificate**

North Carolina Esthetician 8 CE Hour Class Final Exam

CHEMICALS IN SALONS

1. **Products intended to cleanse or beautify are generally regulated as_____.**
   a. cosmetics.
   b. drugs.
   c. cosmeceuticals.
   d. monographs.
2. **A typical foundation cream emulsifier: _____.**
   a. sorbital.
   b. tween 60.
   c. glycerol.
   d. cetyl alcohol.
3. **A typical eye liner film former: _____.**
   a. mineral wax.
   b. stearic acid.
   c. carbon black.
   d. paraffin.
4. **A typical face powder vehicle and texturizer: _____.**
   a. sorbital.
   b. stearic acid.
   c. glycerol.
   d. cetyl alcohol.
5. **Cosmetic fragrances may be _____ (such as herbs or essential oils) or synthetic products.**
   a. manufactured.
   b. mined.
   c. natural.
   d. chemical.
6. **Colors derived from coal tar may be _____.**
   a. opaque.
   b. preferred.
   c. carcinogenic.
   d. substituted for those derived from animal products.

COSMETIC LABELING

7. **A cosmetic is considered misbranded if _____.**
   a. labeling is false or misleading.
   b. label states the name and address of the manufacturer, packer, or distributor.
   c. label states the net quantity of contents
   d. the required information is stated prominently.
8. **The courts, in deciding whether a product is a "cosmetic," a "drug," or both a "drug" and a "cosmetic," have relied principally on _____.**
   a. the licensee's perception of the meaning of a label statement.
   b. the consumer's perception of the meaning of a label statement.
   c. the interpretation of the meaning of a label statement by the labeler.
   d. the interpretation of the meaning of a label statement by a regulatory agency.
9. **A cosmetic is considered misbranded if its safety has not adequately been substantiated, and it does not bear the following conspicuous statement on the Principal Display Panel: _____.**
   a. Warning - The safety of this product has not been determined.
   b. Warning - Avoid spraying in eyes.
   c. Warning - Use only as directed.
   d. Caution - For external use only.

SANITATION AND INFECTION CONTROL

10. **Some ways infections are spread in a salon include but are not limited to the following: _____.**
    a. clean hands and implements.
    b. sanitary salon conditions.
    c. open sores.
    d. use of different implements on infected areas and non infected areas.
11. **If it can be reasonably expected that a worker could have hand contact with blood, OPIM, or contaminated surfaces or items, the employer must ensure that the worker wears: _____.**
    a. gloves.
    b. a mask.
    c. foot protection.
    d. eye protection.
12. **Licensees or students shall not use or possess in a cosmetic art school or shop any of the following: _____.**
    a. Methyl Methacrylate Liquid Monomer, a.k.a. MMA.
    b. razor-type callus shavers designed and intended to cut growths of skin including skin tags, corns, and calluses.
    c. carbolic acid (phenol) over two percent strength
    d. all of the above.

BUSINESS PRACTICES

13. **When you are an independent contractor:**
    a. You cannot deduct business expenses.
    b. You may deduct business expenses on Schedule C of your income tax return.
    c. You will not have any business expenses.
    d. You can deduct business expenses however you choose.
14. **Self-employed cosmetologists _____.**
    a. may not work out of their own home..
    b. may not own their own business.
    c. may rent a work space in someone else's salon.
    d. all of the above.
15. **If you rent a booth at a salon, you _____ claim the rent you pay each year for the booth.**
    a. cannot.
    b. can.
    c. sometimes can.
    d. none of the above.

North Carolina Esthetician 8 CE Hour Class
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Chemicals in Salons

Based on

US Food & Drug Administration's *Cosmetics*

Health Hazard Manual for Cosmetologists, Hairdressers, Beauticians and Barbers by Nellie J. Brown, MS, of Cornell University

U.S. Food and Drug Administration
Protecting and Promoting Your Health

How does FDA regulate cosmetics? Are they FDA approved?

FDA's legal authority over cosmetics is different from other products we regulate, such as drugs, biologics, and medical devices. FDA does not have the legal authority to approve cosmetics before they go on the market, although we do approve color additives used in them (except coal tar hair dyes).

However, under the law, cosmetics must not be "adulterated" or "misbranded." For example, they must be safe for consumers when used according to directions on the label, or in the customary or expected way, and they must be properly labeled. Companies and individuals who market cosmetics have a legal responsibility for the safety and labeling of their products.

FDA can take action against a cosmetic on the market if we have reliable information showing that it is adulterated or misbranded. FDA takes action within our legal authority, based on public health priorities and available resources.

http://www.fda.gov/Cosmetics/ResourcesForYou/Consumers/ucm135709.htm

Are all "personal care products" regulated as cosmetics? Are some drugs or "cosmeceuticals"?

People often use the term "personal care products" to refer to a wide variety of items that we commonly find in the health and beauty departments of drug and department stores. These products may fall into a number of different categories under the law.

Products intended to cleanse or beautify are generally regulated as cosmetics. Some examples are skin moisturizers, perfumes, lipsticks, fingernail polishes, makeup, shampoos, permanent waves, hair colors, toothpastes, and deodorants. These products and their ingredients are not subject to FDA premarket approval, except color additives (other than coal tar hair dyes). Cosmetic companies have a legal responsibility for the safety of their products and ingredients.

Products intended to treat or prevent disease, or affect the structure or function of the body, are drugs. This is true even if a product affects how you look. Some examples are treatments for dandruff or acne, sunscreen products, antiperspirants, and diaper ointments. Generally, drugs must receive premarket approval by FDA or, if they are nonprescription drugs, conform to special regulations, called "monographs," for their category.

Some are both cosmetics and drugs. Examples include anti-dandruff shampoos and antiperspirant-deodorants, as well as moisturizers and makeup with SPF (sun protection factor) numbers. They must meet the requirements for both cosmetics and drugs.

Some may belong to other categories, including medical devices (such as certain hair removal and microdermabrasion devices), dietary supplements (such as vitamin or mineral tablets or capsules), or other consumer products (such as manicure sets).

The law does not recognize any such category as "cosmeceuticals." If a product has drug properties, it must meet the requirements for drugs.

http://www.fda.gov/Cosmetics/ResourcesForYou/Consumers/ucm136560.htm

Makeup

FDA regulates products that we think of as "makeup" - such as lipstick, blush, foundation, face powder, eye shadow, eye liner, and mascara - as cosmetics under the Federal Food, Drug, and Cosmetic Act.

The law does not require cosmetic products and ingredients (except for color additives not intended as coal-tar hair dyes) to have FDA approval before they go on the market, but it does require them to be safe when consumers use them according to their labeling, or as they are customarily used. Also, any color additives used in cosmetics must be approved by FDA.

(Some makeup is labeled with sunscreen claims, such as "SPF" numbers. Sunscreen products intended to protect consumers from the sun are regulated as drugs. Products intended both as makeup and sun protection are both cosmetics and drugs.)

http://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm134054.htm

What ingredients are prohibited from use in cosmetics?

With the exception of color additives and a few prohibited ingredients, a cosmetic manufacturer may use almost any raw material as a cosmetic ingredient and market the product without an approval from FDA. The Federal Food, Drug, and Cosmetic Act requires that color additives used in cosmetics must be tested for safety and be listed by FDA for their intended uses.

Regulations restrict or prohibit the use of the following ingredients in cosmetics: bithionol, mercury compounds, vinyl chloride, halogenated salicylanilides, zirconium complexes in aerosol cosmetics, chloroform, methylene chloride, chlorofluorocarbon propellants and hexachlorophene.

In the early 1970s, FDA received a number of complaints of personal injury associated with the use of fingernail extenders containing methyl methacrylate monomer. On the basis of its investigations of the injuries and discussions with medical experts in the field of dermatology, FDA concluded that liquid methyl methacrylate was a poisonous and deleterious substance that should not be used in fingernail preparations. The agency chose to remove products containing 100 percent liquid methyl methacrylate monomer through court proceedings, which resulted in a preliminary injunction against one firm as well as several seizure actions and voluntary recalls.

In addition to the ingredients that are controlled by regulation or were the subject of a court ruling, cosmetic and fragrance trade associations have recommended eliminating or limiting the use of certain ingredients associated with health risks.

It is against the law to market a cosmetic that is harmful to consumers when they use it according to labeled directions, or in the customary or expected way, even if it does not contain an ingredient that is specifically prohibited or restricted by a regulation.

http://www.fda.gov/Cosmetics/ResourcesForYou/Consumers/ucm167234.htm

Prohibited and Restricted Ingredients
Are harmful ingredients allowed in cosmetics?

It's against the law for a cosmetic to contain any ingredient that makes the product harmful when consumers use it according to directions on the label, or in the customary or expected way. This is true whether or not there is a regulation that specifically prohibits or restricts the use of the ingredient in cosmetics.

The one exception is for coal-tar hair dyes, which the law treats differently. Under the law, FDA cannot take action against a coal-tar hair dye for safety reasons as long as it has a special warning statement on the label and directions for a skin test. The caution statement reads as follows:

> ***Caution - This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do may cause blindness.***

It's also important to understand that some cosmetics that are safe when people use them correctly may be unsafe when used the wrong way. Cosmetics must have any directions for use or warning statements needed to make sure people use the products safely. For example, some ingredients may be safe in products such as cleansers that we wash off the skin immediately, but not in products that we leave on the skin for hours. Similarly, ingredients that are safe for use on the hair or nails may be unsafe when used on the skin or near the eyes.

Under U.S. law, cosmetic products and ingredients, other than color additives, do not need FDA approval before they go on the market. Cosmetic manufacturers have a legal responsibility for the safety and labeling of their products. FDA can and does take action against cosmetics on the market that do not comply with the law.

What ingredients are prohibited or restricted by FDA regulations?

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 photocontact 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. The regulation makes an exception for residual amounts from its use as a processing solvent during manufacture, or as a byproduct from the synthesis of an ingredient (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 nonambulatory 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 products' 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).

What about color additives?

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. To learn more, see "Color Additives and Cosmetics."

What about drug ingredients?

If a product is intended for a therapeutic purpose, such as treating or preventing disease, it's a drug under the law and must meet those requirements, such as premarket approval by FDA, even if it affects the appearance. The presence of certain ingredients with a therapeutic use that is well-known to the public and industry is one factor that can determine whether a product is intended for use as a drug. FDA makes these decisions on a case-by-case basis. To learn more, see "Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)."

Why are different ingredients prohibited in some other countries?

Different countries and regions regulate cosmetics under different legal frameworks.

Under U.S. law, FDA does not have the authority to require cosmetic manufacturers to submit their safety data to FDA, and the burden is on FDA to prove that a particular product or ingredient is harmful when used as intended. We make these decisions based on reliable scientific information available to us. FDA can take other countries' decisions into consideration, but we can only take action within the legal and regulatory framework for cosmetics in the United States.

* "Specified risk material" means the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older and the tonsils and distal ileum of the small intestine of all cattle.

** Tallow must be produced from tissues that are not prohibited cattle materials or must contain not more than 0.15 percent insoluble impurities as determined by the method entitled "Insoluble Impurities" (AOCS Official Method Ca 3a-46), American Oil Chemists' Society (AOCS), 5th Edition, 1997, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a-46.

http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm

EXCERPTS:

Health Hazard Manual for Cosmetologists, Hairdressers, Beauticians and Barbers

by Nellie J. Brown

We will now look at the principal occupational health hazards and exposures for estheticians along with some of the related issues. We will look closely at the chemical composition of cosmetics to see what components appear to be particularly hazardous, how you are exposed to them, and what you can do to minimize exposure.

COSMETICS AND PERFUMES

Basic Cosmetic/Toiletry Ingredients

Colors: See below

Preservatives:

methyl or propyl paraben (p-hydroxybenzoic acid);

quaternary ammonium compounds: Cetrimide, benzalkonium chloride; ethyl or isopropyl alcohol;

p-Chloro-m-cresol, p-chloro-m-xylenol, dichlor-m-xylenol;

ethylene or propylene glycol phenyl ether; glycerol or ethylene glycol, p-chlorophenyl ether;

bithionol;

essential oils: eucalyptus, origanum, thyme, savory and rectified lemongrass oil, undecylenic aldehyde, benzaldehyde, eugenol, octyl alcohol, geraniol, citronellol;

dehydroacetic acid;

citrus oils;

methol;

imidazolidinyl urea;

methyl or methyl chloro isothiazolinone;

boric acid or borax;

cinnamic acid;

salicylic acid or salicylanilide;

acriflavine or proflavine;

vanillates;

propionates.

Antioxidants:

benzoic acid;

BHA (butylated hydroxyanisole), BHT (butylated hydroxytoluene), sometimes with dodecyl gallate, citric acid, hexylene or propylene glycol; tocopherol.

Film-Formers:

acrylic resins.

pH Adjustment:

citric acid;

ammonium carbonate;

ammonium bicarbonate;

calcium carbonate;

tartaric acid.

Moisture Content (Humectants):

glycerine;

propylene glycol;

calcium silicate.

Fragrances: see below

Processing Aids

Surfactants/Emulsifiers/Foaming Agents:

dodecyl benzene sulfonic acid;

sodium lauryl sulfate;

alumina gel;

sodium sulfonate.

Texturizers/Bodying Agents/Thickeners:

acacia (gum);

oils such as spermaceti and castor oil;

mineral waxes such as ceresin, beeswax, carnauba wax;

tragacath mucilage;

lanolin;

cocoa butter;

fats;

PEG (polyethylene glycol) ethers;

clay;

chalk;

starch.

Clarifying and Chelating Agents:

tannin;

EDTA.

Opacifiers:

stearyl alcohol;

cetyl alcohol.

Common Fragrances in Cosmetics and Personal Care Products

These may be natural (such as herbs or essential oils) or synthetic products, including:

sandalwood
oak moss
sweet orange
sassafras
spike
bergamot
eucalyptus
petitgrain Paraguay
abies alba
Balsam of Peru
lavender
juniper berries
bitter orange
cedarwood
clove
camomile
geranium
vetiver
cassia
calamus
peppermint
pine needle
angelica root
lemon
citronella
Balsam of Tolu
cananga
neroli
thyme
coriander
clary sage
guaiac wood
rosemary
ylang-ylang
petitgrain bigarade
litsea cubeba
oak "moss" (atranorin)
bay oil (eugenol, chavicol, methyleugenol, citral, myrcene, pinene,dipentene, phellandrene)

Common Colors in Cosmetics and Personal Care Products

These may be natural colors, minerals, or synthetic colors such as coal tar colors. F D & C dyes are those originally permitted for use in Foods, Drugs and Cosmetics when the batch was certified by the Food and Drug Administration. D & C dyes were originally permitted only for Drugs and Cosmetics. Ext. D & C dyes are permitted for externally applied Drugs and Cosmetics only and are specifically prohibited from use on the lips (such as lipstick) or any mucous membrane (such as around the eyes or lips or in toothpastes or mouthwashes). As more testing and information becomes available permitted usages for colors may change - note the restrictions for the colors described below (accurate as of 1990).

Natural Colors:

Derived from plant or animal sources:

alkanet;

* annatto, also called Natural Orange 4;

* caramel;

* carmine, also called Natural Red 4, aluminum calcium lake of carminic acid (an anthraquinone-type color);

* b-carotene;

chlorophyll, a or b, also called Natural Green 3;

Cochineal;

* guanine, 2-amunohypoxanthine, may also be synthetically prepared (pearlized or iridescent look);

* Henna (coloring scalp hair only, not for eyelashes or eyebrows or in area of eye);

Saffron;

Turmeric, also called Natural Red 3.

Mineral or Metallic Colors:

These may be natural or synthetically prepared:

* aluminum powder: external use only, near eyes is permitted;
* bismuth citrate: may be used only in coloring hair on the scalp, not for the eyelashes, eyebrows, or hair on other parts of the body;
* bismuth oxychloride (BiOCl): external use only, near eyes is permitted;
* bronze powder (alloys of copper with zinc and small amounts of aluminum and tin);
* Chinese white, also called Pigment White 4: a colloidal clay;
* chromium hydroxide green [Cr2O(OH)4]: external use only, near eyes is permitted;
* chromium oxide greens (Cr203): external use only, near eyes is permitted;
* copper powder;
* disodium EDTA - copper: may be used only in shampoos;
* ferric ammonium ferrocyanide: external use only, near eyes is permitted;
* ferric ferrocyanide, also called Prussian blue; external use only, near eyes is permitted;
* iron oxides and hydrated iron oxide [FE2O3, FeO(OH), NH2, Fe3O4]: red, yellow, or brown; hydrated form also called Pigment Brown 6 or 7;
* lead acetate: may be used only for coloring hair on scalp;
* manganese violet (ammonium manganese pyrophosphate);
* mica: silicate minerals, with or without coating of titanium dioxide;
* potassium sodium copper chlorophyllin: may be used only in dentifrices;

pumice, also called Pigment White 26;

* pyrophyllite: external use only;
* silver: may be used only in fingernail polish;

talc, also called Pigment White 26 (magnesium silicates);

* titanium dioxide, also called Pigment White 6;
* ultramarines (blue, green, pink, red, violet): calcined complex sodium aluminum sulfosilicates; external use only, near eyes is permitted;
* zinc oxide (ZnO);

zinc sulfide, also called Pigment White 7.

**According to FDA regulations (as of 1990), unless otherwise noted, these may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice. These are also exempt for certification requirement of the Food, Drug and Cosmetic Act.*

Artificial Colors

* dihydroxyacetone: external use only, to apply color to body;

** D&C Blue 4: external use only, diammonium salt of 4-{[4-(N-ethyl-p- sulfo benzyl amino)-phenyl)}-2(sulfoniumphenyl)-methylene-1- (N-ethyl-N-p-sulfobenzyl)- 2,5 cyclohexadieneimine;

** FD&C Green No. 3: disodium salt of 4-{(4-N-ethyl-p- sulfobenzylamino)-(4- hydroxy-2-sulfoniumphenyl)-methylene}- [1-N-ethyl-N-p-sulfobenzyl- 2,5-cyclohexadienimine];

** D&C Red No. 30: 5,5'-dichloro-3,3'-dimethyl-thioindigo;

Guaiazulene: external use only; 1,4-dimethyl-7-isopropyl-azulene;

** FD&C Blue No. 1: disodium salt of ethyl [4-(p-[ethyl(m- sulfobenzyl) amino)-a-(o-sulfophenyl)benzylidine]-2,5- cyclohexadien-1-ylidine) (m sulfobenzyl) ammonium hydroxide inner salt;

** D&C Blue No. 4: diammonium salt of 4-{[4-(N-ethyl-p- sulfobenzylamino)-phenyl)-(2-sulfoniumphenyl)-methylene}-[1- (N-ethyl-N-p-sulfobenzyl)-2,5-cyclohexadienimine, external use only;

** D&C Green No. 8: external use only; not to exceed 0.01% by weight of finished cosmetic product.

Fluorescent Colors:

Among these, the fluoresceins containing chlorine, bromine, or iodine used in lipsticks have caused irritations or dermatitis of lips (cheilitis) in sensitive persons.

** D&C Yellow No. 7: f1uoroscein, external use only;

** D&C Orange No. 5: dibromofluorescein, for mouthwashes and dentifrices, lipsticks or other lip cosmetics not to exceed 5.0% by weight of finished product;

** D&C Orange No. 10: di-iodofluorescein, external use only;

** D&C Orange No. 11: erythrosine yellowish Na, disodium salt of 9-o- carboxylphenyl-6-hydroxy-4,5-di-iodo-3-isoxanthone, external use only;

** D&C Red No. 19: 3-ethochloride of 9-o-carboxyphenyl-6-diethyl- amino-3-ethliminio-3-isoanthene, rhodamine B; external use only;

** D&C Red No. 21: tetrabromofluorescein;

** D&C Red No. 27: tetrachlorotetrabromofluorescein;

** D&C Red No. 22: disodium salt of 2,4,5,7-tetrabromo-9-o- carboxyphenyl-6- hydroxy-3-isoxanthone, Eosin YS;

** D&C Red No. 28: disodium salt of 2,4,5,7-tetrabromo-9-(3,4,5,6- tetrachloro-o-carboxyphenyl)-6-hydroxy-3-isoxanthone, phloxine;

** D&C Yellow No. 8: disodium salt of 9-o-carboxyphenyl-6-hydroxy-3- isoxanthone; external use only.

Azo Colors:

** D&C Red 17: dioxy-azo-benzene, external use only;

** FD&C Yellow No. 5: tartrazine, 4,5-dihydro-5-oxo-1-(4-sulfophenyl)- 4-[(4-sulfophenyl)azo]-1 H-pyrazole-3-carboxylic acid trisodium salt;

** D&C Brown No. 1: sodium salts of 4[(5-(dialkylphenyl)-azo]-2,4-dihydroxyphenyl)-azo]-2,4-dihydroxyphenyl)-azol-benzene sulfonic acid (alkyl is generally methyl), external use only;

** FD&C Yellow No. 6: disodium salt of 1-p-sulfophenylazo-2-naphthol- 7- sulfonic acid, external use only;

** FD&C Orange No. 4: monosodium salt of l-p-sulfophenylazo-2- naphthol, external use only;

** D&C Orange No 17: 1-(2,4-dinitrophenylazo)-2-naphthol, external use only;

** D&C Red No. 4: disodium salt of 2-(5-sulfo-2,4-xylylazo)-1-naphthol- 4- sulfonic acid, external use only;

** D&C Red No. 6: monosodium salt of 4-(o-sulfo-p-tolylazo)-3-hydroxy- 2- naphthoic acid;

** D&C Red No. 7: calcium salt of 4-(o-sulfo-p-tolylazo)-3-hydroxy-2- naphthoic acid;

** D&C Red No. 8: monosodium salt of 1-(4-chloro-o-sulfo-5-tolylazo)-1- naphthalenesulfonic acid, cosmetic lip products not exceeding 0.1% by weight of finished product, external use only;

** D&C No. 9: barium salt of 1-(4-chloro-o-sulfo-5-tolylazo)-2-napthol, cosmetic lip products not exceeding 0.1% by weight of finished product, external use only;

** D&C No. 17: 1-p-phenylazo-phenylazo-2-naphthol, external use only;

** D&C No. 31: calcium salt of 3-hydroxy-4-phenylazo-2-naphthoic acid, external use only;

** D&C Red No. 34: calcium salt of 4-(o-sulfo-2-naphthylazo)-3-hydroxy- 2- napththoic acid, external use only;

** FD&C Red No. 40: disodium salt of 6-hydroxy-5-[(2-methoxy-6- methyl-4-sulfophenyl)azo]-2-naphthalene sulfonic acid;

** FD&C Yellow No. 6: disodium salt of 1-p-sulfophenylazo-2-naphthol- 7- sulfonic acid;

** Ext. D&C Yellow No. 7: disodium salt of 2,4-dinitro-1-naphthol-7- sulfonic acid; external use only.

Anthraquinone Colors:

** D&C Green No. 5: disodium salt of 1,4-bis(p-toluino)-anthraquinone, not in area of eye;

** D&C Green No. 6: 1,4-bis(p-toluino)-anthraquinone, external use only;

** D&C Violet No. 2: 1-hydroxy-4-p-toluinoanthraquinone, external use only;

** EXT D&C Violet No. 2: monosodium salt of 2-[(9,10-dihydro-4- hydroxy-9,10-dioxo-1-anthracenyl)amino]-5-methyl-benzene sulfonic acid; external use only.

Quinoline Colors:

** D&C Yellow No. 10: disodium salt of disulfonic acid of 2-(2-quinolyl)- 1,3- indandione;

** D&C Yellow No. 11: 2-(2-quinolyl)-1,3-indandione; external use only.

* *According to FDA regulations of 1990, unless otherwise noted, these may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice. These are also exempt from certification requirements of the Food, Drug and Cosmetic Act.*

** *According to FDA regulations of 1990, unless otherwise noted, these may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice. All batches shall be certified as per FDA regulations.*

Common Cosmetic Ingredients

Eye Liner (liquid)

Film formers: usually acrylic resins or PVP colors, usually inorganic, such as:

titanium dioxide;
carbon black;
iron oxides;
chromium oxide;
ultramarine;
carmine.

Humectants:

Emulsifiers and thickeners;
alkanolamine stearate;
higher fatty alcohol;
cellulose ether;
polyol.

Preservatives:

parabens;
propylene glycol;
butylene glycol;
imidazolidinyl urea.

Eye Shadow (powder)

Fillers: usually talc

Inorganic colors (cream-types often add pearlescent agents), usually:

carbon black;
iron oxides;
chromium oxide;
ultramarine;
carmine.

Bodying agents such as oils (cream and stick-type shadows add waxes to this formulation).

Barrier agents: zinc stearate (a metallic soap).

Humectants

Preservatives

Mascara

Bodying agents:

triethanolamine stearate (a soap);
carnauba wax;
beeswax;
paraffin;
lanolin.

Preservatives

Colors and pigments: (insoluble), usually:

carbon black;
iron oxides;
chromium oxide;
ultramarine;
carmine.

Lash-lengthening types may contain rayon or nylon fibers.

Foundation Creams

May be oil-in-water emulsions (oil phase may represent 10-40% of the formulation), water-in oil emulsions, solvent-based (usually water), or water-free anhydrous forms (such as the stick or crayon-type). These consist of:

Bodying agents:

stearic acid;

mineral oil;

lanolin isolates and derivatives;

synthetic esters (glyceryl, glycol, polyethylene glycol monostearate);

waxes (beeswax, spermaceti);

content of kaolin clay and talc control the degree of matte finish on the skin.

Emulsifiers (such as anionic, cationic, and nonionic surfactants):

Arlacel 60 (sorbitan monostearate);

Tween 60 (polyoxyethylene sorbitan monostearate);

triethanolamine;

soaps often used to disperse pigments.

Humectants:

sorbital;

propylene glycol;

glycerol.

Opacifiers:

cetyl alcohol.

Pigments (insoluble):

titanium dioxide (in the water phase) is used to control the coverage (ability of cream to conceal skin blemishes or conceal or alter skin coloring). These pigments are wet in the oil phase already - this makes them less likely to turn "orangy" when they contact skin oils.

Perfume

Preservatives:

borax

parabens

Barrier agents:

zinc stearate, cellulose derivatives, silicones.

Thickeners:

sodium alginate, gum tragacanth, quince seed, mucilage.

Lipsticks

Bodying agents:

castor oil;

spermaceti;

cocoa butter;

hydrogenated fats and oils;

mineral waxes (ceresine);

tetrahydrofufuryl acetate;

waxes (beeswax, candelilla);

lanolin.

Fragrance

Color (FDA approved, including pearlescent agents) soluble dyes and insoluble color lakes.

Antioxidants

Flavoring agents

Opacifiers:

cetyl alcohol.

Emulsifiers/surfactants:

polyethylene glycol ethers;

propylene glycol monoesters.

Preservatives (parabens)

Rouges and Blushers (Powder types)

Bodying agents powders:

talc (transparent and regular);

clay;

chalk;

starch, with liquid petrolatum (oily binder) and thickeners such as tragacanth, mucilage barrier agents such as zinc oxide, zinc stearate.

Perfume

Colorants:

titanium dioxide or titanium dioxide-coated mica pearlizing agents;

red, yellow, or brown iron oxides;

inorganics such as ultramarine blue, pink, and violet;

for vivid shades, organic colors and lakes are used such as carmine, D&C Red #7, 9, 19, 30.

Preservatives

Rouges and Blushers (Liquid or cream types)

Bodying agents:

mineral and/or vegetable oils;
lanolin;
stearic acid;
oleic monoglyceride;
beeswax;
cocoa butter.

Color

Fragrances:

essential oils.

Thickeners:

ethyl cellulose.

Preservatives may also contain:

opacifiers, such as cetyl alcohol;
pH adjusters, such as potassium hydroxide, ammonium hydroxide;
humectants, such as glycerin, sorbital;
emulsifiers, such as sorbitan sesquioleate, ethyl alcohol.

Face Powder

Powder:

talc (finely powdered hydrous magnesium silicate).

Vehicles and Texturizers:

polyethylene;
demethicone (dimethyl polysiloxanes and silica gel);
stearic acid.

Preservatives:

methyl paraben;
propyl paraben;
imidazolidinyl urea.

Antioxidants:

tocopherol.

Pigments/ Colors:

(see earlier tables).

Adverse Health Effects Associated With Cosmetics

Typical problems with make-up involve irritations or allergies. Allergic or sensitization reactions may occur to an ingredient resulting from previous sensitization to that chemical or to a structurally similar one. Allergic reactions do not have a typical relationship of dose to response. For an allergic reaction to occur the chemical or a metabolic product of the chemical must combine with a body protein to form an antigen; the body produces antibodies as a result and the antigen-antibody interaction provokes the allergy. For cosmetics, common responses include dermatitis and itching of the skin or inflammation of the eye membranes.

Some problems are isolated incidents, such as products applied to damaged skin or use of weak sensitizers affecting a very small portion of the population. "Hypersensitivity" refers to individuals that are at the low end of the response to dose reaction.

Studies probably show only a fraction of the adverse reactions which actually occur since a consumer who suspects a product is causing a problem will discontinue its use without making a complaint to the FDA or visiting a physician. As a result, reports tend to come from products causing acute, disabling, or chronic dermatoses.

Pre-market testing by manufacturers typically uses animal studies such as the Draize rabbit eye test to screen eye make-up for irritancy or the rabbit ear tests for comedogenicity. However, these tests have limitations. For example, some ingredients cause human skin to form pustules rather than comedones (blackheads). The rabbit ear can only respond with comedones, and thus this could cause an under-reporting of an ingredient's ability to cause pustules.

Common problems or ingredients include:

- Fragrances are often removed when studies indicate irritation or allergic reactions.
- Preservatives may cause adverse reactions, yet the product is used in such a way that microbial contamination readily occurs. Organic mercury is allowed to be used in mascara because of the serious nature of eye infections (especially Pseudomonas aeruginosa).
- Residual monomer is often present in incompletely purified polymers.
- Nitrosamine may form due to the presence of 2-nitro-1,3 propanediol.
- Comedongenic effects of oils such as isopropyl myristate and other isopropyl esters and usually related to the concentration of the ingredient. A low

level may be safe, but past a threshold of 15% -20%, the formulation may cause comedones in products intended to remain on the skin. If more than one comedogenic ingredient is used in a product, the effects are additive.

- Glycols, especially propylene glycol, are common and should be substituted with butylene glycol or polyethylene glycol (PEG).
- Soap emulsifiers can be irritating.
- Volatile bases can be irritating, such as morpholine, ammonia, 2-amino-methyl-1- propanol.
- Rayon and nylon fibers used in lash-lengthening mascara are irritants, especially for contact lens wearers.
- Allergic reactions to shellac, used as thickener, are common.
- Solvents used in eye make-up can be irritants.
- Irritations may occur from removers for waterproof mascara and eye shadow.

Reactions to eye area cosmetics can be particularly serious.

- Stinging or burning of the eyes and eye lids, usually short-lasting and without obvious irritation; generally caused by the evaporation of volatiles (mineral spirits, isoparaffins, alcohol) or potential irritants (propylene glycol, soap emulsifiers). Sometimes the repeated use of the product produces tolerance to it.

Allergic (so-called) conjunctivitis, not always a delayed hypersensitivity, may be caused by:

- physical irritants - mascara flakes, eye shadow dust, particles of eyeliner, mascara extenders of nylon or rayon fibers
- chemical irritants - solvents, soap emulsifiers
- potential allergens - fragrance, preservatives

Contact dermatitis of the lids and periorbital area is most frequently caused by cosmetics applied to the hair (especially dyes), face, fingernails (especially nail polish); although the reaction may not be produced on these sites. This may also be a reaction to face creams, foundations, and blushers, or the rubber edges or nickel in eyelash curlers. Allergic or irritant contact dermatitis is possible, and may involve make-up removers or treated tissues used for make-up removal. Hypersensitivity may also be caused by preservatives (parabens, imidazolidinyl urea), propylene glycol, antioxidants, and lanolin derivatives.

Infection due to contaminated or inadequately preserved products can cause chronic conjunctivitis and blepharitis (inflammation of the eyelid) due to mascara and eyeliner. Keratitis and corneal ulcers (especially caused by Pseudomonas aeruginosa) can cause vision loss, especially where damage to the cornea has occurred by a mascara wand or a fingernail scratch. Besides Pseudomonas, other common organisms include Staphylococcus epidermis, Staphylococcus aureus, and Fusarium solanae (a fungus).

Conjunctival pigmentation caused by eyeliner applied to the conjunctival side of the eyelid instead of the exterior lid back of the lashes may sometimes cause discomfort, tearing, and itching, but is usually asymptomatic.

Colors derived from coal tar may be carcinogenic. See above for sensitization reactions to fluorescent colors.

Fragrances cause allergies or skin pigmentation (especially photosensitization, which occurs after exposure to sunlight or tanning lamps). Sensitization can occur from:

- the essential oil itself;
- the fragrant chemical itself (which has been purified or extracted from the oil);
- additives which retard the evaporation of perfumes (such as benzyl salicylate);
- additives used to strengthen the odor (such as the fixative musk ambrette).

Protection and Prevention

Product Substitution

- Consider using products containing vegetable oil derivatives such as propylene glycol caprate or propylene glycol caprylate, octyl palmitate, isostearyl neopentenoate.
- Change preservatives. Reduce the use of products preserved with parabens, formaldehyde or formaldehyde releasers (such as Quaternium-15). Use synergistic blends instead, such as combinations of alcohol, glycols, and phenoxyethanol.
- Consider changing color families; for example, D&C Green No. 5 is an anthraquinone color and is a possible skin irritant. An individual who reacts to one anthraquinone color may react to others of this family.
- Avoid shellac and natural resin containing products due to allergic and spoilage potential.
- Consider changing color types such as mineral colors rather than natural or synthetic colors.
- Consider uncolored products.
- Consider changing fragrance families such as terpenes vs. nonterpenes; or natural vs. synthetic. The terpenes include limonene, geraniol, citronellol, linalool, citral; the nonterpenes include cinnamon

oil (cinnamic aldehyde, "oriental bouquets"), clove oil (eugenol, vanillin), coumarin, Balsam of Peru (coniferyl benzoate).

- Avoid soap emulsifiers.
- Avoid propylene glycol; substitute butylene glycol or polyethylene glycol (PEG).
- Consider unscented products; that is, truly unscented products, not those containing masking fragrance.
- Avoid irritating volatile bases such as morpholine, ammonia, 2-amino-methyl-1- propanol.
- Consider using mascara which only colors the lashes, but does not thicken them or extend them using fibers.
- Handle cosmetics carefully to avoid contamination. Do not spit in products to moisten them. Use disposable or washable applicators instead of the fingers.
- Replace products frequently; especially avoid old makeup around the eyes.
- Do not apply products to broken or irritated skin.
- Apply makeup carefully around the eyes; avoid touching the conjunctival membrane.

Cosmetic Labeling: Relevant Laws

Based on:

Food and Drug Administration: *Cosmetic Labeling Guide*

As a professional, you know that your clients come to you for your expertise. Are you doing everything you can to ensure they not only look their best, but are doing so safely?

Protect your clients and your salon's reputation:

- ❖ know what laws govern the cosmetics you use,
- ❖ understand what labels should look like and what information they should hold,
- ❖ be aware of warning statements and what they mean,
- ❖ and hold your suppliers accountable to these standards.

The Cosmetic Labeling Guide provides step-by-step help with cosmetic labeling, with examples and answers to questions manufacturers often ask about labeling requirements under U.S. laws and related regulations.

Laws Regulating Cosmetic Labeling

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, drugs, devices, and cosmetics.

21 U.S.C. 321-392

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.

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 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.

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

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.

A cosmetic is considered misbranded if.....

- labeling is false or misleading
- label does not state
  - the name and address of the manufacturer, packer, or distributor
  - the net quantity of contents
- the required information is not stated prominently, with conspicuousness and in terms that it is read and understood by consumers under customary conditions of purchase and use
- the container or its fill is misleading

Sec. 602, FD&C Act

Sec. 602 of the FD&C Act defines the conditions which cause a cosmetic to be deemed misbranded.

Factors Determining Whether Labeling Is Misleading

1. Representations made or suggested

2. Failure to reveal material facts:

a. Material in light of such representations

b. Material with respect to consequences resulting from the intended use

Sec. 201(n), FD&C Act
21 CFR 1.21

Labeling may be considered misleading not only because a label statement is deceptive but also because a material fact is not revealed on a label.

A fact may be material in light of a statement made on a label or because certain consequences may result from the recommended use of a product.

Legal Definitions of Terms

What is a cosmetic?

A cosmetic is a product, except soap, intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance.

Sec. 201(i) FD&C Act

As defined in section 201(i) of the FD&C Act, a cosmetic is a product, except soap, intended to be applied to the human body for cleansing, beautifying, promoting attractiveness or altering the appearance.

In short, one may say that a cosmetic is a product intended to exert a physical, and not a physiological, effect on the human body.

The raw materials used as ingredients of cosmetic products are by law also cosmetics.

In section 701.20 of Title 21 of the Code of Federal Regulations [21 CFR 701.20], the Food and Drug Administration (FDA) defines the term "soap" as a product in which the non-volatile portion consists principally of an alkali salt of fatty acids, i.e., the traditional composition of soap; the product is labeled as soap; and the label statements refer only to cleansing. If cosmetic claims, e.g., moisturizing, deodorizing, skin softening etc., are made on a label, the product is a cosmetic. Synthetic detergent bars are also considered cosmetics, although they may be labeled as "soap."

"Intended use" within the meaning of the FD&C Act is determined from its label or labeling.

Senate Report No. 493
73d Cong. 2d Sess. (1934)
U.S. Courts of Appeals Decisions

According to Senate Report No. 493 and court decisions, the term "intended" in the legal definition of the term "cosmetic" or in other definitions means, with respect to the use of a product, its directed or prescribed use as determined from the statements made on a product's label or labeling.

The courts, in deciding whether a product is a "cosmestic," a "drug," or both a "drug" and a "cosmetic", have relied principally on the consumer's perception of the meaning of a label statement and less so on the interpretation of the meaning of a label statement by the labeler or a regulatory agency.

When is a cosmetic also a drug?

A cosmetic is also a drug when it is intended to cleanse, beautify or promote attractiveness as well as treat or prevent disease or otherwise affect the structure or any function of the human body.

Sec. 201(g) and (i), FD&C Act
Sec. 509, FD&C Act

A cosmetic is legally also a drug if it is intended to exert a physical as well as a physiological effect because the FD&C Act defines in section 201(g) the term "drug" to mean, among other things, "articles intended for use in the ... cure, mitigation, treatment, or prevention of disease ... and ... articles ... intended to affect the structure or any function of the body ..."

Section 509 of the FD&C Act provides that the categories of "drug" and "cosmetic" are not mutually exclusive.

What is a consumer commodity?

A product customarily distributed for retail sale for use by consumers or for the performance of services at home and usually consumed during such use.

Sec. 10(a), FP&L Act.

A cosmetic is legally also a drug if it is intended to exert a physical as well as a physiological effect because the FD&C Act defines in section 201(g) the term "drug" to mean, among other things, "articles intended for use in the ... cure, mitigation, treatment, or prevention of disease ... and ... articles ... intended to affect the structure or any function of the body ..."

Section 509 of the FD&C Act provides that the categories of "drug" and "cosmetic" are not mutually exclusive.

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 package is defined in the Fair Packaging and Labeling Act [sec. 10(b)] and the Code of Federal Regulations [21 CFR 1.20].

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.

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 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.

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)

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.

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

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.

Placement and Size of Principal Display Panel

Location
Size
Multiple PDPs

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)

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.

The PDP of a "boudoir-type" or decorative cosmetic container, e.g., cartridge, pill box, compact or special variety, and those containing 1/4 oz or less may be a tear-away tag or tape affixed to the container [21 CFR 701.13(e)(1)]. It may also be the display panel of a card to which the immediate container is affixed [21 CFR 701.13(e)(2)].

Placement of Information on Labels

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

The information above 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.

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. 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.

Form of Stating Required Information

Section 602(c) of the FD&C deems a cosmetic misbranded if any word, statement, or other label or labeling information required by law or regulation is not placed on the label or labeling with such prominence and conspicuousness that it is likely to be read, or if it is not stated in such terms that it is likely to be understood by ordinary individuals.

Prominence and Conspicuousness

Regulations [21 CFR 701.2] published by the FDA offer detailed information on how to comply with the requirement for prominent and conspicuous placement of information on cosmetic labels or labeling.

Panel display: The required information must be on a panel which is presented or displayed under customary conditions of purchase. This eliminates placement of required information on a bottom panel of a cosmetic unless it is very small and customarily picked up by hand where inspected for possible purchase.

Panel Size: The label must be large enough to provide sufficient space for prominent display of the required information.

Style and Size of Letters: The type must be of such size, and at least of the required minimum size, and of such style that the required label statements are easily readable.

Background Contrast: The contrast must be sufficient to make the required label statements conspicuous and easily readable.

Obscuring Designs, Vignettes: The required statements must not be obscured by vignettes or other designs or by crowding with other printed or graphic matter.

21 CFR 701.2

Language

English Language Statements: All label 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.

Foreign Language Statements: If the label contains any foreign language representation, all statements required by regulation must also appear on the label in the foreign language. If labeling bears foreign language representations, the required statements must appear on the label or other labeling as required in English.

21 CFR 701.2(b)

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)

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)].

Identity Labeling

Common or usual name
Descriptive name
Fanciful name
Illustration
Prominence
Placement

Sec. 10(t), FP&L Act
21 CFR 701.11

Sec. 4 of the FP&L Act [21 U.S.C. 14554] requires that a consumer commodity bear a statement of identity. Regulations [21 CFR 701.11] published by the FDA require that the identity statement appear on the PDP.

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. It may also be expressed in form of an illustration.

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

Corporate name
Manufactured for...
Distributed by...
Address
Principal place of business

21 CFR 701.12

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.

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

- **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 ration
  Type size
  § 701.13 (h) and (i)

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.

Exemptions from Net Contents Declaration

Cosmetics of less than 1/4 av. oz. or 1/8 fl. oz.

- **On display card**
- **In outer container**

21 CFR 1.24

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 [21 CFR 1.24].

When a cosmetic is required to bear net quantity of contents declarations on the inner and outer container, the declaration on the outer container must appear on the PDP; on the inner container, it may appear on an information panel other than the panel bearing the name of the product, i.e., the front panel.

Quantity of Contents

- Accuracy§ 701.13 (g) and (s)
- Declaration by Product Consistency§ 701.13 (a)
- Systems of Measures and Weights§ 701.13(b) and (r)
- Unit Terms and Abbreviations§ 701.13 (j) (2) & (n)
- Dual Form of Declaration701.13 (j) (1)
- Declaration of Fraction§ 701.13 (d)

Examples of Net Quantity Statements

"Net Wt. 6 Oz." or "6 oz. Net Wt."
"Net Contents 6 fl. Oz." or "Net 6 Fl. Oz." or "6 Fl. Oz."
"Net Wt. 1/4 Oz." or "Net Wt. 0.25 Oz."
"Net 1/8 Fl. Oz." or "0.12 Fl. Oz."
"Net Wt. 24 Oz. (1-1/2 Lbet" or "Net Wt. 24 Oz. (1.5 Lb.)
"Net 56 Fl. Oz. (1 Qt. 1 Pt. 8 Fl. Oz.)" or "... (1 Qt. 1-1/2 Pt.)" or "... (1 Qt. 1.5 Pt.)"

Accuracy: The net quantity of contents (net contents) declaration must accurately reveal the quantity of cosmetic in the container in terms of weight, volume, measure, numerical count, or combinations of count and weight, volume or measure. Reasonable variations due to loss or gain of moisture, or deviations in good manufacturing practice, are acceptable. In case of an aerosol product, the net contents statement must express the net quantity of contents expelled.

Product Consistency: Unless there is a firmly established, general consumer usage or trade custom to the contrary, the statement must be in terms of fluid measure if the cosmetic is liquid and in terms of weight if the cosmetic is solid, semi-solid, viscous, or a mixture of solid and liquid. Fluid measures must express the volume at 68°F (20°C). The customary net contents declaration for aerosol products is in terms of weight.

Systems: Weight is expressed in terms of avoirdupois pound and ounce. Fluid measures are expressed in terms of the U.S. gallon, quart, pint and fluid ounce. Net contents may additionally be stated also in the metric system.

Unit Terms: The term "net weight" or "net wt." must be used in conjunction with a weight statement, and the term "net contents," "net" or nothing must be used in connection with a liquid statement.

Additional abbreviations are for: weight - wt., fluid - fl., gallon - gal., quart - qt., pint - pt., ounce - oz., pound - lb.

In case of a weight ounce statement, the term "oz." is sufficient. A fluid ounce is expressed as "fl. oz."

Examples:

- Net wt. 4 av. oz.
- Net contents 4 fl. oz.
- 4 av. oz. net wt.
- 4 oz. net wt.
- Net 4 fl. oz.
- 4 fl. oz.

Dual Declaration: If the net weight exceeds one pound but is less than 4 pounds, the net contents statement must reveal the total number of ounces followed, in parenthesis, by the number of pounds and ounces or by the number of pounds and fraction thereof. Fluid measures exceeding one pint, but being less than one gallon, must be expressed in terms of the total number of fluid ounces followed, in parenthesis, by the number of quarts, pints and ounces or by the fractions of the quart or pint.

Examples:

- Net Wt. 24 oz. (1 lb. 8 oz.)
- Net Wt. 24 oz. (1 - 1/2 lb.)
- Net Wt. 24 oz. (1.5 lb.)
- 56 fl. oz. (1 qt. 1 pt. 8 fl. oz.)
- 56 fl. oz. (1 qt. 1-1/2 pt.)
- 56 fl. oz. (1 qt. 1.5 pt.)
- 56 fl. oz. (1-3/4 qt.)

Declaration of fractions: Fractions may be expressed in terms of common fractions ranging from 1/2 to 1/32 or as decimal fractions of no more than two significant numbers.

Quantity of Contents on Principal Display Panel

"Economy Size" or "Budget Size"
"Giant Pint" or "Full Quart"
"Net 6 Fl. Oz." and "Six Applications"
"Net 6 Fl. Oz." and "6 Bottles of 1 Fl. Oz. Each"

Quantity of Contents on Information Panel

Any non-deceptive supplemental statement

21 CFR 1.31 and 701.13 (g)

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)].

Cosmetic Warning Statements

General Requirement:

Prominence

- Placement
- Spacing

Conspicuousness

- Contrast
- Type size

21 CFR 740 (1) and (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.

Cosmetics with Unsubstantiated Safety

- ***Warning--The safety of this product has not been determined.***

21 CFR 740.10

A cosmetic is considered misbranded if its safety has not adequately been substantiated, and it does not bear the following conspicuous statement on the PDP:

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

The safety of a cosmetic may be considered adequately substantiated if experts qualified by scientific training and experience can reasonably conclude from the available toxicological and other test data, chemical composition, and other pertinent information that the product is not injurious to consumers under conditions of customary use and reasonably foreseeable conditions of misuse.

The safety of a cosmetic can adequately be substantiated by:

a. Reliance on available toxicological test data on its ingredients and on similar products, and

b. Performance of additional toxicological and other testing appropriate in the light of the existing data.

Even if the safety of each ingredient has been substantiated, there usually still is at least some toxicological testing needed with the formulated product to assure adequate safety substantiation.

Cosmetic Aerosols

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.

21 CFR 740.11 (a)

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.

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.

Warning—Use only as directed. Intentional misues by deliberately concentrating and inhaling the contents can be harmful or fatal.

21 CFR 740.11 (b)

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.

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

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.

21 CFR 740.12

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.

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

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.

21 CFR 740.17

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."

The caution stated below 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

Declaration of ingredients except flavor, fragrance, and trade secret ingredients in descending order of predominance

21 CFR 701.3

Cosmetic ingredient labeling became an issue in the early 1970s. Guidelines for ingredient labeling were published in mid-1972. Regulations were proposed in early 1973. After publication of two final regulations, stays of final regulations, terminations of stays, and lengthy court proceedings challenging the legality of the published regulations, the requirement for cosmetic ingredient labeling became fully effective in early 1977.

The regulations requiring the declaration of cosmetic ingredients were published under the authority of the FP&L Act [secs. 5(c) and 6(a); 15 U.S.C. 1454 and 1455] and FD&C Act [sec. 701(e); 21 U.S.C. 371(e)].

Since the FP&L Act applies only to consumer commodities and their packages as defined in the Act, cosmetic ingredient declarations are required only on the label of the outer container of cosmetics customarily sold at retail or used in the performance of services conducted within the households. It does not apply, for example, to products used at professional establishments or samples distributed free of charge, unless such products are customarily also sold at retail, even if they were labeled "For professional use only."

The ingredients must be declared in descending order of predominance. Exceptions to this requirement are discussed later.

Prominence of Ingredient Declaration

Prominent and conspicuous to render it easy to be read and understood by ordinary individuals under normal conditions of purchase

Letter Height **1/16 inch**

Exception: **1/32 inch**
If total available labeling surface area is less than 12 sq. in.

Information panel

Firmly affixed tag, tape, or card

21 CFR 701.3(b) and (p)

The ingredient declaration may appear on any information panel of the package which is the outer container in form of a folding carton, box, wrapper etc. if the immediate container is so packaged, or which is the jar, bottle, box etc. if the immediate container is **not** packaged in an outer container. It may also appear on a tag, tape or card firmly affixed to a decorative or small size container.

Prominence: The declaration must appear with prominence and conspicuousness so that it is likely to be read and understood (read with ease) by ordinary individuals under normal conditions of purchase. The letters must not be obscured by design, vignettes, background or crowding.

Type Size: Not less than 1/16 inch in height. It may be not less than 1/32 inch in height if the total surface area available to bear labeling (which excludes bottom, shoulder, neck, flange, decorative or sculptured surfaces) is less than 12 square inches.

The type size consisting of upper and lower case letters is determined by the height of the lower case letter "o".

The ingredient declaration may appear on any information panel of the package which is the outer container in form of a folding carton, box, wrapper etc. if the immediate container is so packaged, or which is the jar, bottle, box etc. if the immediate container is not packaged in an outer container. It may also appear on a tag, tape or card firmly affixed to a decorative or small size container.

Prominence: The declaration must appear with prominence and conspicuousness so that it is likely to be read and understood (read with ease) by ordinary individuals under normal conditions of purchase. The letters must not be obscured by design, vignettes, background or crowding.

Type Size: Not less than 1/16 inch in height. It may be not less than 1/32 inch in height if the total surface area available to bear labeling (which excludes bottom, shoulder, neck, flange, decorative or sculptured surfaces) is less than 12 square inches.

The type size consisting of upper and lower case letters is determined by the height of the lower case letter "o".

Identification of Ingredients by Name

1. The name established by the commissioner as specified in § 701.30.
2. The name adopted for the ingredient as listed in:
   (a) CTFA Cosmetic Ingredient Dictionary
   (b) United States Pharmacopeia
   (c) National Formulary
   (d) Food Chemical Codex
   (e) USAN and the USP Dictionary of Drug Names

3. The name generally recognized by consumers

4. The chemical or technical name or description

21 CFR 701.3(c)

Section 701.3(c) requires that an ingredient be identified by the name established by the Commissioner for the purpose of cosmetic ingredient labeling or, in the absence of a name established by the Commissioner, the name adopted for that ingredient in the editions and supplements of the compendia listed below.

The Commissioner may establish a name as petitioned or propose such a name on his own initiative. See section 701.3(e). The names specified by the Commissioner are listed in section 701.30.

The currently recognized edition of the CTFA (Cosmetic, Toiletry and Fragrance Association, Inc.) Cosmetic Ingredient Dictionary is the second edition published in 1977. This edition is recognized only in part, i.e., not all names listed in the second edition have been adopted.

The third edition of the CTFA Cosmetic Ingredient Dictionary published in 1982 and the Supplement published in 1985 have not yet been recognized. However, FDA has informed the CTFA that the agency will not take regulatory action against products labeled in accordance with these editions while their review is in progress.

The compendia are listed in the descending order by which they must be utilized for identification of an ingredient name. If none lists a name for an ingredient, the name generally recognized by consumers, or the chemical or technical name or description, must be used.

Order of Ingredient Declaration

Descending Order of Predominance

Exceptions...
Active drug ingredients
Ingredients with less than 1% concentration
Color additives
"And other ingredients"

21 CFR 701.3(a), (d), (f) (2), (f) (3)

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)].

Order of Predominance

Lipstick	
Incorrect Label Copy:	**Correct Label Copy:**
Caster Oil (58)	Castor Oil
Beeswax (6.5)	Lanolin
Candelilla Wax (6.5)	Beeswax
Carnauba Wax (3)	Candelilla Wax
Lanolin (8)	Carnauba Wax
Ozokerite (2)	Ozokerite
Propylene Glycol (and) BHA	Propylene Glycol
(And) Propyl Gallate	BHA
(And) Citric Acid (1.3)	Propyl Gallate
Titanium Dioxide (2)	Citric Acid
D&C Red No. 21 (2)	Fragrance
D&C Red No. 6 Barium Lake (4)	Titanium Dioxide
D&C Yellow No. 5 Aluminum Lake (5)	D&C Red No. 21
Fragrance (0.5)	D&C Red No. 6 Barium Lake
	D&C Yellow No. 5 Aluminum Lake

In this example, the correct ingredient declaration lists castor oil (58), lanolin (8), candelilla wax (6.5), carnauba wax (3), and ozokerite (2) in descending order of predominance. The concentrations (which need not be declared by regulation) are provided in parentheses.

The compounds of the proprietary antioxidant mixture dissolved in propylene glycol must be integrated into the product formulation and declared individually in order of decreasing predominance without the term "(and)."

The color additives titanium dioxide (2) etc. may be declared in any order after the other ingredients.

Declaration of Color Additives and Ingredients Present at One Percent or Less

Pressed Powder	
Label Declaration:	**Alternate Declaration:**
Talc (75)	Talc
Kaolin (7.5)	Kaolin
Zinc Stearate (5)	Zinc Stearate
Titanium Dioxide (5)	Mineral Oil
Mineral Oil (3)	Lanolin
Iron Oxides (2.5)	Isopropyl Myristate
Isopropyl Myristate (0.9)	Fragrance
Lanolin Oil (0.5)	Lanolin Oil
Lanolin (0.2)	Titanium Dioxide
Fragrance (0.1)	Ultramarine Blue
Ultramarine Blue (0.05)	Iron Oxides

The hypothetical pressed powder formulation portrayed in this example illustrates the two options for the listing of ingredients.

On the left side, the ingredients are listed in descending order of predominance according to § 701.3(2).

On the right side, the ingredients are listed according to § 701.3(f)(1), (2), and (3), i.e., ingredients other than colors present at a concentration exceeding 1% in descending order or predominance, followed by ingredients other than colors present at 1% or less in any order, followed by colors present at any concentration listed in any order.

Declaration of Fragrance and Flavor Ingredients

- Fragrance
- Flavor
- Fragrance and flavor

21 CFR 701.3(a)

Fragrance and flavor compounds may be declared in descending order of predominance as "fragrance" and "flavor." If a fragrance compound also serves as a flavor, it must be declared as "flavor and fragrance."

The components (ingredient) of a fragrance or flavor may also be declared individually by their appropriate label names.

The ingredient or mixture of ingredients acting as a masking agent, i.e., covering the undesirable off-odor of a product without adding a discernable odor to it, may be declared by their individual name(s) or as "fragrance" (in lieu of a better designation). A masking agent present in a product at an insignificant level may be considered an incidental ingredient under § 701.3(1)(2)(iii) in which case it need not be declared on the label.

Trade Secret Ingredients

Declaration of Trade Secret Ingredients

By the Phrase "And Other Ingredients"

If accepted by FDA as exempt from public disclosure pursuant to the procedure of § 720.8.

21 CFR 701.3(a)

The FP&L Act states in section 5(c)(3)(B) [15 U.S.C. 1454(c)(3)(B)] that "nothing ... shall be deemed to require that any trade secret be divulged." Accordingly, the cosmetic ingredient labeling regulation does not require the declaration of the identity of an ingredient FDA has accepted as exempt from public disclosure. In lieu of the declaration of the name of a confidential ingredient, the phrase " and other ingredients" may be used at the end of the ingredient declaration.

The policy the agency is following for processing requests for confidentiality of cosmetic ingredient identities has been codified under § 720.8.

What is a trade secret?

A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business and which gives one an opportunity to obtain an advantage over competitors who do not know or use it.

21 CFR 20.61

The question "what is a trade secret" may be answered by restating the definition of the term "trade secret" as provided in § 20.61(a) of regulations published in 1974 for enforcement of the law commonly known as the "Freedom of Information Act" (the public information section of the Administrative Procedures Act; 5 U.S.C. 552).

Procedure for Requesting Exemption of an Ingredient Identity From Public Disclosure

1. Submission of information

2. Review of data for adequacy
3. Tentative determination of trade secrecy
4. Final determination of trade secrecy
5. Judicial review under 5 U.S.C. Chapter 7

1. Submission of information

- **Cosmetic formulation or raw material composition statement (Form 2512 OR 2513)**
- **Statement of factual and legal grounds justifying trade secrecy**
- **Statement of prior non-disclosure (§ 20.81)**

21 CFR 720.8

The first step in processing a request for trade secrecy, i.e., a request for exemption from label declaration, of the identity of a cosmetic ingredient is the submission to FDA of the following information:

(a) A semi-quantitative cosmetic formulation statement of the product in question on forms FD-2512 and 2512a.

(b) A full statement of the factual and legal grounds for the request, including all data and other information on which the petitioner relies (as well as any information known to the petitioner that is unfavorable to petitioner's position).

The statement of factual grounds should include scientific or technical data, reports, tests, and other relevant information that address the factors FDA considers in determining whether the identity of an ingredient qualifies as a trade secret. (The factors FDA considers are stated elsewhere.)

(c) A statement that the identity of the ingredient in question has not previously been disclosed to anyone without appropriate safeguards for secrecy as further explained in § 20.81.

2. Review of data for adequacy

21 CFR 720.8

FDA reviews the submitted information to determine whether the data are sufficient to permit a review of the merits of the request.

A request that contains insufficient data to conduct a confidentiality review on the merits is returned and petitioner is advised about the additional information that is necessary to enable the agency to proceed with the review of the request.

3. Tentative determination of trade secrecy

21 CFR 720.8

When the submitted information is sufficient to permit a review of the merits of a request, FDA proceeds with the review.

When the agency concurs with petitioner and decides that the ingredient identity is a trade secret, the request for exemption from label disclosure is granted. If FDA does not concur with petitioner, the agency tentatively denies the request. The person requesting trade secrecy is informed in writing of the agency's determination. In case of a tentative denial, FDA informs petitioner of the grounds on which it relied in making this tentative determination.

Factors Considered in Determining Trade Secret Status

1. Is the information publicly known?
(a) Prior public disclosure by petitioner
(b) Public disclosure in the literature
(c) Measures taken to guard secrecy

When FDA reviews the merits of a confidentiality request and determines whether the identity of an ingredient qualifies as a trade secret, it considers the following three principal factors by seeking answers to the following three questions:

1. Is the ingredient's identity and intended use publicly known?
2. Does the intended use of the respective ingredient have value?
3. Can the identity of the ingredient readily be acquired by legal means and its intended use duplicated?

These questions are based on the factors considered in Comment B to section 757 of the Restatement of Torts in determining whether given information is a trade secret.

Since the same factors are also being considered by FDA in determining whether the identity of an ingredient qualifies as a trade secret, a person requesting trade secrecy must address them factually and convincingly in the statement of grounds.

Absence of public knowledge of an ingredient's identity under conditions of intended use may be demonstrated by documenting the extent to which the information is known by employees or others in petitioner's business, the extent the information is publicly disclosed in pertinent literature, and the extent of measures taken by petitioner to guard the secrecy of the information.

2. Does the information have value?
(a) Importance to the product
(b) Product profitability
(c) Future market performance of product
(d) Effort and financial resources invested

The value of knowing the identity and intended use of the ingredient in question may be determined in terms of the importance of the ingredient to the product formulation. It must be assumed that, to be of value, the ingredient significantly contributes to the claimed performance or other pertinent characteristics of the cosmetic and that a cosmetic not containing the claimed trade secret ingredient, or containing conventional substitutes in place of the respective ingredient, could not be expected to perform equally well or otherwise meet certain requirements. Appropriate comparative testing of a cosmetic containing the trade secret ingredient, or one containing conventional substitutes, as well as testing of petitioner's cosmetic against competitor's cosmetic of the same use category may provide factual documentation to this effect and thus demonstrate the value of the information to petitioner. The value of the ingredient information may also be determined in terms of future market performance of a cosmetic or its profitability. However, this kind of value assessment is usually a difficult and inexact task and often provides little factual data to support a value assessment.

Documentation of the effort expended and financial resources invested in the development of the product formulation containing the ingredient in question and providing the claimed characteristics may further support a request for trade secrecy.

3. Can the information readily be acquired or duplicated?

The factor concerning the ease or difficulty with which the identity of the ingredient in question could properly be acquired or duplicated by others may be addressed by documenting an ingredient's rare or unexpected use for the intended purpose in cosmetics of a particular product category or by demonstrating the complexity of the analytical methodology necessary to identify it.

4. Final determination of Trade Secrecy

- **Cosmetic formulation or raw material composition statement (Form 2512 OR 2513)**
- **Statement of factual and legal grounds justifying trade secrecy**
- **Statement of prior n**on-disclosure (§ 20.81)

21 CFR 720.8

When FDA tentatively decides to deny a request, the petitioner may withdraw the records for which FDA has tentatively denied a request for confidentiality. Petitioner may also submit, within 60 days from the date of receipt of the written notice of the tentative denial, additional relevant information and arguments and request that the agency reconsider its decision in light of both the additional material and the originally submitted information.

If the petitioner submits new data, the agency considers that material together with the initially submitted information and makes its final determination. This constitutes final agency action. The petitioner is informed of the agency's final determination in writing.

5. Judicial review under 5 U.S.C. Chapter 7

21 CFR 720.8

The agency's final decision may be challenged in the courts under 5 U.S.C., Chapter 7. If suit is brought within 30 days after such determination, FDA will not disclose the records involved until the matter is finally determined in the courts. If suit is not brought within 30 days and the petitioner does not withdraw the records for which a request for confidentiality has been denied, the records involved will be made part of FDA's files and will then be available to the public upon request.

It should be noted that until the agency has completed its determination that the identity of a cosmetic ingredient is a trade secret, the cosmetic product in question may not bear the label statement "and other ingredients" in lieu of a declaration of the identity of the ingredient for which confidentiality has been requested. The phrase "and other ingredients" may be used on the label only after an ingredient is accepted by FDA as exempt from public disclosure or, when confidentiality has been denied, if suit is brought within 30 days after a final determination that the ingredient in question is not a trade secret.

Cosmetics That Are Also Drugs

Declaration

1. The established name of any active drug ingredient and the quantity, kind, and proportion of any alcohol, in compliance with Sec. 502(e) of the FD&C Act, as "Active Ingredients"

2. The remaining ingredients, in compliance with § 701.3, as "Cosmetic Ingredients"

21 CFR 701.3(d)

A product intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance is a cosmetic. If this product claims to accomplish these deeds through physiological activity or by changing the structure of the skin, it is also a drug. The product categories "drug" and "cosmetic" are not mutually exclusive. This is recognized in sec. 509 of the FD&C Act.

If a cosmetic is also a drug, the label must list first the established name of the drug ingredient(s) and the quantity, kind and proportion of any alcohol,

Aerosol Antiperspirant	
Incorrect Label Copy:	**Correct Label Copy:**
Isobutane	Active Ingredient:
Silicone Oil	Aluminum Chlorohydrate
Butane	Cosmetic Ingredients:
Aluminum Chlorohydrate	Isobutane
Isopropyl Myristate	Cyclomethicone
Denatured Alcohol	Butane
Propane	Isopropyl Myristate
Bentone 38	SD Alcohol 40
	Propane
	Quaternium 18 Hectorite

in compliance with sec. 502(e) of the FD&C Act, as "Active Ingredients" and then the remaining ingredients, in compliance with § 701.3(a) or (f), as "Cosmetic Ingredients."

This hypothetical aerosol antiperspirant formulation illustrates on the right side the correct label declaration of the ingredients of a cosmetic which is also a drug.

The active drug ingredient aluminum chlorohydrate is identified as "Active Ingredient" in accordance with sec. 502(e) of the FD&C Act. The remaining ingredients may be identified as "Cosmetic Ingredients" as shown or as "Other Ingredients."

Color Additives Added Sometimes for Color Matching

Listed after the declaration of other color additives and after the pharase"May contain"

21 CFR 701.3(g) (1)

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."

D&C Yellow No. 10 used for Color Adjustment

This hypothetical toilet water formulation in which D&C Yellow No. 10 is added to some batches for the purpose of color adjustment shows on the right side the correct label declaration of the color additive D&C Yellow No. 10.

Toilet Water	
Incorrect Label Copy:	**Correct Label Copy:**
SD Alcohol 39C	SD Alcohol 39C
Water	Water
Fragrance	Fragrance
Propylene Glycol	Propylene Glycol
Cetyl Lactate	Cetyl Lactate
FD&C Red No. 40	FD&C Red No. 40
FD&C Blue No. 1	FD&C Blue No. 1
	May contain:
	D&C Yellow No. 10

Incidental Ingredients

Definition:

Any processing aid added and removed or converted to a declared ingredient

or

Any ingredient of another ingredient or processing aid present at an insignificant level and having no technical or functional effect

Need not be declared

Incidental ingredients need not be declared on the label.

An incidental ingredient is defined in § 701.3(1) as:

1. A substance added during manufacture and removed from the cosmetic in accordance with good manufacturing practices before the cosmetic is packaged in finished form. Example: Filter aid.
2. A substance that is added during manufacture of a cosmetic, is converted to an ingredient declared on the label, and does not significantly increase the concentration of the declared ingredient. Example: Sodium hydroxide added to a sodium stearate and stearic acid-containing cosmetic.
3. A substance added to a cosmetic during manufacture for its technical effect in processing but present in the finished cosmetic at an insignificant level and not having any technical or functional effect in that cosmetic. Example: Defoaming agent.
4. A substance added to a cosmetic as a component of a cosmetic ingredient and having no technical or functional effect in the finished cosmetic. Example: Preservative of a raw material added to a cosmetic as an ingredient at a concentration which reduces the preservative to a level at which it is no longer effective.

Multiunit or Multicomponent Packages

Examples:
Gift set of makeup assortment
Hair coloring kit or home permanent

Declaration:
On outside retail package only if components are not customarily sold individually.

21 CFR 701.3 (q)

The ingredients of the units of cosmetics marketed as multiunit or multicomponent packages must be declared on the label of the outside container. They must also be declared on the labels of the inside containers of the units if the inside containers are customarily separated from the outer container for individual retail sale.

A MULTIUNIT package is a package which contains an assortment of similar or dissimilar products. Examples: A shade assortment of eye shadows in an eye make-up kit or a gift set consisting of a lotion, powder and toilet water in a gift box.

A MULTICOMPONENT package is "a package which contains the integral components making up a complete kit, and which is designed to deliver the components in the manner of an application." See 21 CFR 701.13(g)(2). Examples: A hair coloring kit consisting of dye solution and hydrogen peroxide or a permanent wave set consisting of thioglycolate solution and sodium bromate solution.

Multiunit Packages (Assortments in Same Package)
Dissimilar products
Similar products intended same use
Labeling surface area
Less than 12 square inches
Over 12 square inches
Branded shade lines
Single units and assortments

For the purpose of cosmetic ingredient labeling and to take advantage of provisions for consolidated ingredient listing in place of sometimes repetitive listing of ingredients unit by unit, a distinction must be made between packages containing:

1. Dissimilar products. Example: Gift set containing a shave cream and an after shave lotion.
2. Products of similar composition and intended for the same use in a package with a total surface area available for labeling of **12 square inches or more.** Example: Two toilet waters of different fragrance or color in gift set.
3. Products of similar composition and intended for the same use in a package with a total surface area available for labeling of **less than 12 square inches.** Example: Eye shadows of different color in a compact case.
4. Products that are single units or assortments of a branded shade line. A branded shade line is a series of products of similar composition, intended for the same use, and sharing a common label with the same brand name. Example: A shade line of lipsticks.

Assortments of Dissimilar Products

Alternate Declaration

Single composite list of color additives with statement that list pertains to all products.

21 CFR 701.3(h)

The package of an assortment of dissimilar products, i.e., a multiunit package, as, for example, a toilet water and a dusting powder in a gift box, may bear:

A **conventional** ingredient declaration in which each ingredient of each product is identified under an appropriate product heading, or

An **alternate** ingredient declaration in which the color additives of all products of the assortment are integrated into a single composite list that indicates that the list pertains to all products.

Please note that if the units of an assortment are customarily separated from the outer package for retail sale, the ingredients must also be declared on the label of each inside unit.

Toilet Water and Dusting Powder	
Label Copy:	**Alternate Label:**
Toilet Water:	**Toilet Water:**
SD Alcohol 40	SD Alcohol 40
Water	Water
Fragrance	Fragrance
FD&C Red No. 40	**Dusting Powder:**
FD&C Blue No. 1	Talc
Dusting Powder:	Kaolin
Talc	Fragrance
Kaolin	Color Additives Pertaining to Both Products:
Fragrance	FD&C Red No. 40
D&C Red No 21 Aluminum Lake	FD&C Blue No. 1
	D&C Red No. 21 Aluminum Lake

This example of a hypothetical assortment of dissimilar products consisting of a toilet water and a dusting powder illustrates on the right side the alternate ingredient labeling option in which all color additives are declared in a single composite list. The declaration advises that the color additives pertain to both products.

If, for example, Red 40 or Blue 1 were present in both products, they would have to be listed only once in the declaration.

Assortments of Similar Products Intended for Same Use

Available Labeling Surface Area Less Than 12 Square Inches

Alternate Declaration

1. Ingredients common to all products listed in cumulative descending order of predominance (or according to paragraph (f)), and
2. Ingredients not common to all products identified by product in which used, and
3. Single composite list of all color additives without product identification

21 CFR 701.3 (O) (1)

An assortment of products of similar composition and intended for the same use in a package with a total surface area available for labeling of **12 square inches or more** as, for example, two toilet waters of different fragrance or color in a gift set, may bear either:

A **conventional** ingredient declaration in which the ingredients of each product are identified under appropriate product headings, listing either all the ingredients in descending order of predominance according to § 701.3(a) or listing the ingredients according to § 701.3(f), declaring first in descending order the ingredients other than colors present at concentrations exceeding 1%, followed in any order by the ingredients other than color present at concentrations of 1% or less, followed in any order by the color additives present at any concentration, or

An **alternate** ingredient declaration, listing:

1. The ingredients other than colors **common** to all products in cumulative descending order of predominance according to § 701.3(a), or according to § 701.3(f) [permitting listing of ingredients present at 1% or less in any order], followed by
2. The ingredients other than color **not common** to all products, identified by the products in which they are present, followed by
3. The color additives of all products without identification of products in which they are present.

Assortments of Similar Products Intended for Same Use

Available Labeling Surface Area Less Than 12 Square Inches

Alternate Declaration

Single list of all ingredients in cumulative descending order of predominance

or

Single list of all ingredients according to paragraph (f)

An assortment of products of similar composition and intended for the same use in a package with a total surface area available for labeling of **less than 12 square inches** as, for example, several eye shadows in a compact, may bear either:

A **conventional** ingredient declaration in which the ingredients of each product are identified under appropriate product headings, listing either all the ingredients in descending order or according to § 701.3(a) or listing the ingredients according to § 701.3(f), declaring first in descending order the ingredients other than colors present at concentrations exceeding 1%, followed in any order by the ingredients other than color present at concentrations of 1% or less, followed in any order by the color additives present at any concentration,

or

An **alternate** ingredient declaration listing the ingredients of all products in a single integrated list in cumulative descending order of predominance according to § 701.3(a), or cumulatively according to § 701.3(f).

21 CFR 701.3 (o) (2)

This example of an assortment consisting of two similar hypothetical eye shadow formulations demonstrates the optional ingredient declarations for packages with a total surface area available for labeling of **12 square inches or more** (center) and for packages with a total surface area available for labeling of **less than 12 square inches** (right side).

On the **left side** are shown two conventional ingredient declarations, each representing one shade.

In the **center** is shown the integrated ingredient declaration for the two shades in the package with **12 square inches or more** of available labeling area. Note that the ingredients other than color not common to all products are listed after the ingredients that are common and are identified by the products in which they are used. (Bentonite in Blue Shade, Lanolin in Green Shade.)

On the **right side** is shown the integrated ingredient

Assortments of Similar Products Eye Shadow—Two Shades—Alternate Labels		
Label Copy	**Labeling Area 12 Sq. In. or More**	**Labeling Area Less Than 12 Sq. In.**
Blue, Pearly Shade:	Talc	Talc
Talc	Zinc Stearate	Zinc Stearate
Zinc Stearate	Kaolin	Kaolin
Kaolin	Mineral Oil	Bentonite
Bentonite	Bentonite in Blue Shade	Mineral Oil
Mineral Oil	Lanolin in Green Shade	Lanolin
Bismuth Oxychloride	Bismuth Oxychloride	Bismuth Oxychloride
Titanium Dioxide	Titanium Dioxide	Titanium Dioxide
Ultramarine Blue	Ultramarine Blue	Ultramarine Blue
Ultramarine Violet	Ultramarine Violet	Ultramarine Violet
Green Shade:	Ultramarine Green	Ultramarine Green
Talc	Chromium Hydroxide Green	Chromium Hydroxide Green
Zinc Stearate		
Kaolin		
Mineral Oil		
Lanolin		
Titanium Dioxide		
Ultramarine Green		
Chromium Hydroxide Green		

declaration for the two shades in the package with **less than 12 square inches** of available labeling area. Note that the ingredients not common to all formulations need not be identified by the products in which they are used.

Branded Shade Lines and Branded Shade Line Assortments

Definition:
Individually packaged, or assortments of eye or facial makeup cosmetics or nail enamels bearing the same name

21 CFR 701.3 (g) (2) and (o) (3) (g) (2) and (o) (4)

According to §§ 701.3(g)(2) and (o)(3), a branded shade line may be defined as a line of individually packaged eye or facial make-up cosmetics or nail enamels bearing a label that is shared with other products, i.e., bearing the same product name. Example: A line of lipsticks with the same brand name.

According to §§ 701.3(g)(2) and (o)4), a branded shade line assortment may be defined as several assortments of eye or facial make-up cosmetics or nail enamels in packages bearing the same label. Example: Several compacts with the same name and label, each containing several eye shadows.

According to 701.3(g)(2) and (o)(4), a branded shade line assortment may be defined as several assortments of eye or facial make-up cosmetics or nail enamels in packages bearing the same label. Example: Several compacts with the same name and label, each containing several eye shadows.

Branded Shade Lines and Branded Shade Line Assortments Alternate Declaration

Single ingredient declaration for all branded shades listing ...

1. **Ingredients common to all products, in cumulative descending order of predominance**
2. **Ingredients not common, identified by product in which used**
3. **Color additives common to all products, in any order**
4. **Color additives not common, preceded by "May contain"**

Branded Shade Lines and Branded Shade Line Assortments Lipstick—Cherry Red	
Incorrect Label Copy:	**Correct Label Copy:**
Castor Oil	Castor Oil
Isopropyl Myristate	Isopropyl Myristate
Beeswax	Beeswax
Candelilla Wax	Candelilla Wax
Oleyl Alcohol	Oleyl Alcohol
Ozokerite	Ozokerite
Sorbitan Trioleate	Sorbitan Trioleate in Pearl Peach and Pearl Cherry Shades
May contain:	Titanium Dioxide
Mica (and) Titanium Dioxide (and) Iron Oxides	D&C Red No. 21
D&C Red No. 21	D&C Orange No. 5
D&C Orange No. 5	May contain:
D&C Red No. 6 Barium Lake	Mica
D&C Red No. 7 Calcium Lake	Iron Oxides
D&C Red No. 27 Aluminum Lake	D&C Red No. 6 Barium Lake
D&C Orange No. 5 Aluminum Lake	D&C Red No. 7 Calcium Lake
D&C Yellow No. 10 Aluminum Lake	D&C Red No. 27 Aluminum Lake
	D&C Orange No. 5 Aluminum Lake
	D&C Yellow No. 10 Aluminum Lake

This example of a hypothetical shade of a line of lipsticks bearing the same brand name illustrates three common errors found in cosmetic ingredient declarations, namely:

1. **Proprietary mixtures of ingredients identified in the ingredient dictionary by a parenthetical "(and)" are often declared on the label as shown in the dictionary section listing chemical/trade names and their respective label names. The compounds of such mixtures must be separated, the "(and)" omitted, and the components treated as individual ingredients for labeling purposes. See "Mica (and) Titanium dioxide (and) Iron oxides."**
2. **Many labels list all color additives of a shade line after the phrase "May contain." The color additives common to all shades must be listed before "May contain," and only those not found in all shade formulations may be listed after "May contain."**
3. **The ingredients other than colors which are not included in all shade formulations must be identified as to the shades in which they are present.**

21 CFR 701.3 (g) (2) and (o) (3) (g) (2) and (o) (4)

Branded shade lines and branded shade line assortments may bear either:

A **conventional ingredient** declaration for each product in which the ingredients of each product are identified in descending order of predominance according to § 701.3(a) or, alternately, according to § 701.3(f) [in the case of an assortment the ingredients may be declared cumulatively in a single list for each assortment according to §§ 701.3(a) or (f)]

or

An **alternate** ingredient declaration listing all ingredients for all branded shades in the cumulative order shown below. In this case, each shade of a branded shade line or each package of a branded shade line assortment bears the same ingredient declaration.

Direct Mail Cosmetics

Definition

Cosmetics ordered by and delivered to consumers through the mail without involvement of an intermediary sales agent

21 CFR 701.3 (r)

Direct mail cosmetics may utilize off-package ingredient labeling as an alternative to the declaration of ingredients on an information panel.

For the purpose of cosmetic ingredient labeling, direct mail cosmetics are defined as cosmetics ordered by mail and delivered to consumers through the mail without the involvement of an intermediary sales agent.

Cosmetics sold to consumers through "door-to-door" salespersons are not considered direct mail cosmetics even though they may be delivered to consumers directly by mail.

Declaration on

labeling accompanying the mailed cosmetic

or

labeling furnished to each consumer ordering cosmetics by mail

21 CFR 701.3 (r)

As an alternative to the declaration of ingredients on an information panel, the declaration may appear in letters not less than 1/16 of an inch in height in:

Labeling that accompanies and specifically relates to the cosmetic(s) mailed, e.g., a brochure, insert or written directions for safe use, or Labeling furnished to each consumer for personal use and from which cosmetics are ordered through the mail, e.g., a direct mail sales catalog or brochure.

Direct Mail Cosmetics Requirements

Notice in 3/16-inch lettering located or affixed to top, inside, or outside of package, stating:

1. Location of ingredient declaration

2. Availability on request through mail

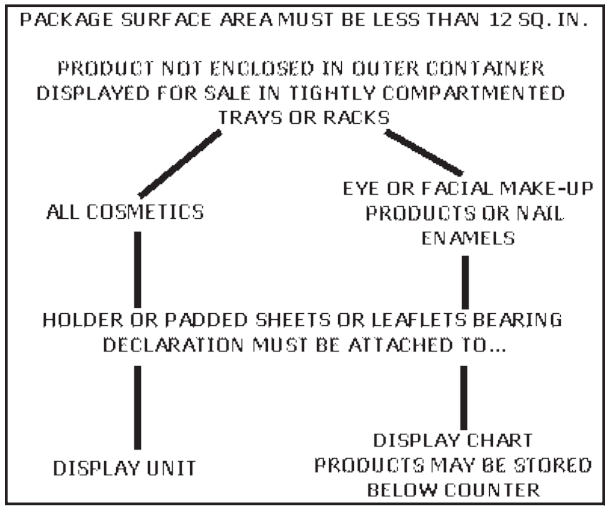
3. Name and address of distributor

21 CFR 701.3(r)

If the ingredients of cosmetics distributed to consumers by direct mail are made available through off-package labeling, the following requirement must be met:

1. The package mailed to consumers must be accompanied by a notice in 3/16 of an inch lettering informing the consumer of the location of the ingredient declaration(s), of the name and address of the mail order distributor, and that a copy of the ingredient declaration(s) will be mailed to any person requesting it.
2. The mail order distributor must promptly mail a copy of an ingredient declaration to any person requesting it.
3. The notice in 3/16 of an inch lettering must be located on, or affixed to, the top of the package; or it must be inside the package on top of the contents or on the face of the platform surrounding and holding the product(s) and must be readily visible to the consumer on opening.
4. The ingredient declarations must be conspicuous and presented in a way that the consumer can readily associate each ingredient declaration with each cosmetic.

Off-package Ingredient Labeling Qualifying Conditions



21 CFR 701.3(i)

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.

The ingredient declaration must be in letters not less than 1/16 of an inch in height and may appear on padded sheets, leaflets or similar labeling accompanying the product.

Products which are **not** eye or facial make-up cosmetics or nail enamels must be displayed for sale in tightly compartmented trays or racks of a display unit. The holder of the padded sheets or leaflets bearing the ingredient declaration(s) must be attached to the display unit.

Products which **are** eye or facial make-up cosmetics or nail enamels may be held for sale in tightly compartmented trays or racks located below the sales

counter. The holder of the ingredient labeling must be attached to a display chart which bears samples of the product shades and is displayed to purchasers.

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)

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:

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).

2. **Padded sheets or leaflets must be attached to the display unit and be fully visible on the front**

or

partially visible on the front and bear a notice in 3/16-inch lettering describing their location

or

located on the side only and bear the location notice.

21 CFR 701.3 (j)

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."

Additional Requirements

1. **Leaflets must bear declarations of all products sold with display unit or chart.**
2. **Leaflets must be identical.**
   The following additional conditions must be met to comply with the requirements for off-package ingredient labeling of cosmetics:
   1. The padded sheets or leaflets attached to the display unit or chart must declare the ingredients of all products sold with the display.
   2. The padded sheets or leaflets must be identical.
3. **Leaflets and displays must be shipped together.** The number of copies of padded sheets or leaflets provided with each shipment of a cosmetic must be sufficient so that each purchaser may obtain a copy of an ingredient declaration. Further, the display units and replacement labeling must be accompanied by appropriate instructions to the retailer to assure that retailers display the padded sheets or leaflets.
4. **Leaflets must be sufficient in number and replaced with refills with replacement instructions to retailer.** Shipments of refill items also must be accompanied by sufficient copies of ingredient declarations, and the container holding the refill items and the respective copies of ingredient declarations must not contain other cosmetic products.
5. **Label firm must send copy of ingredient declaration to requesting person.** The firm engaged in off-package cosmetic ingredient labeling must promptly mail a copy of the ingredient declaration to any person requesting it.
6. **In case of formulation change, leaflet must declare both formulations.** In case of a formulation change, the new padded sheet or leaflet must be dated if not shipped together with the display unit or chart. If a padded sheet or leaflet is to be used in conjunction with the old and the new formulations, it must bear both ingredient declarations, and the declarations must be identified in a way that the purchaser can determine which declaration pertains to which product. As an alternative, the padded sheet or leaflet bearing the two ingredient declarations may advise the purchaser that the formulation has been changed and that either declaration may be applicable.

21 CFR 701.3 (k)

Sanitation and Infection Control

Based on:

Based on *OSHA* and *U.S. EPA Publications*

What should infection control mean to you? In order to fully understand all that infection control encompasses you must first be aware of where it all begins. Keep in mind that it is the responsibility of all licensees and the North Carolina Board of Cosmetic Arts Examiners to ensure a safe and healthy salon environment for the public. This can be accomplished by understanding and putting to use the important infection control and safety information you will learn in this material.

Protecting Your Clients and Yourself

No matter what branch of cosmetology your license falls under: cosmetologist, nail technician, esthetician, natural hair stylist, or hair designer it is your responsibility as a licensee of the North Carolina Board of Cosmetic Arts Examiners to protect your client's health, as well as your own by performing services in a healthy and safe environment. This can be done by taking the proper steps to ensure that all implements, tools, and areas of the salon are properly cleaned and disinfected according to the Board's "Rules and Regulations". These regulations are your guideline for proper infection control. Infection control (decontamination) consists of three categories: 1) sanitation, 2) disinfection, and 3) sterilization. Each of these areas means something completely different when it comes to keeping a salon or spa environment healthy and safe. Therefore, it is vital to fully understand the differences between these three areas of infection control.

Some of you may be coming back to the industry after some time away. It is important to make sure that you are up to date on changes that may have taken place, particularly when it comes to infection control. Gone are the days when the term sanitation could be used to cover the subject of infection control in salons. Infection control refers to the prevention of the transmission of infectious and communicable diseases. A communicable disease is one that can be passed from one person to another. It seems that everywhere you turn today there is talk about this very issue. The media has brought forth awareness that there can be dangers lurking in the salons the public trust to be safe. Methicillin Resistant Staphylococcus (MRSA), Hepatitis (HBV), HIV, Tuberculosis (TB), Fungus, and the common cold are among the list of infectious diseases that proper infection control procedures in a salon can help prevent.

Knowing the correct terminology and definitions of the words and items associated with infection control can be very helpful in keeping salons healthy and in return keeping the licensee and the public safe as well.

The term sanitation that most of us are familiar with is no longer a choice word to use when referring to the most effective way to keep a salon disease free. **Sanitation is simply cleaning;** it is the lowest level of infection control and is the removal of dirt and debris. Although sanitation methods clean and reduce microbes on the surface, germs are not killed.

Disinfection is the level of decontamination that should be used in a salon environment. Disinfection is the second level of infection control and destroys or kills some bacteria, fungi and viruses. It is important that all tools, implements, and areas of the salon be properly cleaned and disinfected.

Sterilization is the highest level of decontamination as it kills or destroys all microbes. Sterilization is only required for tools or implements that puncture the skin. Therefore, this level of infection control usually does not apply to salons/spas.

There are **three types** of infectious microorganisms: 1) bacteria, 2) fungus, and 3) virus. All persons working in a salon/spa environment should have a basic understanding of what they do.

Bacteria (also known as germs) are one-celled microorganisms that contain both plant and animal characteristics. Bacteria are so small they are not visible to the naked eye. Bacteria can live and reproduce on their own and can be found in a variety of places that include but are not limited to:

- On skin
- In water
- Decayed Matter
- Body Secretions
- On clothing
- Under the free edge of nails

There are two primary types of bacteria - pathogenic and non pathogenic:

Nonpathogenic Bacteria are harmless, and do not cause disease.

Pathogenic Bacteria are harmful, and may cause disease or infection.

There are two stages in the life cycle of bacteria. The **active stage** is when bacteria grow and reproduce.

Bacteria reproduce best in a warm, dark, moist, and dirty environment. If conditions are not favorable then it becomes difficult for bacteria to survive. The **inactive (spore-forming) stage** happens when conditions are not favorable for growth or reproduction. Certain bacteria can coat themselves with a waxy outer shell, this helps the bacteria withstand long periods of famine and unfavorable conditions. During this stage bacteria are not harmed by disinfectants.

Fungus (fungi) include mold, mildews, and yeast. A fungus can cause contagious diseases such as tinea capitis (ringworm) and nail fungus. Non contagious conditions such as dandruff and seborrheic dermatitis can also be caused by a fungus.

A **Virus** is a sub-microscopic particle that can only be seen under a powerful microscope. Viruses can cause a variety of health issues including the common cold, respiratory, gastrointestinal infections, measles, mumps, chicken pox, rabies, influenza, and HIV, which causes AIDS. A virus can only live by penetrating other cells and becoming part of them.

An **infection** can occur when pathogenic bacteria or viruses enter the body. A **contagious** infection is one that can be passed from person to person. The spread of infection in a salon/spa is why it is important to practice personal hygiene and infection control procedures. Some ways infections are spread in a salon include but are not limited to the following:

- Open sores
- Unclean hands and implements
- Coughing or sneezing
- Common use of drinking cups and towels
- Use of same implements on infected areas and non infected areas
- Unsanitary salon conditions

Parasites are plant or animal organisms that live on or in another living organism. This is the only way they can survive.

Pediculosis Capitus (head lice) is a type of parasite. Lice are wingless insects that feed on human blood. These insects do not fly or jump; however, they can be passed from one person to another by direct contact, through sharing of brushes, combs, cloths, hats, etc.

Once a person is infected, the female insect lays approximately 3 to 6 eggs (more commonly known as nits) daily. These eggs then cement to the hair shaft about 1/4" away from the scalp. After the eggs are attached they begin to hatch in about 7-12 days and reach a mature status in roughly two days, once mature, they begin to lay their own eggs. Nits can stay alive for up to a month off of the head and adult lice can survive without a host for 24-48 hours. As you can see it does not take long to have an infestation problem.

Therefore, if a client comes into a salon with head lice there are important infection control procedures that need to be followed in order to prevent the spread of lice to other clients and employees. The steps to maintaining a healthy salon environment after the presence of lice are as follows:

- Discontinue service immediately.
- Immediately sweep hair from area
- Trash where contaminated hair and materials were discarded should be sealed and removed from the salon immediately.
- Contaminated area(s) including station, chair, shampoo bowl/area and reusable items should be immediately disinfected with an Environmental Protection Agency (EPA) registered disinfectant or bleach solution. Both of these solutions should remain on the area(s) for at least 10 minutes.
- Disinfect combs, brushes, shears, clippers and other implements used on the client with an EPA registered disinfectant.
- Towels, capes and any cloth items used should be laundered separately in hot water with a bleach solution. Items should be dried in a hot dryer for at least 20 minutes.
- Chairs located in the reception area/lobby should be disinfected with an EPA registered disinfectant or bleach solution.
- If carpet is present in reception area it should be vacuumed.

Hand Washing

This is where infection control begins. By completing a task as simple as washing your hands before and after each client, you are helping to prevent the spread of germs.

The following guidelines should be followed for proper hand washing.

1. Dampen hands with warm water.
2. Apply antibacterial, liquid soap.
3. Spend 15-20 seconds working up a good lather. Be sure to wash spaces between fingers and finger nails.
4. Rinse with warm water
5. Dry hands thoroughly; always use a single use paper towel or air blower.

Disinfectants

It is important to be aware of the guidelines to follow when selecting a proper disinfectant for a salon/spa. All chemical disinfectants should be Environmental Protection Agency (EPA) registered, and hospital effective. Hospital effective or broad spectrum

disinfectant means a chemical that is efficient for bactericidal, fungicidal, pseudomonacidal, and virucidal purposes. This information can be located on all disinfectant product labels. Keep in mind this does not include household cleaners, disinfectants, etc. Any time you are mixing or using a chemical disinfectant it is important to follow the manufacturer's directions for mixing and safe use. Disinfectants are not designed to be used on the skin therefore, gloves should be worn.

Alcohol

There are some common misconceptions surrounding the use of alcohol as a disinfectant. Alcohol is a low-level disinfectant therefore; it should not be used to disinfectant implements, tools, stations, or salon areas. Alcohol can be used on the skin as a sanitizer. An alcohol based hand sanitizer should be kept available for use by licensee and public.

Bleach

Sodium Hypochlorite (Household Bleach) can be used as a disinfectant in salons. All bleach solutions must be mixed **daily** in a ten to one solution (nine parts water and one part bleach). Bleach must be kept in a covered container and not exposed to sunlight. Vapors from bleach may react with other chemicals therefore, should be stored alone.

When using a chemical disinfectant you should always refer to the following guidelines:

1. Always mix disinfectants according to manufacturer's directions.
2. Mix all disinfectants daily or more often if solution becomes visibly contaminated (dirty). Once a chemical disinfectant is dirty it becomes ineffective and should be changed prior to use.
3. Leave surfaces (work areas, shampoos bowls, etc.) wet or completely immersed for a ten-minute contact time or longer if required by the manufacturer's instructions.
4. All implements/tools should be disinfected after each use. Example: combs, brushes, clippies, shears, etc.
5. Implements should first be cleaned of all visible dirt, debris, and bodily fluids by washing with warm, soapy/detergent water and then rinsed. Second, the implement should be completely immersed (enough liquid to completely cover all surfaces of the implement) in an Environmental Protection Agency (EPA) registered, hospital grade tuberbucidial, bactericidal, fungicidal, virucidal disinfectant. Allow implements to soak in disinfectant according to manufactures directions.
6. Remove implements from disinfectant with gloves or tongs. Rinse and dry completely.
7. Store implements in a closed, dry container or drawer.

Caring for Porous Items

The most sanitary way to store porous (absorbent) items are to keep them in a closed, dry, dust-free container or drawer until ready for use. **Porous items can not be disinfected;** consequently, these types of items are considered to be single-use and should be used once and discarded unless the item can be laundered in a washing machine. For example, cloth towels, capes, smocks, robes, linens, and similar items should be laundered using detergent and chloride bleach. Examples of porous items include cloth towels, paper towels, cotton, orangewood sticks, cushion nail files, buffer blocks, etc.

Disposable/Single Use Items

It is important to understand the difference between items that can be disinfected and those that should be discarded after use.

Single-use items such as paper towels, tissues, cotton, and some files and buffers are considered porous therefore, cannot be disinfected.

Multi-use implements can be cleaned, disinfected, and used on more than one person.

Storage/Handling of Chemicals – Material Safety Data Sheet (MSDS) are required for all potentially hazardous products that are used in salons. These sheets should be kept readily available in case of an emergency. The MSDS sheets provide information on hazardous ingredients, safe storage and handling, product usage as well as information on allergic reactions or injury. Refer to MSDS sheets for proper handling if a spill occurs and procedures for contact with eyes or skin. MSDS sheets should be obtained from the products' manufacturers.

Label all containers as to the contents and cover tightly. All containers should be stored in a cool, dry and well ventilated location. Always follow manufactures instructions as to specific guidelines.

Avoid inhaling or spilling any chemicals. When handling chemicals gloves and safety glasses should always be worn. It is important to wash hands and dispose of gloves after the handling of any chemical.

Safety Standards

In order to keep products such as creams, lotions, solutions, chemicals, etc. from becoming contaminated lids should be kept on at all times.

Product should be removed from containers with

a disposable single-use applicator or nonabsorbent applicators that can be disinfected after each use. All single use items should be disposed of immediately. Fingers should never be used to remove product directly from a container.

Dispose of razor blades after individual use by placing in a puncture proof container.

All contaminated, single use items should be disposed of in a trash container immediately after use.

Items dropped on the floor should be picked up immediately. These items should be properly cared for by either discarding it as a single use item or disinfecting if reusable. Be sure to keep curling iron cords off the floor as they are a trip hazard. Sweep hair from floor immediately following any haircut service. If liquid is spilled on the floor be sure to clean up liquid and dry floor immediately.

To prevent damage to hair by an overheated curling iron always test temperature the of thermal curling iron(s) on end papers, paper towels or neck strips prior to use on hair to ensure correct temperature.

Disconnect or turn off all electrical appliances when not in use.

Use protective cream around hairline to protect skin from chemicals. Cream should be applied up to hairline but not in hair while covering the skin.

Wear protective goggles and gloves for application of primer and other nail products.

Do not use nail products that contain Methyl Methacrylate (MMA). MMA is an ingredient found in some artificial nail products. This ingredient has been banned by the Food and Drug Administration due to health issues. These issues include skin allergies, loss of nail plate, respiratory, liver and kidney problems, etc.

OSHA HEALTH HAZARDS IN NAIL SALONS

Biological Hazards

Biological hazards include bacteria, fungi, and viruses. Nail salon workers can be exposed to bloodborne pathogens, such as hepatitis B, hepatitis C, and human immunodeficiency virus (HIV), if they come into contact with infected blood from a co-worker or client. Workers can also be exposed to fungal infections of the nails and feet by touching infected client skin or by using equipment that has not been cleaned.

OSHA's Bloodborne Pathogens Standard, 29 CFR 1910.1030 (discussed later), covers exposures to blood and other potentially infectious materials in workplaces, including nail salons. Employers must evaluate whether an employee may contact with blood or other potentially infectious material. If the employer determines that this risk exists, then the employer must follow the requirements of the standard to protect the exposed employees, including providing training, vaccination, and personal protective equipment.

Steps to Prevent Exposure and Protect Worker Health

- Avoid all contact with blood or bodily fluids.
- Wear gloves, and avoid clients with cuts, open wounds/sores, blisters, or visibly infected skin on their hands, feet, or nails. As per North Carolina Administrative Code, 21 NCAC 14H .0401 (d) (4): A licensee or student shall not perform services on a client if the licensee has reason to believe the client has any of the following: (A) fungus, lice, or nits; (B) an inflamed, infected, broken, raised, or swollen skin or nail tissue in the area to be worked on; or (C) an open wound or sore in the area to be worked on.

- Throw away disposable gloves immediately after using them.
- Always wash hands with soap and water to avoid spreading germs. Wash hands before and after working with clients.
- Bandage open cuts or broken skin to prevent contact with blood or other potentially infectious materials from a client or coworker.
- If an individual is bleeding, do not touch the blood. Ask the individual to use a cotton ball or tissue to stop the bleeding and to throw the used material directly into the trash once the bleeding has stopped.
- Consider immunization against hepatitis B. Immunization practices can vary by state, so contact your local or state health department for information on current hepatitis B immunization policies in your area. Employers must offer employees hepatitis B immunization without charge if they are likely to be exposed to blood or other infectious materials during their work.
- Clean and disinfect tools after each client as per North Carolina Administrative Code, 21 NCAC 14H .0403. Some common steps for cleaning and disinfecting tools are:
- Wear gloves when cleaning and handling disinfectants or tools soaked in disinfectant.

- Wash tools with soap and water. Use a scrub if needed.
- Soak tools in an EPA-registered disinfectant for 10-30 minutes, according to manufacturer directions. Be careful to follow the manufacturer's instructions when mixing the product ratios.
- Rinse in clean water.
- Dry with a clean cloth.
- Store all disinfected tools in a clean, covered area. Only use ultraviolet (UV) sanitizing boxes to store clean and disinfected reusable metal tools. The UV boxes do not disinfect tools.
- Disinfect foot basins and spas after each client and at the end of the day to prevent exposure to workers and other clients. Follow the U.S. EPA's *Recommended Cleaning and Disinfection Procedures for Foot Spa Basins in Salons*.

OSHA'S BLOODBORNE PATHOGENS STANDARD

Bloodborne pathogens are infectious microorganisms present in blood that can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV), the virus that causes AIDS. Workers exposed to bloodborne pathogens are at risk for serious or life-threatening illnesses.

Protections Provided by OSHA's Bloodborne Pathogens Standard

All of the requirements of OSHA's Bloodborne Pathogens standard can be found in Title 29 of the Code of Federal Regulations at 29 CFR 1910.1030. The standard's requirements state what employers must do to protect workers who are occupationally exposed to blood or other potentially infectious materials (OPIM), as defined in the standard. That is, the standard protects workers who can reasonably be anticipated to come into contact with blood or OPIM as a result of doing their job duties.

In general, the standard requires employers to:

Establish an exposure control plan. This is a written plan to eliminate or minimize occupational exposures. The employer must prepare an exposure determination that contains a list of job classifications in which all workers have occupational exposure and a list of job classifications in which some workers have occupational exposure, along with a list of the tasks and procedures performed by those workers that result in their exposure.

Employers must update the plan annually to reflect changes in tasks, procedures, and positions that affect occupational exposure, and also technological changes that eliminate or reduce occupational exposure. In addition, employers must annually document in the plan that they have considered and begun using appropriate, commercially-available effective safer medical devices designed to eliminate or minimize occupational exposure. Employers must also document that they have solicited input from frontline workers in identifying, evaluating, and selecting effective engineering and work practice controls.

Implement the use of universal precautions (treating all human blood and OPIM as if known to be infectious for bloodborne pathogens).

Identify and use engineering controls. These are devices that isolate or remove the blood- borne pathogens hazard from the workplace. They include sharps disposal containers, self- sheathing needles, and safer medical devices, such as sharps with engineered sharps-injury protection and needleless systems.

Identify and ensure the use of work practice controls. These are practices that reduce the possibility of exposure by changing the way a task is performed, such as appropriate practices for handling and disposing of contaminated sharps, handling specimens, handling laundry, and cleaning contaminated surfaces and items.

Provide personal protective equipment (PPE), such as gloves, gowns, eye protection, and masks. Employers must clean, repair, and replace this equipment as needed. Provision, maintenance, repair and replacement are at no cost to the worker.

Make available hepatitis B vaccinations to all workers with occupational exposure. This vaccination must be offered after the worker has received the required bloodborne pathogens training and within 10 days of initial assignment to a job with occupational exposure.

Make available post-exposure evaluation and follow-up to any occupationally exposed worker who experiences an exposure incident. An exposure incident is a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or OPIM. This evaluation and follow-up must be at no cost to the worker and includes documenting the route(s) of exposure and the circumstances under which the exposure incident occurred; identifying and testing the source individual for HBV and HIV infectivity, if the source individual consents or the law does not require consent; collecting and testing the exposed worker's blood, if the worker consents; offering post- exposure prophylaxis; offering counseling; and evaluating reported illnesses. The healthcare professional will provide a limited written opinion to the employer and all diagnoses must remain confidential.

Use labels and signs to communicate hazards. Warning labels must be affixed to containers of regulated waste; containers of contaminated reusable sharps; refrigerators and freezers containing blood or OPIM; other containers used to store, transport, or ship blood or OPIM; contaminated equipment that is being shipped or serviced; and bags or containers of contaminated laundry, except as provided in the standard. Facilities may use red bags or red containers instead of labels. In HIV and HBV research laboratories and production facilities, signs must be posted at all access doors when OPIM or infected animals are present in the work area or containment module.

Provide information and training to workers. Employers must ensure that their workers receive regular training that covers all elements of the standard including, but not limited to: information on bloodborne pathogens and diseases, methods used to control occupational exposure, hepatitis B vaccine, and medical evaluation and post-exposure follow-up procedures. Employers must offer this training on initial assignment, at least annually thereafter, and when new or modified tasks or procedures affect a worker's occupational exposure. Also, HIV and HBV laboratory and production facility workers must receive specialized initial training, in addition to the training provided to all workers with occupational exposure. Workers must have the opportunity to ask the trainer questions. Also, training must be presented at an educational level and in a language that workers understand.

Maintain worker medical and training records. The employer also must maintain a sharps injury log, unless it is exempt under Part 1904—Recording and Reporting Occupational Injuries and Illnesses, in Title 29 of the Code of Federal Regulations.

Additional Information

For more information, go to OSHA's Bloodborne Pathogens and Needlestick Prevention Safety and Health Topics web page at: https://www.osha.gov/SLTC/bloodbornepathogens/index.html.

To file a complaint by phone, report an emergency, or get OSHA advice, assistance, or products, co tact your nearest OSHA office under the "U.S. Department of Labor" listing in your phone book, or call us toll-free at **(800) 321-OSHA (6742)**.

BLOODBORNE PATHOGEN EXPOSURE INCIDENTS

OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) requires employers to make immediate confidential medical evaluation and follow-up available for workers who have an exposure incident, such as a needlestick. An exposure incident is a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials (OPIM), as defined in the standard that results from the performance of a worker's duties.

Reporting an Exposure Incident

Exposure incidents should be reported immediately to the employer since they can lead to infection with hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), or other bloodborne pathogens. When a worker reports an exposure incident right away, the report permits the employer to arrange for immediate medical evaluation of the worker. Early reporting is crucial for beginning immediate intervention to address possible infection of the worker and can also help the worker avoid spreading bloodborne infections to others. Furthermore, the employer is required to perform a timely evaluation of the circumstances surrounding the exposure incident to find ways of preventing such a situation from occurring again.

Reporting is also important because part of the follow-up includes identifying the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law, and determining the source's HBV and HIV infectivity status. If the status of the source individual is not already known, the employer is required to test the source's blood as soon as feasible, provided the source individual consents. If the individual does not consent, the employer must establish that legally required consent cannot be obtained. If state or local law allows testing without the source individual's consent, the employer must test the individual's blood, if it is available. The results of these tests must be made available to the exposed worker and the worker must be informed of the laws and regulations about disclosing the source's identity and infectious status.

Medical Evaluation and Follow-up

When a worker experiences an exposure incident, the employer must make immediate confidential medical evaluation and follow-up available to the worker. This evaluation and follow-up must be: made available at no cost to the worker and at a reasonable time and place; performed by or under the supervision of a licensed physician or other licensed healthcare professional; and provided according to the recommendations of the U.S. Public Health Service (USPHS) current at the time the procedures take place. In addition, laboratory tests must be conducted by an accredited laboratory and also must be at no cost to the worker. A worker who participates in post-exposure evaluation and follow-up may consent to have his or her blood drawn for determination of a baseline infection status, but has the option to withhold consent for HIV testing at that time. In this instance, the employer must ensure that

the worker's blood sample is preserved for at least 90 days in case the worker changes his or her mind about HIV testing.

Post-exposure prophylaxis for HIV, HBV, and HCV, when medically indicated, must be offered to the exposed worker according to the current recommendations of the U.S. Public Health Service. The post-exposure follow-up must include counseling the worker about the possible implications of the exposure and his or her infection status, including the results and interpretation of all tests and how to protect personal contacts. The follow-up must also include evaluation of reported illnesses that may be related to the exposure.

Written Opinion

The employer must obtain and provide the worker with a copy of the evaluating healthcare professional's written opinion within 15 days of completion of the evaluation. According to OSHA's standard, the **written opinion** should only include: whether hepatitis B vaccination was recommended for the exposed worker; whether or not the worker received the vaccination, and that the healthcare provider informed the worker of the results of the evaluation and any medical conditions resulting from exposure to blood or OPIM which require further evaluation or treatment. Any findings other than these are not to be included in the written report.

Additional Information

For more information, go to OSHA's Bloodborne Pathogens and Needlestick Prevention Safety and Health Topics web page at: https://www.osha.gov/SLTC/bloodbornepathogens/index.html.

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PERSONAL PROTECTIVE EQUIPMENT (PPE) REDUCES EXPOSURE TO BLOODBORNE PATHOGENS

OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030) requires employers to protect workers who are occupationally exposed to blood and other potentially infectious materials (OPIM), as defined in the standard. That is, the standard protects workers who can reasonably be anticipated to come into contact with blood or OPIM as a result of doing their job duties.

One way the employer can protect workers against exposure to bloodborne pathogens, such as hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV), the virus that causes AIDS, is by providing and ensuring they use personal protective equipment, or PPE. Wearing appropriate PPE can significantly reduce risk, since it acts as a barrier against exposure. Employers are required to provide, clean, repair, and replace this equipment as needed, and at no cost to workers.

Selecting Personal Protective Equipment

Personal protective equipment may include gloves, gowns, laboratory coats, face shields or masks, eye protection, pocket masks, and other protective gear. The PPE selected must be appropriate for the task. This means the level and type of protection must fit the expected exposure. For example, gloves may be the only PPE needed for a laboratory technician who is drawing blood.

However, a pathologist conducting an autopsy would need much more protective clothing because of the different types of exposure (e.g., splashes, sprays) and the increased amount of blood and OPIM that are encountered. PPE must be readily accessible to workers and available in appropriate sizes.

If it can be reasonably expected that a worker could have hand contact with blood, OPIM, or contaminated surfaces or items, the employer must ensure that the worker wears gloves. Single- use gloves cannot be washed or decontaminated for reuse. Utility gloves may be decontaminated if their ability to provide an effective barrier is not compromised. They should be replaced when they show signs of cracking, peeling, tearing, puncturing, or deteriorating. Non-latex gloves, glove liners, powderless gloves or similar alternatives must be provided if workers are allergic to the gloves normally provided.

Gloves are required for all phlebotomies outside of volunteer blood donation centers. If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary, then the employer is required to periodically re-evaluate this policy; make gloves avail- able for workers who want to use them; and can- not discourage their use. In addition, employers must ensure that workers in volunteer blood donation centers use gloves (1) when they have cuts, scratches or other breaks in their skin, (2) while they are in training, or (3) when the worker believes that hand contamination might occur.

When splashes, sprays, splatters, or droplets of blood or OPIM pose a hazard to the eyes, nose or mouth, then masks in conjunction with eye protection (such as goggles or glasses with solid side shields) or chin-length face shields must be worn. Protection against exposure to the body is provided by protective clothing, such as gowns, aprons, lab coats, and similar garments.

Surgical caps or hoods, and shoe covers or boots are needed when gross contamination is expected, such as during orthopedic surgery or autopsies.

In HIV and HBV research laboratories and production facilities, laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing must be used in work areas and animal rooms.

Also, protective clothing must not be worn outside of the work area and must be decontaminated before being laundered.

Exception to Use of Personal Protective Equipment

A worker may choose, temporarily and briefly, under rare and extraordinary circumstances, to forego use of personal protective equipment. It must be the worker's professional judgment that using the personal protective equipment would prevent the delivery of health care or public safety services or would pose an increased hazard to the safety of the worker or coworker. When such a situation occurs, the employer is required to investigate and document the circumstances to determine if there is a way to avoid it from happening again in the future. Employers and workers should be aware that this is not a blanket exemption to the requirement to use PPE. OSHA expects that this will be an extremely rare occurrence.

Decontaminating and Disposing of Personal Protective Equipment

Employers must ensure that workers remove personal protective equipment before leaving the work area. If a garment is penetrated by blood or OPIM, it must be removed immediately or as soon as feasible. Once PPE is removed, it must be placed in an appropriately designated area or container for storage, washing, decontamination, or disposal. In addition, employers must ensure that workers wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.

Additional Information

For more information, go to OSHA's Bloodborne Pathogens and Needlestick Prevention Safety and Health Topics web page at: https://www.osha.gov/SLTC/bloodbornepathogens/index.html.

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RECOMMENDED CLEANING AND DISINFECTION PROCEDURES FOR FOOT SPA BASINS IN SALONS

December 2006

Customer precautions - protecting the client

1. **Check the condition of the client's feet and legs:** If open sores or skin wounds are present (including insect bites, scratches, scabbed-over wounds, or any condition that weakens the skin barrier), explain to the client why they should not use the foot bath.
2. **Complete pedicure or wax after the foot bath soak:** Any procedure that risks damage to a client's skin should not be done before soaking feet in the foot spa basin.

Step by step instructions for disinfecting pedicure foot spa equipment

After Each Client: (this can take place any time after the client's feet are out of the footbath, while feet are massaged, toes are painted, or other opportunities)

1. **Drain** the water from the foot spa basin or bowl and remove any visible debris.
2. **Clean** the surfaces of the foot spa with soap or detergent, rinse with clean water, and drain.
3. **After cleaning, disinfect*** the surfaces with an EPA-registered hospital disinfectant according to the manufacturer's directions on the label. Surfaces must remain wet with the disinfectant for 10 minutes or the time stated on the label, which may be shorter.

* **For whirlpool foot spas, air-jet basins, "pipe-less" foot spas, and other circulating spas:** It is best to disinfect by filling the basin with clean water, adding the appropriate amount of liquid disinfectant, and turning the unit on to circulate the disinfectant for the entire contact time.

4. After disinfection, **drain and rinse** with clean water.

Nightly:

For whirlpool foot spas, air-jet basins, "pipe-less" foot spas, and other circulating spas:

1. **Remove** the filter screen, inlet jets, and all other removable parts from the basin and clean out any debris trapped behind or in them.
2. Using a brush, **scrub** these parts with soap or disinfectant (following cleaning directions).

3. **Rinse** the removed parts with clean water and place them back into the basin apparatus.
4. **Fill** the basin with clean water and add an **EPA-registered hospital disinfectant**, following label directions. Turn the unit on and **circulate** the system with the liquid for 10 minutes, or the label-indicated time if different. (The whirlpool mechanism of the tub must be operating for the entire disinfection period so the piping and internal components that contain hidden bacteria are disinfected.)
5. **After disinfection, drain, rinse**, and air dry.

For simple basins (no circulation):

1. **Drain** the basin and remove any visible debris.
2. **Scrub** the bowl with a clean brush and soap or disinfectant (following cleaning directions). R**inse and drain.**
3. **Disinfect** basin surfaces with an **EPA-registered hospital disinfectant**, following manufacturer's instructions. Surfaces must remain wet with the disinfectant for 10 minutes or the contact time stated on the label.
4. **Drain** the basin, **rinse** with clean water, and let air-dry.

Label information on disinfectant products

The label should clearly state that the product is a hospital or medical disinfectant. It may also list the following organisms: Staphylococcus aureus, Salmonella enteric (formerly S. choleraesuis), Pseudomonas aeruginosa

The product label should clearly identify an EPA Registration Number.

The label will also specify use sites that are health care related.

Important additional measures

- **Follow your state guidelines and regulations:** Some states require a weekly flush of the whirlpool mechanism with bleach and that the bleach remain in contact for over eight hours. Salons should consult state cosmetology regulations to make sure they are in compliance.
- **Read all labels and instruction manuals:** Always follow label directions for disinfectant products, and consult operating manuals for foot spa basins. Care should be taken to use appropriate doses of products to prevent damage to foot spas.
- **Know the condition of your equipment:** If your whirlpool foot spa has not been regularly cleaned and disinfected, you may need to do more than just the maintenance steps listed above to remove bacterial buildup from the system. Consult the foot spa manufacturer for further information. A higher level EPA-registered disinfectant, such as those labeled "Tuberculocides," may be used initially. Once the system has been adequately disinfected, regular maintenance with cleaning and use of a hospital disinfectant, as described in this document, may be used.

North Carolina Administrative Code for Cosmetology: Title 21, Chapter 14, Subchapter H

SECTION .0100—SANITATION

21 NCAC 14H .0101—COPY OF RULES TO COSMETOLOGY STUDENTS

Cosmetic art schools shall give a copy of the sanitation rules governing the practice of the cosmetic arts to each student for study.

History Note: Authority G.S. 88-23; 88-30; Eff. February 1, 1976; Amended Eff. April 1, 1991; January 1, 1989.

21 NCAC 14H .0102—COPY OF RULES TO BEAUTY ESTABLISHMENTS

The Board shall give copies of the rules of sanitation governing the practice of cosmetic art to all beauty establishments.

History Note: Authority G.S. 88-23; 88-30; Eff. February 1, 1976; Amended Eff. April 1, 1991; January 1, 1989.

21 NCAC 14H .0103—FAILURE TO ADHERE TO RULES

21 NCAC 14H .0104—BUILDING

History Note: Authority G.S. 88-23; Eff. February 1, 1976; ***Repealed Eff. January 1, 1989.***

21 NCAC 14H .0105—SANITARY RATINGS AND POSTING OF RATINGS

History Note: Authority G.S. 88B-4; 88B-23; 88B-24; Eff. February 1, 1976; Amended Eff. January 1, 2011; June 1, 2009; June 1, 2007; August 1, 1998; June 1, 1994; April 1,1991; January 1, 1989; ***Repealed Eff. September 1, 2012.***

21 NCAC 14H .0106—RESIDENTIAL BEAUTY SHOPS

History Note: Authority G.S. 88-23; Eff. February 1, 1976; ***Repealed Eff. January 1, 1989.***

21 NCAC 14H .0107—WATER SUPPLY

21 NCAC 14H .0108—FLOOR COVERINGS

21 NCAC 14H .0109—VENTILATION AND LIGHT

21 NCAC 14H .0110—BATHROOM FACILITIES

21 NCAC 14H .0111—CLEANLINESS OF OPERATORS

21 NCAC 14H .0112—CLEANLINESS OF CLINIC AREA

21 NCAC 14H .0113—CLEANLINESS OF SCISSORS: SHEARS: RAZORS AND OTHER EQUIPMENT

21 NCAC 14H .0114—CAREOF CREAMS: LOTIONS: AND COSMETICS

21 NCAC 14H .0115—FIRST AID

History Note: Authority G.S. 88B-4; 88B-4(a)(9); 88B-14; 88-23; Eff. February 1, 1976; Amended Eff. August 1, 1998; June 1, 1994; April 1, 1991; January 1, 1989; April 1, 1988; Temporary Amendment Eff. January 20, 1999; Amended Eff. April 1, 2011; January 1, 2011; July 1, 2010; December 1, 2008; January 1,2008;October 1, 2006; February 1, 2006 November 1, 2005; December 1, 2004; September 1, 2004; February 1,2004; August 1, 2000; ***Repealed Eff. September 1, 2012.***

21 NCAC 14H .0116—HEALTH OF OPERATORS

History Note: Authority G.S. 88-23; 88-26(3); Eff. February 1, 1976; Amended Eff. January 1, 1989; ***Repealed Eff. December 1, 2008.***

21 NCAC 14H .0117—ANIMALS

21 NCAC 14H .0118—SYSTEMS OF GRADING BEAUTY ESTABLISHMENTS

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; 88B-17; 88B-23; Eff. February 1, 1976; Amended Eff. August 1, 1998; June 1, 1994; April 1, 1991; January 1, 1989; Temporary Amendment Eff. January 20, 1999; Amended Eff. Amended Eff. July 1, 2010; December 1, 2008; August 1, 2000; ***Repealed Eff. September 1, 2012.***

21 NCAC 14H .0119—NOTICE TO BOARD

History Note: Authority G.S. 88-23; 88-29; Eff. March 1, 1993; Amended Eff. March 1, 1994; ***Repealed Eff. August 1, 1998.***

21 NCAC 14H .0120—WHIRLPOOL, FOOTSPA AND FACIAL STEAMER SANITATION

History Note: Authority G.S. 88B-4; 88B-14; Eff. February 1, 2004; Amended Eff. January 1, 2011; December 1, 2008; May 1, 2007; October 1, 2006; November 1, 2005; ***Repealed Eff. September 1, 2012.***

21 NCAC 14H .0121—PROHIBITED PRACTICES

History Note: Authority G.S. 88B-2; 88B-4; Eff. April 1, 2004; Amended Eff. January 1, 2011; January 1, 2008 ; May 1, 2007; December 1, 2004; ***Repealed Eff. September 1, 2012.***

SECTION .0200—SHOP LICENSING AND PHYSICAL DIMENSIONS

21 NCAC 14H .0201—APPLICATION FOR SHOP LICENSE

(a) Rules in this Subchapter apply to all cosmetic art shops making initial application to operate a cosmetic art shop after the effective date of these Rules.

(b) Shops licensed prior to March 1, 2012 may choose to comply with Rules .0202, .0203(c), .0204 and .0301ofthis Subchapter.

(c) Shops licensed prior to March 1, 2012 must comply with Rules .0201, .0203(a)-(b), .0302-.0304 and Sections .0400and .0500 of this Subchapter.

(d) Shops licensed prior to March 1, 2012 that make any structural changes must come into compliance with all rules in this Subchapter.

(e) Persons desiring to open a cosmetic art shop in the State of North Carolina shall make application to the North Carolina State Board of Cosmetic Art Examiner on the Board's application form. Persons desiring to change ownership of a cosmetic art shop, relocate or reopen a shop which has been closed more than 90 days shall make application to the North Carolina State Board of Cosmetic Art Examiner on the Board's application form.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; 88B-22; Eff. April 1, 2012.

21 NCAC 14H .0202—RESERVED FOR FUTURE CODIFICATION

21 NCAC 14H .0203—NEWLY ESTABLISHED SHOPS

(a) A cosmetic art shop shall be separate and apart from any building or room used for any other business or purpose, separated by a solid wall of at least seven feet in height and must have a separate outside entrance.

(b) A newly established cosmetic art shop, shall be separate and apart from any building or room used for living, dining or sleeping and shall be separate and apart from any other room used for any other purpose by a solid wall of ceiling height, making separate and apart rooms used for a cosmetic art shop. All entrances to the cosmetic art shop shall be through solid, full length doors installed in solid walls of ceiling height.

(c) A residential cosmetic art shop shall furnish bathroom facilities separate and apart from the residence.

(d) An entrance to a cosmetic art shop from a passageway, walkway or mall area used only for access to the shop, or to the shop and other businesses, may be open.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; Eff. April 1, 2012.

21 NCAC 14H .0204—DIMENSIONS WITHIN COSMETIC ART SHOPS

Within the clinic area each shop shall maintain no less than the following working distances:

(1) 48 inches of space from the center to the center of each styling chair, esthetics table or manicuring table;

(2) 24 inches from the center of the chair forward;

(3) 48 inches from the backrest behind the chair to any other styling chair, esthetics table or manicuring table; and

(4) at least 30 inches of space from the back of each styling chair, esthetics table or manicuring table to the wall of the shop.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; Eff. April 1, 2012.

SECTION .0300— COSMETIC ART SHOP AND EQUIPMENT

21 NCAC 14H .0301—WATER

(a) Cosmetic art shops shall have a sink with hot and cold running water in the clinic area, separate from restrooms.

(b) When a service is provided in a room closed off by a door, the sink required in this Rule must be within 20feet of the door or 25 feet from the service table or chair. The restroom sink shall not be used to meet this requirement.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; Eff. April 1, 2012; Amended Eff. June 1, 2013.

21 NCAC 14H .0302—VENTILATION AND LIGHT

(a) Ventilation shall be provided at all times in the areas where patrons are serviced in all cosmetic art shops and there must be a continuous exchange of air.

(b) All doors and windows, if open for ventilation, must be effectively screened.

(c) Light shall be provided in the service area.

(d) All cosmetic art shops must adhere to any federal, state and local government regulation or ordinance regarding fire safety codes, plumbing and electrical work.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; Eff. April 1, 2012.

21 NCAC 14H .0303—BATHROOM FACILITIES

(a) Toilet and hand washing facilities consisting of at least one commode and one hand washing sink with hot and cold running water, liquid soap and individual clean towels or hand air dryer shall be provided.

(b) Shops with an initial licensure date after March 1, 2012 must have toilet and hand washing facilities in the bathroom.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; Eff. April 1, 2012.

21 NCAC 14H .0304—EQUIPMENT

Cosmetic art shops shall maintain equipment and supplies to safely perform any cosmetic art service offered in the shop.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; Eff. April 1, 2012.

SECTION .0400— SANITATION PROCEDURES AND PRACTICES

21 NCAC 14H .0401—LICENSEES AND STUDENTS

(a) Notwithstanding Rule .0201 in this Subchapter, this Rule applies to licensees and students in practice in cosmetic art schools and shops. Each licensee and student shall wash his or her hands with soap and water or an equally effective cleansing agent immediately before and after serving each client.

(b) Each licensee and student shall wear clean garments and shoes while serving patrons.

(c) Licensees or students shall not use or possess in a cosmetic art school or shop any of the following:

(1) Methyl Methacrylate Liquid Monomer, a.k.a. MMA;

(2) razor-type callus shavers designed and intended to cut growths of skin including skin tags, corns, and calluses;

(3) FDA rated Class III devices;

(4) carbolic acid (phenol) over two percent strength;

(5) animals including insects, fish, amphibians, reptiles, birds, or non-human mammals to perform any service; or

(6) a variable speed electrical nail file on a natural nail unless it has been designed for use on a natural nail.

(d) A licensee or student shall not:

(1) use any product, implement, or piece of equipment in any manner other than the product's, implement's, or equipment's intended use as described or detailed by the manufacturer;

(2) treat any medical condition unless referred by a physician;

(3) provide any service unless trained prior to performing the service;

(4) perform services on a client if the licensee has reason to believe the client has any of the following:

(A) fungus, lice, or nits;

(B) an inflamed, infected, broken, raised, or swollen skin or nail tissue in the area to be worked on; or

(C) an open wound or sore in the area to be worked on;

(5) alter or duplicate a license issued by the Board;

(6) advertise or solicit clients in any form of communication in a manner that is false or misleading;

(7) use any FDA rated Class II device without the documented supervision of a licensed physician;

(8) use any product that will penetrate the dermis; or

(9) make any statement to a member of the public either verbally or in writing stating or implying action is required or forbidden by Board rules when such action is not required or forbidden by Board rules. A violation of this prohibition is considered practicing or attempting to practice by fraudulent misrepresentation.

(e) In using a disinfectant, the user shall wear any personal protective equipment, such as gloves, recommended by the manufacturer in the Material Safety Data Sheet.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; 88B-24; Eff. April 1, 2012; Amended Eff. August 1, 2014; March 1, 2013.

21 NCAC 14H .0402—COSMETIC ART SHOPS AND SCHOOLS

(a) Notwithstanding Rule .0201 in this Subchapter, this Rule applies to all cosmetic art schools and shops. A cosmetic art school or shop shall be kept clean.

(b) Waste material shall be kept in receptacles with a disposable liner. The area surrounding the waste receptacles shall be maintained in a sanitary manner.

(c) All doors and windows shall be kept clean.

(d) Furniture, equipment, floors, walls, ceilings and fixtures must be clean and in good repair.

(e) Animals or birds shall not be in a cosmetic art shop or school. Fish in an enclosure and animals trained for the purpose of accompanying disabled persons are exempt from the prohibition in this Paragraph.

(f) Cosmetic art shops and schools shall designate the entrance by a sign or lettering.

(g) The owner of a cosmetic art shop or school shall not post any sign that states or implies that some action is required or forbidden by Board rules when such action is not required or forbidden by Board rules. A violation of this prohibition is considered practicing or attempting to practice by fraudulent misrepresentation.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; 88B-24; Eff. April 1, 2012; Amended Eff. March 1, 2013.

21 NCAC 14H .0403—DISINFECTION PROCEDURES

(a) Sanitation rules which apply to towels and cloths are as follows:

(1) Clean protective capes, drapes, linens and towels shall be used for each patron;

(2) After a protective cape has been in contact with a patron's neck it shall be placed in a clean, closed container until laundered with soap and hot water and dried in a heated dryer. Capes that cannot be laundered and dried in a heater dryer may be disinfected with an EPA registered hospital grade disinfectant mixed and used in accordance with the manufacturer directions; and

(3) After a drape, linen or towel has been in contact with a patron's skin it shall be placed in a clean, covered container until laundered with soap and hot water and dried in a heated dryer. A covered container may have an opening so soiled items may be dropped into the container.

(b) Any paper or nonwoven protective drape or covering shall be discarded after one us e.

(c) There shall be a supply of clean protective drapes, linens and towels at all times.

(d) Clean drapes, capes, linens, towels and all other supplies shall be stored in a clean area.

(e) Bathroom facilities must be kept cleaned.

(f) All implements shall be cleaned and disinfected after each use in the following manner:

(1) They shall be washed with warm water and a cleaning solution and scrubbed to remove debris and dried.

(2) They shall be disinfected in accordance with the following:

(A) EPA registered hospital/pseudomonacidal (bactericidal, virucidal, and fungicidal) or tuberculocidal that is mixed and used according to the manufacturer's directions. They shall be rinsed with hot tap water and dried with a clean towel before their next use. They shall be stored in a clean, closed cabinet or container until they are needed; or

(B) 1 and 1/3 cup of 5.25 percent household bleach to one gallon of water for 10 minutes. They shall be rinsed with hot tap water and dried with a clean towel before their next use. They shall be stored in a clean, closed cabinet or container until they are needed; or

(C) UV-C, ultraviolet germicidal irradiation used accordance with the manufacturer's directions.

(3) If the implement is not immersible or is not disinfected by UV-C irradiation, it shall be cleaned by wiping it with a clean cloth moistened or sprayed with a disinfectant EPA registered, hospital/pseudomonacidal (bactericidal, virucidal, and fungicidal) or tuberculocidal, used in accordance with the manufacturer's directions.

(4) Implements that come in contact with blood, shall be disinfected by:

(A) disinfectant, used in accordance with the manufacturer's instructions, that states the solution will destroy HIV, TB or HBV viruses and approved by the Federal Environmental Protection Agency; or

(B) EPA registered hospital/pseudomonacidal (bactericidal, virucidal, and fungicidal) and tuberculocidal that is mixed and used according to the manufacturer's directions; or

(C) household bleach in a 10 percent solution (1 and 2/3 cup of bleach to 1 gallon of water) for 10 minutes.

(g) All disinfected non-electrical implements shall be stored in a clean closed cabinet or clean closed container.

(h) All disinfected electrical implements shall be stored in a clean area.

(i) Disposable and porous implements and supplies must be discarded after use or upon completion of the service.

(j) Product that comes into contact with the patron must be discarded upon completion of the service.

(k) Clean, closable storage must be provided for all disinfected implements not in use. Containers with open faces may be covered/closed with plastic wrapping. Disinfected implements must be kept in a clean closed cabinet or clean closed container and must not be stored with any implement or item that has not been disinfected.

(l) Lancets, disposable razors, and other sharp objects shall be disposed in puncture-resistant containers.

(m) All creams, lotions, wax, cosmetics, and other products dispensed to come in contact with patron's skin must be kept in clean, closed containers, and must conform in all respects to the requirements of the Pure Food and Drug Law. Any product apportioned for use and removed from original containers must be distributed in a sanitary manner that prevents contamination of product or container. Any product dispensed in portions into another container must be dispensed into a sanitized container and applied to patrons by means of a disinfected or disposable implement or other sanitized methods. Any product dispensed in portions not dispensed into another container must be used immediately and applied to patrons by means of a disinfected or disposable implement or other sanitized methods. No product dispensed in portions may be returned to the original container.

(n) As used in this Rule whirlpool or footspa means any basin using circulating water.

(o) After use by each patron each whirlpool or footspa must be cleaned and disinfected as follows:

(1) All water must be drained and all debris removed from the basin;

(2) The basin must be disinfected by filling the basin with water and circulating:

(A) Two tablespoons of automatic dishwashing powder and 1/4 cup of 5.25 percent household bleach to one gallon of water through the unit for 10 minutes; or

(B) Surfactant or enzymatic soap with an EPA registered disinfectant with bactericidal, tuberculocidal, fungicidal and virucidal activity used according to manufacturer's instructions through the unit for 10 minutes;

(3) The basin must be drained and rinsed with clean water; and

(4) The basin must be wiped dry with a clean towel.

(p) At the end of the day each whirlpool or footspa must be cleaned and disinfected as follows:

(1) The screen must be removed and all debris trapped behind the screen removed;

(2) The screen and the inlet must be washed with

surfactant or enzymatic soap or detergent and rinsed with clean water;

(3) Before replacing the screen one of the following procedures must be performed:

(A) The screen must be totally immersed in a household bleach solution of 1/4 cup of 5.25 percent household bleach to one gallon of water for 10 minutes; or

(B) The screen must be totally immersed in an EPA registered disinfectant with bactericidal tuberculocidal, fungicidal and virucidal activity in accordance to the manufacturer's instructions for 10 minutes;

(4) The inlet and area behind the screen must be cleaned with a brush and surfactant soap and water to remove all visible debris and residue; and

(5) The spa system must be flushed with low sudsing surfactant or enzymatic soap and warm water for at least 10 minutes and then rinsed and drained.

(q) Every week after cleaning and disinfecting pursuant to Paragraphs (a) and (b) of this Rule each whirlpool and footspa must be cleaned and disinfected in the following manner:

(1) The whirlpool or footspa basin must be filled with water and 1/4 cup of 5.25 percent household bleach for each one gallon of water or EPA registered disinfectant with bactericidal, tuberculocidal, fungicidal and virucidal activity in accordance to the manufacturer's instructions; and

(2) The whirlpool or footspa system must be flushed with the bleach and water or EPA registered disinfectant solution for 10 minutes and allowed to sit for at least six hours; and

(3) The whirlpool or footspa system must be drained and flushed with water before use by a patron.

(r) A record must be made of the date and time of each cleaning and disinfecting as required by this Rule including the date, time, reason and name of the staff member who performed the cleaning. This record must be made for each whirlpool or footspa and must be kept and made available for at least 90 days upon request by either a patron or inspector.

(s) The water in a vaporizer machine must be emptied daily and the unit disinfected daily after emptying.

(t) The area where services are performed that come in contact with the patron's skin including treatment chairs, treatment tables and beds shall be disinfected between patrons.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; Eff. April 1, 2012.

21 NCAC 14H .0404—FIRST AID

(a) Each cosmetic art shop and school must have antiseptics, gloves or finger guards, sterile bandages and other necessary supplies available to provide first aid.

(b) If the skin of the licensee or student is punctured, the licensee or student shall immediately do the following:

(1) Apply antiseptic and a sterilized bandage;

(2) Disinfect any implement exposed to blood before proceeding; and

(3) Put on disposable, protective gloves or a finger guard.

(c) If the skin of the patron is punctured, the licensee or student shall immediately do the following:

(1) Make available to the patron antiseptic and a sterilized bandage;

(2) Disinfect any implement exposed to blood before proceeding; and

(3) Put on disposable, protective gloves or a finger guard.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; Eff. April 1, 2012.

SECTION .0500—ENFORCEMENT, MAINTENANCE OF LICENSURE

21 NCAC 14H .0501—INSPECTION OF COSMETIC ART SHOPS

(a) A newly established cosmetic art shop, a shop which has been closed for more than 90 days, or a shop which has changed ownership must file an application for licensure with the Board prior to opening. A newly established cosmetic art shop, a shop which has been closed for more than 90 days, a shop which has changed ownership or a shop which has been operating without a license shall be inspected before a license will be issued.

(b) Each cosmetic art shop must pass inspection by an agent of the Board pursuant to this Subchapter. Inspections shall be conducted annually and may be conducted without notice.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; 88B-27; Eff. April 1, 2012.

21 NCAC 14H .0502—FAILURE TO PERMIT INSPECTION

If an inspector is twice unable to inspect a salon after making an appointment to inspect the salon the Board may initiate proceedings to revoke or suspend the salon license or may refuse to renew the shop license.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; 88B-27; Eff. April 1, 2012.

21 NCAC 14H .0503—SANITARY RATINGS AND POSTING OF RATINGS

(a) The sanitary rating of a beauty establishment shall be based on a system of grading outlined in this Subchapter. Based on the grading, all establishments shall be rated in the following manner:

(1) all establishments receiving a rating of at least 90 percent or more shall be awarded a grade A;

(2) all establishments receiving a rating of at least 80 percent, and less than 90 percent, shall be awarded grade B;

(3) all establishments receiving a rating of at least 70 percent or more, and less than 80 percent shall be awarded grade C;

(4) any cosmetic art shop or school with a sanitation grade of 70 percent or below shall be awarded a failed inspection notice.

(b) Every beauty establishment shall be given a sanitary rating. A cosmetic art school shall be graded no less than three times a year, and a cosmetic art shop shall be graded once a year.

(c) The sanitary rating or failed inspection notice given to a beauty establishment shall be posted in plain sight near the front entryway at all times.

(d) All new establishments must receive a rating of at least 90 percent before a license will be issued.

(e) The operation of a cosmetic art shop or school which fails to receive a sanitary rating of at least 70 percent (grade C) shall be sufficient cause for revoking or suspending the license.

(f) A re-inspection for the purpose of raising the sanitary rating of a beauty establishment shall not be given within 30days of the last inspection unless the rating at the last inspection was less than 80 percent.

(g) A whirlpool and footspa sanitation record must be kept on each whirlpool and footspa for inspection on a form provided by the Board.

(h) All cosmetic art shops and schools with a failed inspection report shall be sufficient cause for the immediate suspension of licensure. All cosmetic art shops and schools with a failed inspection report must close until the sanitation conditions have improved to be awarded a passing grade.

(i) Mobile cosmetic art shops and schools are prohibited.

(j) A copy of the itemized and graded inspection report must be provided to the operator at the time of the inspection.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; 88B-26; 88B-27; Eff. April 1, 2012.

21 NCAC 14H .0504—SYSTEMS OF GRADING BEAUTY ESTABLISHMENTS

The system of grading the sanitary rating of cosmetic art schools and shops based on the rules set out in this subchapter shall be as follows, setting out areas to be inspected and considered, and the maximum points given for compliance:

Sanitation	Point Value
Each licensee and student shall wash his or her hands with soap and water or an equally effective cleansing agent immediately before and after serving each client.	2
Each licensee and student shall wear clean garments and shoes while serving patrons.	2
The cosmetic art facility shall be kept clean.	3
Waste material shall be kept in receptacles with a disposable liner. The area surrounding the waste receptacles shall be maintained in a sanitary manner.	4
All doors and windows shall be kept clean.	2
Furniture, equipment, floors, walls, ceilings and fixtures shall be clean and in good repair.	3
Clean protective capes, drapes, linens, and towels shall be used for each patron.	3
After a cape, drape, linen, or towel has been in contact with a patron's skin, it shall be placed in a clean, closed container until laundered with soap and hot water and dried in a heated dryer.	5
Any paper or nonwoven protective drape or covering shall be discarded after one use.	2
There shall be a supply of clean protective drapes, linens and towels at all times.	2
Clean drapes, capes, linens, and towels shall be stored in a clean area.	5
Bathroom facilities shall be kept cleaned.	3
All implements shall be washed with warm water and a cleaning solution and scrubbed to remove debris and dried.	2

Sanitation *(continued)*	Point Value
All implements shall be disinfected.	10
All disinfected electrical implements shall be stored in a clean area.	2
Disposable and porous implements and supplies shall be discarded after use or upon completion of the service.	10
Any product that comes into contact with the patron shall be discarded upon completion of the service.	3
Disinfected implements shall be kept in a clean closed cabinet or clean closed container and shall not be stored with any implement or item that has not been disinfected.	10
Lancets, disposable razors, and other sharp objects shall be disposed in puncture-resistant containers.	1
The presence of animals or birds. Fish in an enclosure and animals trained for the purpose of accompanying disabled persons are exempt.	1
All creams, lotions, wax, cosmetics, and other products dispensed to come in contact with patron's skin shall be kept in clean, closed containers and dispensed in a sanitary manner. No product dispensed in portions shall be returned to the container.	10
After each patron's use each whirlpool or footspa shall be cleaned and disinfected.	10
The water in a vaporizer machine shall be emptied daily and the unit disinfected daily.	2
The area where services are performed that come in contact with the patron's skin including chairs, tables, and beds shall be disinfected between patrons.	3

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; 88B-23; 88B-26; Eff. April 1, 2012; Amended Eff. August 1, 2014.

21 NCAC 14H .0505—RULE COMPLIANCEAND ENFORCEMENT MEASURES

(a) The use of or possession of the following products or equipment in a school or shop shall result in civil penalty in the amount of three hundred dollars ($300.00) per container of product or piece of equipment:

(1) Methyl Methacrylate Liquid Monomer a.k.a. MMA; or

(2) razor-type callus shavers designed and intended to cut growths of skin including skin tags, corns, and calluses.

(b) The use of or possession of the following in a school or shop shall result in civil penalty in the amount of one hundred dollars ($100.00) per use or possession:

(1) animals including insects, fish, amphibians, reptiles, birds, or non-human mammals to perform any service; or

(2) variable speed electrical nail file on the natural nail unless it has been designed for use on the natural nail.

(c) The action of any student or licensee to violate the Board rules in the following manner shall result in civil penalty in the amount of one hundred dollars ($100.00) per instance of each action:

(1) use of any product, implement, or piece of equipment in any manner other than the product's, implement's, or equipment's intended use as described or detailed by the manufacturer;

(2) treatment of any medical condition unless referred by a physician;

(3) use of any product that will penetrate the dermis;

(4) provision of any service unless trained prior to performing the service;

(5) performance of services on a client if the licensee has reason to believe the client has any of the following:

(A) fungus, lice, or nits;

(B) inflamed infected, broken, raised, or swollen skin or nail tissue in the area to be worked on; or

(C) an open wound or sore in the area to be worked on; or

(6) alteration of or duplication of a license issued by the Board;

(7) advertisement or solicitation of clients in any form of communication in a manner that is false or misleading; or

(8) use of any FDA rated Class II device without the documented supervision of a licensed physician.

(d) The failure to record the date and time of each cleaning and disinfecting of a footspa in a cosmetic art school or shop as required by this Subchapter including the date, time, reason, and name of the staff member who performed the cleaning or the failure to keep or make such record available for at least 90 days upon request by either a patron or inspector shall result in civil penalty in the amount of twenty-five dollars ($25.00) per footspa.

(e) The failure to clean and disinfect a footspa in a cosmetic art shop or school as required by this Subchapter shall result in civil penalty in the amount of one hundred dollars ($100.00) per footspa.

(f) The failure to maintain in a cosmetic art shop and school antiseptics, gloves or finger guards, and sterile bandages available to provide first aid shall result in civil penalty in the amount of twenty-five dollars ($25.00) per item.

(g) The failure to maintain a sink with hot and cold running water in the clinic area, separate from restrooms, shall result in civil penalty in the amount of one hundred dollars ($100.00).

(h) The failure to provide ventilation at all times in the areas where patrons are serviced in cosmetic art shops shall result in civil penalty in the amount of twenty-five dollars ($25.00).

(i) The failure to screen all doors and windows open for ventilation shall result in civil penalty in the amount of twenty-five dollars ($25.00).

(j) The failure to maintain equipment and supplies necessary to perform any cosmetic art service offered in the shop shall result in civil penalty in the amount of one hundred dollars ($100.00).

(k) The failure to maintain a sanitation grade of 80 percent or higher shall result in a civil penalty in the amount of two hundred dollars ($200.00).

(l) Repeated violations of the rules in this Subchapter exceeding three written notifications of any one rule documented to any one individual, shop, or school shall result in a mandatory disciplinary hearing in accordance with 21 NCAC 14C.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; 88B-23; 88B-24; 88B-26; 88B-27; 88B-29; Eff. April 1, 2012; Amended Eff. August 1, 2014.

Business Practices for Salon Owners and Employees

Based on:

IRS Publications *583, 1779, Tax Tips for the Cosmetology and Barber Industry*

Tax Tips for the Cosmetology and Barber Industry

Whether a shop owner, an employee, or a booth renter (independent contractor), you need to know your federal tax responsibilities, including how to report your income and tips you receive from your customers.

The most common forms of business are the sole proprietorship, partnership, and corporation. Your form of business determines which income tax return form you have to file. Publication 583, *Starting a Business and Keeping Records*, available free from the IRS, can help you decide.

The purpose of this publication is to describe some of the Federal tax responsibilities that owners and workers must address each day.

Shop Owner

As a shop owner you can elect to structure your business in different forms. You can choose to operate your business as a sole proprietorship, partnership, or as a corporation. Your business may have employees who work for you or you may decide to operate without employees. Another common arrangement is renting space to another individual who operates an independent business. This is commonly referred to as a booth renter and will be discussed later in this publication.

It doesn't matter which business structure you choose; there are basic principles that do not change. Income received in the course of your business is taxable income and must be reported on the appropriate income tax return form.

If you operate your business without employees, where you are the only worker, then your federal tax responsibilities would be limited to reporting your income earned (including tip income) and expenses on the appropriate tax form. For example, a sole proprietorship would file Form 1040, using Schedule C to report business income and expenses and Schedule SE to report Self-Employment tax.

Once you decide to hire workers you must make a determination if they are your employees or if they will operate their own independent business (booth renters).

Who is an Employee?

Simply stated, an employee is an individual who works at the control and direction of another. It is important to remember that as the employer you do not have to control the worker all of the time, you simply have to have the right to control. The following questions are helpful in determining if someone is your employee or an independent contractor:

- As the owner, do you establish the hours the shop is open?
- Who makes the determination regarding who works specific shifts?
- Do the workers purchase their own supplies with their own money?
- Who determines the prices charged to customers?
- Do the workers each set their own appointments?
- Who is responsible for expenses, such as insurance, advertising, etc.?

These questions are not all inclusive, but they will provide insight as to whether you are their employer. If you give extensive instructions as to how, when, or where to do the work and where to purchase the supplies, then more than likely you are the employer and the worker is your employee. For additional information, see Publication 1779, *Independent Contractor or Employee,* included at the end of this chapter.

Shop Owner/Employer Tax Responsibilities

As an employer, federal law requires you to withhold taxes from your employees' paychecks. Depending on the wages, you must take out of your employees' paychecks certain amounts for federal income tax, social security tax, and Medicare tax. You must then pay any liability for the employer's share of social security and Medicare taxes. This portion, your share, is not withheld from employees. You may also be required to pay unemployment (FUTA) taxes on these wages. In addition to reporting all taxable income on the appropriate income tax form, you would also have the responsibility for issuing Form W-2, *Wage and Tax Statement.*

The wages paid, along with the taxes withheld, are reported on a quarterly basis by filing Form 941, *Employer's QUARTERLY Federal Tax Return*. You may also be required to file an annual form to pay Federal unemployment taxes. This is done by filing Form 940, *Employer's Annual Federal Unemployment (FUTA) Tax Return*. Form W-2 is furnished to employees after the close of the calendar year, but no later than January 31st.

For more information about payroll taxes, see Publication 15 *(Circular E)*, Employer's Tax Guide that you can download at www.irs.gov/businesses and click on the Employment Taxes link.

Booth Renters

A booth renter is someone who leases space from an existing business and operates their own business as an independent contractor. As a booth renter, or independent contractor, you are responsible for your own record-keeping and timely filing of returns and payments of taxes related to your business.

Indications that you are an independent contractor include, but are not limited to:

- Having a key to the establishment
- Setting your own hours
- Purchasing your own products
- Having your own phone number and business name
- Determining the prices to be charged

If these factors are not present, then you are likely an employee of the business who is providing the space to you.

If the above factors are present, then as an independent contractor you would be responsible for your federal taxes. Your tax responsibilities would include:

- Reporting all income (including tips) on the appropriate income tax return form, such as Form 1040, using Schedule C or Schedule C-EZ. Social Security and Medicare Taxes are reported on Schedule SE.
- As a booth renter you must issue Form 1099-MISC for business rent paid of more than $600 or more to non-corporate landlords each year.
- Issue Form 1099 MISC or W-2 to workers you hire or employ.

As a booth renter, or independent contractor, you may need to make estimated tax payments during the year to cover your tax liabilities. This is because as a booth renter (independent contractor), the business does not withhold taxes from your pay. Estimated tax is the method used to pay tax on income that is not subject to withholding, such as earnings from self-employment you receive as a booth renter.

Estimated tax payments are made each quarter using Form 1040-ES, *Estimated Tax for Individuals*. For additional information regarding tax withholding and estimated tax, see Publication 505, *Tax Withholding and Estimated Tax*.

If you hire others to work for you it is possible that these workers would be your employees. As a booth renter you can hire others to work for you as your employees. If you have employees in your business, you would be required to deduct from their pay social security, Medicare and federal income taxes. This would require you to file quarterly Forms 941, as well as an annual Form 940. You would also be required to file Forms W-2 for each employee who worked for you during the calendar year.

Tip Income Responsibilities for the Employer or Booth Renter

Tips are considered taxable income and are subject to Federal income taxes. Tips that your employee receives from customers are generally subject to withholding. Your employees must report tips they receive to you by the 10th of the month after the month that the tips are received. The report should include tips that you paid over to the employee from customers that added the tip to their charged or debit card receipt and tips that the employee received directly from customers.

You must collect income tax, employee social security tax, and employee Medicare tax on the employee's tips. For more information on the taxation of tips, see Publication 15, *Circular E – Employer's Tax Guide,* available free from the IRS.

Employees are required by law to keep a daily record of all tips they receive. The IRS furnishes free, Publication 1244, *Employee's Daily Record of Tips and Report to Employer,* which employees can use to record their tips on a daily basis. Publication 1244 includes Form 4070, *Employee's Report of Tips to Employer* and Form 4070A, *Employee's Daily Record of Tips*.

If you operate your own business as a sole proprietor or booth renter, any tips received in the normal course of your business must be reported in gross receipts, and then reported on the appropriate income tax form.

See Publication 531, *Reporting Tip Income,* for more information regarding tip income reporting.

Employee Tip Reporting Responsibilities

All tips you receive are income and are subject to federal income tax. You must include in gross income all tips you receive directly from customers, charged tips paid to you by your employer, and your share of any tips you receive under a tip-splitting or tip-pooling arrangement.

You can use Form 4070A, *Employee's Daily Record of Tips* to record your tips, or any diary of your choosing. You can also keep copies of documents that show your tips, such as customer receipts and credit card slips. Publication 1244 includes Form 4070, *Employee's Report*

of Tips to Employer and Form 4070A, *Employee's Daily Record of Tips,* available free from the IRS. You can use an electronic system provided by your employer to record your daily tips. If you do, you must receive and keep a copy of this record.

Reporting Tips to Your Employer

Why report tips to your employer? You must report tips to your employer so that:

- Your employer can withhold federal income tax and social security, Medicare, Additional Medicare, or railroad retirement taxes,
- Your employer can report the correct amount of your earnings to the Social Security Administration or Railroad Retirement Board (which affects your benefits when you retire or if you become disabled, or your family's benefits if you die), and
- You can avoid the penalty for not reporting tips to your employer (explained later).

What tips to report. Report to your employer only cash, check, and debit and credit card tips you receive.

If your total tips for any 1 month from any one job are less than $20, do not report the tips for that month to that employer.

If you participate in a tip-splitting or tip-pooling arrangement, report only the tips you receive and retain. Do not report to your employer any portion of the tips you receive that you pass on to other employees. However, you must report tips you receive from other employees.

Do not report the value of any noncash tips, such as tickets or passes, to your employer. You do not pay social security, Medicare, Additional Medicare, or railroad retirement taxes on these tips.

How to report. If your employer does not give you any other way to report your tips, you can use Form 4070, *Employee's Report of Tips to Employer.* Fill in the information asked for on the form, sign and date the form, and give it to your employer. To get a 1-year supply of the form, ask the IRS or your employer for Publication 1244.

If you do not use Form 4070, give your employer a statement with the following information.

- Your name, address, and social security number.
- Your employer's name, address, and business name (if it is different from your employer's name).
- The month (or the dates of any shorter period) in which you received tips.
- The total tips required to be reported for that period.

You must sign and date the statement. Be sure to keep a copy with your tax or other personal records.

Your employer may require you to report your tips more than once a month. However, the statement cannot cover a period of more than 1 calendar month.

Electronic tip statement. Your employer can have you furnish your tip statements electronically.

When to report. Give your report for each month to your employer by the 10th of the next month. If the 10th falls on a Saturday, Sunday, or legal holiday, give your employer the report by the next day that is not a Saturday, Sunday, or legal holiday.

Example. You must report your tips received in September 2014 by October 10, 2014.

Final report. If your employment ends during the month, you can report your tips when your employment ends.

Penalty for not reporting tips. If you do not report tips to your employer as required, you may be subject to a penalty equal to 50% of the social security, Medicare, Additional Medicare, or railroad retirement taxes you owe on the unreported tips. The penalty amount is in addition to the taxes you owe. You can avoid this penalty if you can show reasonable cause for not reporting the tips to your employer. To do so, attach a statement to your return explaining why you did not report them.

Giving your employer money for taxes. Your regular pay may not be enough for your employer to withhold all the taxes you owe on your regular pay plus your reported tips. If this happens, you can give your employer money until the close of the calendar year to pay the rest of the taxes.

If you do not give your employer enough money, your employer will apply your regular pay and any money you give to the taxes, in the following order.

1. All taxes on your regular pay.
2. Social security, Medicare, Additional Medicare, or railroad retirement taxes on your reported tips.
3. Federal, state, and local income taxes on your reported tips.

Any taxes that remain unpaid can be collected by your employer from your next paycheck. If withholding taxes remain uncollected at the end of the year, you may be subject to a penalty for underpayment of estimated taxes. See Publication 505, Tax Withholding and Estimated Tax, for more information.

Tip Rate Determination and Education Program (TRD/EP)

Employers may participate in the Tip Rate Determination and Education program. The program consists of various voluntary agreements designed for specific industries where tipping is customary. There is one designed specifically for this industry. TRAC, Tip Reporting Alternative Commitment, has characteristics unique to the Cosmetology and Barber industry.

The IRS developed this program to encourage voluntary compliance with tip income reporting through outreach and education and using enforcement actions as a last resort.

To learn more about the voluntary agreement program, access the irs.gov website at Market Segment Understandings (MSU).

You can get copies of the forms and publications referenced in this publication, at www.irs.gov.

What Can You Claim for Taxes as a Self-Employed Cosmetologist?

Self-employed cosmetologists may rent a work space in someone else's salon ("booth renter"), work out of their home or own their own business. In any of these cases, cosmetologists are entitled to deduct business expenses. To insure that you are able to calculate and claim all allowable deductions, keep records of all your income and expenses.

Advertising Expense

You probably need to advertise your business throughout the year. You can claim advertising expenses such as business cards, website setup and maintenance, printing and paper expense for fliers, phone book ad fees, radio ads fees and newspaper ad fees. You can even deduct the cost of an ad placed in a school yearbook or special event program.

Supplies and Equipment

The bulk of your expenses will be for hair supplies. Such supplies include scissors, clippers, combs, brushes, mirrors, hair products, hair dye, capes, hair dryers, curling irons and straightening irons. Also make sure to claim purchases such as hair washing bowls, hair washing sinks, swivel chairs, even brooms and dustpans. Also deductible are expenses for towel services, sharpening services and equipment repairs.

Professional Expenses

Cosmetologists can deduct professional expenses such as fees required to obtain cosmetologist licenses and business licenses. Also, you may deduct fees paid for tax preparation and premiums paid for professional liability insurance.

Rent or Mortgage

If you rent a booth at a salon, you can claim the rent you pay each year for the booth. If you work out of your home, you can claim a home office expense. If you own the salon real estate, you can deduct the costs of the mortgage and insurance, and deduct the gradual depreciation of the property.

Repairs & Maintenance

This category applies mainly to salon owners. You can write off things such as fees paid to someone to clean your salon, floor maintenance (waxing & buffing) and any repairs that had to be made to your salon for upkeep.

Travel

You also may be able to deduct an amount for mileage. You can not typically deduct the cost of going from your home to your place of work, but you usually can deduct a mileage expense for obtaining beauty supplies and products and driving to beauty shows and continuing education classes. If you went away for a beauty trade show or conference, you may deduct the cost of getting to and from the event (plane or train tickets or mileage if you drove your own car) and the cost of food and lodging (hotel) while at the event.

Other Expenses

Other business expenses that you can claim include continuing-education classes, hair shows, hair magazine subscriptions, appointment books, pens and postage and envelopes for mailing business-related correspondence. You will be responsible for your own health and disability insurance, and can often deduct the premiums for these, or at least a certain percentage. If you employ other cosmetologists or helpers, you can deduct employee salaries and health insurance premiums you pay for them.

Claiming Deductions

You can claim business deductions against business income by filing a Schedule C, Profit or Loss from Business, along with your Form 1040. You cannot file Form 1040EZ for this purpose. Since you are self-employed, you must also file Schedule SE to file self employment tax if your self-employment earnings exceed $400 for the year.

Important IRS Forms and Publications

- Form 941: *Employer's QUARTERLY Federal Tax Return*
- Form 940: *Employer's Annual Federal Unemployment (FUTA) Tax Return*
- Form 1040-ES: *Estimated Tax for Individuals*
- Publication 15: *Circular E – Employer's Tax Guide*
- Publication 505: *Tax Withholding and Estimated Tax*
- Publication 531: *Reporting Tip Income*
- Publication 583: *Starting a Business and Keeping Records*
- Publication 1244: *Employee's Daily Record of Tips and Report to Employer*
- Publication 1779: *Independent Contractor or Employee*
- Publication 3144: *Tips on Tips for Employees*
- Publication 3148: *Tips on Tips for Employers*

IRS Record Keeping

(from IRS Publication 583 *Starting a Business and Keeping Records*)

Why Keep Records?

Everyone in business must keep records. Good records will help you do the following:

Monitor the progress of your business. You need good records to monitor the progress of your business. Records can show whether your business is improving, which items are selling, or what changes you need to make. Good records can increase the likelihood of business success.

Prepare your financial statements. You need good records to prepare accurate financial statements. These include income (profit and loss) statements and balance sheets. These statements can help you in dealing with your bank or creditors and help you manage your business. A balance sheet shows the assets, liabilities, and your equity in the business on a given date.

Identify source of receipts. You will receive money or property from many sources. Your records can identify the source of your receipts. You need this information to separate business from nonbusiness receipts and taxable from nontaxable income.

Keep track of deductible expenses. You may forget expenses when you prepare your tax return unless you record them when they occur.

Prepare your tax returns. You need good records to prepare your tax returns. These records must support the income, expenses, and credits you report. Generally, these are the same records you use to monitor your business and prepare your financial statements.

Support items reported on tax returns. You must keep your business records available at all times for inspection by the IRS. If the IRS examines any of your tax returns, you may be asked to explain the items reported. A complete set of records will speed up the examination.

Kinds of Records to Keep

Except in a few cases, the law does not require any specific kind of records. You can choose any recordkeeping system suited to your business that clearly shows your income and expenses.

The business you are in affects the type of records you need to keep for federal tax purposes. You should set up your recordkeeping system using an accounting method that clearly shows your income for your tax year (see IRS Publication 583 for more information). If you are in more than one business, you should keep a complete and separate set of records for each business. A corporation should keep minutes of board of directors' meetings.

Your recordkeeping system should include a summary of your business transactions. This summary is ordinarily made in your books (for example, accounting journals and ledgers). Your books must show your gross income, as well as your deductions and credits. For most small businesses, the business checkbook (discussed later) is the main source for entries in the business books. In addition, you must keep supporting documents, explained later.

Electronic records. All requirements that apply to hard copy books and records also apply to electronic storage systems that maintain tax books and records. When you replace hard copy books and records, you must maintain the electronic storage systems for as long as they are material to the administration of tax law. An electronic storage system is any system for preparing or keeping your records either by electronic imaging or by transfer to an electronic storage media. The electronic storage system must index, store, preserve, retrieve and reproduce the electronically stored books and records in legible format. All electronic storage systems must provide a complete and accurate record of your data that is accessible to the IRS. Electronic storage systems are also subject to the same controls and retention guidelines as those imposed on your original hard copy books and records.

The original hard copy books and records may be destroyed provided that the electronic storage system has been tested to establish that the hard copy books and records are being reproduced in compliance with IRS requirements for an electronic storage system and procedures are established to ensure continued compliance with all applicable rules and regulations. You still have the responsibility of retaining any other books and records that are required to be retained.

The IRS may test your electronic storage system, including the equipment used, indexing methodology, software and retrieval capabilities. This test is not considered an examination and the results must be shared with you. If your electronic storage system meets the requirements mentioned earlier, you will be in compliance. If not, you may be subject to penalties for non-compliance, unless you continue to maintain your original hard copy books and records in a manner that allows you and the IRS to determine your correct tax. For details on electronic storage system requirements, see Revenue Procedure 97-22, available in Internal Revenue Bulletin 1997-13.

Supporting Documents

Purchases, sales, payroll, and other transactions you have in your business generate supporting documents. Supporting documents include sales slips, paid bills, invoices, receipts, deposit slips, and canceled checks. These documents contain information you need to record in your books.

It is important to keep these documents because they support the entries in your books and on your tax return. Keep them in an orderly fashion and in a safe place. For instance, organize them by year and type of income or expense.

Gross receipts. Gross receipts are the income you receive from your business. You should keep supporting documents that show the amounts and sources of your gross receipts. Documents that show gross receipts include the following:

- Cash register tapes.
- Bank deposit slips.
- Receipt books.
- Invoices.
- Credit card charge slips.
- Forms 1099-MISC.

Purchases. Purchases are the items you buy and resell to customers. If you are a manufacturer or producer, this includes the cost of all raw materials or parts purchased for manufacture into finished products. Your supporting documents should show the amount paid and that the amount was for purchases. Documents for purchases include the following.

- Cancelled checks.
- Cash register tape receipts.
- Credit card sales slips.
- Invoices.

These records will help you determine the value of your inventory at the end of the year. See IRS Publication 538 for information on methods for valuing inventory.

Expenses. Expenses are the costs you incur (other than purchases) to carry on your business. Your supporting documents should show the amount paid and that the amount was for a business expense. Documents for expenses include the following.

- Cancelled checks.
- Cash register tapes.
- Account statements.
- Credit card sales slips.
- Invoices.
- Petty cash slips for small cash payments.

A petty cash fund allows you to make small payments without having to write checks for small amounts. Each time you make a payment from this fund, you should make out a petty cash slip and attach it to your receipt as proof of payment.

Travel, transportation, entertainment, and gift expenses. Specific recordkeeping rules apply to these expenses. For more information, see Publication 463.

Employment taxes. There are specific employment tax records you must keep. For a list, see Publication 15.

Assets. Assets are the property, such as machinery and furniture you own and use in your business. You must keep records to verify certain information about your business assets. You need records to figure the annual depreciation and the gain or loss when you sell the assets. Your records should show the following information:

- When and how you acquired the asset.
- Purchase price.
- Cost of any improvements.
- Section 179 deduction taken.
- Deductions taken for depreciation.
- Deductions taken for casualty losses, such as losses resulting from fires or storms.
- How you used the asset.
- When and how you disposed of the asset.
- Selling price.
- Expenses of sale.

The following documents may show this information.

- Purchase and sales invoices.
- Real estate closing statements.
- Canceled checks.

What if I don't have a canceled check? If you do not have a canceled check, you may be able to prove payment with certain financial account statements prepared by financial institutions. These include account statements prepared for the financial institution by a third party. These account statements must be highly legible. The following table lists acceptable account statements:

Proof of payment of an amount, by itself, does not establish you are entitled to a tax deduction. You should also keep other documents, such as credit card sales slips and invoices, to show that you also incurred the cost.

Recording Business Transactions

A good recordkeeping system includes a summary of your business transactions. (Your business transactions are shown on the supporting documents just discussed.) Business transactions are ordinarily summarized in books called journals and ledgers. You can buy them at your local stationery or office supply store.

IF payment is by...	THEN the statement must show the...
Check	Check number, amount, payee's name, date the check amount was posted to the account by the financial institution
Electronics funds transfer	Amount transferred, payee's name, date the transfer was posted to the account by the financial institution
Credit card	Amount charged, payee's name, transaction date

A journal is a book where you record each business transaction shown on your supporting documents. You may have to keep separate journals for transactions that occur frequently. A ledger is a book that contains the totals from all of your journals. It is organized into different accounts.

Whether you keep journals and ledgers and how you keep them depends on the type of business you are in. For example, a recordkeeping system for a small business might include the following items:

- Business checkbook.
- Daily summary of cash receipts.
- Monthly summary of cash receipts.
- Check disbursements journal.
- Depreciation worksheet.
- Employee compensation record.

The system you use to record business transactions will be more effective if you follow good recordkeeping practices. For example, record expenses when they occur, and identify the source of recorded receipts. Generally, it is best to record transactions on a daily basis.

Business checkbook. One of the first things you should do when you start a business is open a business checking account. You should keep your business account separate from your personal checking account.

The business checkbook is your basic source of information for recording your business expenses. You should deposit all daily receipts in your business checking account. You should check your account for errors by reconciling it.

Consider using a checkbook that allows enough space to identify the source of deposits as business income, personal funds, or loans. You should also note on the deposit slip the source of the deposit and keep copies of all slips.

You should make all payments by check to document business expenses. Write checks payable to yourself only when making withdrawals from your business for personal use. Avoid writing checks payable to cash. If you must write a check for cash to pay a business expense, include receipt for the cash payment in your records. If you cannot get a receipt for a cash payment, you should make an adequate explanation in your records at the time of payment.

Use the business account for business purposes only. Indicate the source of deposits and the type of expense in the checkbook.

How Long to Keep Records

You must keep your records as long as they may be needed for the administration of any provision of the Internal Revenue Code. Generally, this means you must keep records that support an item of income or deduction on a return until the period of limitations for that return runs out. The period of limitations is the period of time in which you can amend your return to claim a credit or refund, or the IRS can assess additional tax. Table 3 contains the periods of limitations that apply to income tax returns. Unless otherwise stated, the years refer to the period after the return was filed. Returns filed before the due date are treated as filed on the due date.

Keep copies of your filed tax returns. They help in preparing future tax returns and making computations if you file an amended return.

Employment taxes. If you have employees, you must keep all employment tax records for at least 4 years after the date the tax becomes due or is paid, whichever is later. For more information about recordkeeping for employment taxes, see Publication 15.

Assets. Keep records relating to property until the period of limitations expires for the year in which you dispose of the property in a taxable disposition. You must keep these records to figure any depreciation, amortization, or depletion deduction, and to figure your basis for computing gain or loss when you sell or otherwise dispose of the property.

Generally, if you received property in a nontaxable exchange, your basis in that property is the same as the basis of the property you gave up, increased by any money you paid. You must keep the records on the old property, as well as on the new property, until the period of limitations expires for the year in which you dispose of the new property in a taxable disposition.

Records for nontax purposes. When your records are no longer needed for tax purposes, do not discard them until you check to see if you have to keep them longer for other purposes. For example, your insurance company or creditors may require you to keep them longer than the IRS does.

Table 3: Period of Limitations	
IF you...	**THEN the period is...**
1. Owe additional tax and situations (2), (3), and (4), below, do not apply to you	3 years
2. Do not report income that you should report and it is more than 25% of the gross income shown on the return	6 years
3. File a fraudulent return	Not limited
4. Do not file a return	Not limited
5. File a claim for credit or refund after you filed your return	Later of: 3 years or 2 years after tax was paid
6. File a claim for a loss from worthless securities or a bad debt deduction	7 years

Independent Contractor or Employee

(from IRS Publication 1779)

Which are you?

For federal tax purposes, this is an important distinction. Worker classification affects how you pay your federal income tax, social security and Medicare taxes, and how you file your tax return. Classification affects your eligibility for social security and Medicare benefits, employer provided benefits and your tax responsibilities. If you aren't sure of your work status, you should find out now. This brochure can help you.

The courts have considered many facts in deciding whether a worker is an independent contractor or an employee. These relevant facts fall into three main categories: behavioral control; financial control; and relationship of the parties. In each case, it is very important to consider all the facts – no single fact provides the answer. Carefully review the following definitions.

Behavioral Control

These facts show whether there is a right to direct or control how the worker does the work. A worker is an employee when the business has the right to direct and control the worker. The business does not have to actually direct or control the way the work is done – as long as the employer has the right to direct and control the work. For example:

Instructions – if you receive extensive instructions on how work is to be done, this suggests that you are an employee. Instructions can cover a wide range of topics, for example:

- how, when, or where to do the work
- what tools or equipment to use
- what assistants to hire to help with the work
- where to purchase supplies and services

If you receive less extensive instructions about what should be done, but not how it should be done, you may be an independent contractor. For instance, instructions about time and place may be less important than directions on how the work is performed.

Training – if the business provides you with training about required procedures and methods, this indicates that the business wants the work done in a certain way, and this suggests that you may be an employee.

Financial Control

These facts show whether there is a right to direct or control the business part of the work. For example:

Significant Investment – if you have a significant investment in your work, you may be an independent contractor. While there is no precise dollar test, the investment must have substance. However, a significant investment is not necessary to be an independent contractor.

Expenses – if you are not reimbursed for some or all business expenses, then you may be an independent contractor, especially if your unreimbursed business expenses are high.

Opportunity for Profit or Loss – if you can realize a profit or incur a loss, this suggests that you are in business for yourself and that you may be an independent contractor.

Relationship of the Parties

These are facts that illustrate how the business and the worker perceive their relationship. For example:

Employee Benefits – if you receive benefits, such as insurance, pension, or paid leave, this is an indication that you may be an employee. If you do not receive benefits, however, you could be either an employee or an independent contractor.

Written Contracts – a written contract may show what both you and the business intend. This may be very significant if it is difficult, if not impossible, to determine status based on other facts.

When You Are an Employee...

- Your employer must withhold income tax and your portion of social security and Medicare taxes. Also, your employer is responsible for paying social security, Medicare, and unemployment (FUTA) taxes on your wages. Your employer must give you a Form W-2, Wage and Tax Statement, showing the amount of taxes withheld from your pay.
- You may deduct unreimbursed employee business expenses on Schedule A of your income tax return, but only if you itemize deductions and they total more than two percent of your adjusted gross income.

When You Are an Independent Contractor...

- The business may be required to give you Form 1099-MISC, Miscellaneous Income, to report what it has paid to you.
- You are responsible for paying your own income tax and self-employment tax (Self-Employment Contributions Act – SECA). The business does not withhold taxes from your pay. You may need to make estimated tax payments during the year to cover your tax liabilities.
- You may deduct business expenses on Schedule C of your income tax return.

Beauty Academy

North Carolina Esthetician 8 CE Hour Class Evaluation

Name of Student/Date: _____/_____

	Low				High	
Orientation was thorough and clear	1	2	3	4	5	
Organization of content	1	2	3	4	5	
Course objectives clearly stated	1	2	3	4	5	
Content was what I expected	1	2	3	4	5	
Satisfied with my learning experience	1	2	3	4	5	
Program met my needs	1	2	3	4	5	
Satisfied with customer service, if applicable	1	2	3	4	5	n/a

What suggestions do you have to improve this program, if any? _____

_____

_____

_____

_____

_____

Notes

PULL OUT SECTION

SECTION .0400—SANITATION PROCEDURES AND PRACTICES

21 NCAC 14H .0401—LICENSEES AND STUDENTS

(a) Notwithstanding Rule .0201 in this Subchapter, this Rule applies to licensees and students in practice in cosmetic art schools and shops. Each licensee and student shall wash his or her hands with soap and water or an equally effective cleansing agent immediately before and after serving each client.

(b) Each licensee and student shall wear clean garments and shoes while serving patrons.

(c) Licensees or students shall not use or possess in a cosmetic art school or shop any of the following:

(1) Methyl Methacrylate Liquid Monomer, a.k.a. MMA;

(2) razor-type callus shavers designed and intended to cut growths of skin including skin tags, corns, and calluses;

(3) FDA rated Class III devices;

(4) carbolic acid (phenol) over two percent strength;

(5) animals including insects, fish, amphibians, reptiles, birds, or non-human mammals to perform any service; or

(6) a variable speed electrical nail file on a natural nail unless it has been designed for use on a natural nail.

(d) A licensee or student shall not:

(1) use any product, implement, or piece of equipment in any manner other than the product's, implement's, or equipment's intended use as described or detailed by the manufacturer;

(2) treat any medical condition unless referred by a physician;

(3) provide any service unless trained prior to performing the service;

(4) perform services on a client if the licensee has reason to believe the client has any of the following:

(A) fungus, lice, or nits;

(B) an inflamed, infected, broken, raised, or swollen skin or nail tissue in the area to be worked on; or

(C) an open wound or sore in the area to be worked on;

(5) alter or duplicate a license issued by the Board;

(6) advertise or solicit clients in any form of communication in a manner that is false or misleading;

(7) use any FDA rated Class II device without the documented supervision of a licensed physician;

(8) use any product that will penetrate the dermis; or

(9) make any statement to a member of the public either verbally or in writing stating or implying action is required or forbidden by Board rules when such action is not required or forbidden by Board rules. A violation of this prohibition is considered practicing or attempting to practice by fraudulent misrepresentation.

(e) In using a disinfectant, the user shall wear any personal protective equipment, such as gloves, recommended by the manufacturer in the Material Safety Data Sheet.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; 88B-24; Eff. April 1, 2012; Amended Eff. August 1, 2014; March 1, 2013.

21 NCAC 14H .0402—COSMETIC ART SHOPS AND SCHOOLS

(a) Notwithstanding Rule .0201 in this Subchapter, this Rule applies to all cosmetic art schools and shops. A cosmetic art school or shop shall be kept clean.

(b) Waste material shall be kept in receptacles with a disposable liner. The area surrounding the waste receptacles shall be maintained in a sanitary manner.

(c) All doors and windows shall be kept clean.

(d) Furniture, equipment, floors, walls, ceilings and fixtures must be clean and in good repair.

(e) Animals or birds shall not be in a cosmetic art shop or school. Fish in an enclosure and animals trained for the purpose of accompanying disabled persons are exempt from the prohibition in this Paragraph.

(f) Cosmetic art shops and schools shall designate the entrance by a sign or lettering.

(g) The owner of a cosmetic art shop or school shall not post any sign that states or implies that some action is required or forbidden by Board rules when such action is not required or forbidden by Board rules. A violation of this prohibition is considered practicing or attempting to practice by fraudulent misrepresentation.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; 88B-24; Eff. April 1, 2012; Amended Eff. March 1, 2013.

21 NCAC 14H .0403—DISINFECTION PROCEDURES

(a) Sanitation rules which apply to towels and cloths are as follows:

(1) Clean protective capes, drapes, linens and towels shall be used for each patron;

(2) After a protective cape has been in contact with a patron's neck it shall be placed in a clean,

closed container until laundered with soap and hot water and dried in a heated dryer. Capes that cannot be laundered and dried in a heater dryer may be disinfected with an EPA registered hospital grade disinfectant mixed and used in accordance with the manufacturer directions; and

(3) After a drape, linen or towel has been in contact with a patron's skin it shall be placed in a clean, covered container until laundered with soap and hot water and dried in a heated dryer. A covered container may have an opening so soiled items may be dropped into the container.

(b) Any paper or nonwoven protective drape or covering shall be discarded after one us e.

(c) There shall be a supply of clean protective drapes, linens and towels at all times.

(d) Clean drapes, capes, linens, towels and all other supplies shall be stored in a clean area.

(e) Bathroom facilities must be kept cleaned.

(f) All implements shall be cleaned and disinfected after each use in the following manner:

(1) They shall be washed with warm water and a cleaning solution and scrubbed to remove debris and dried.

(2) They shall be disinfected in accordance with the following:

(A) EPA registered hospital/pseudomonacidal (bactericidal, virucidal, and fungicidal) or tuberculocidal that is mixed and used according to the manufacturer's directions. They shall be rinsed with hot tap water and dried with a clean towel before their next use. They shall be stored in a clean, closed cabinet or container until they are needed; or

(B) 1 and 1/3 cup of 5.25 percent household bleach to one gallon of water for 10 minutes. They shall be rinsed with hot tap water and dried with a clean towel before their next use. They shall be stored in a clean, closed cabinet or container until they are needed; or

(C) UV-C, ultraviolet germicidal irradiation used accordance with the manufacturer's directions.

(3) If the implement is not immersible or is not disinfected by UV-C irradiation, it shall be cleaned by wiping it with a clean cloth moistened or sprayed with a disinfectant EPA registered, hospital/pseudomonacidal (bactericidal, virucidal, and fungicidal) or tuberculocidal, used in accordance with the manufacturer's directions.

(4) Implements that come in contact with blood, shall be disinfected by:

(A) disinfectant, used in accordance with the manufacturer's instructions, that states the solution will destroy HIV, TB or HBV viruses and approved by the Federal Environmental Protection Agency; or

(B) EPA registered hospital/pseudomonacidal (bactericidal, virucidal, and fungicidal) and tuberculocidal that is mixed and used according to the manufacturer's directions; or

(C) household bleach in a 10 percent solution (1 and 2/3 cup of bleach to 1 gallon of water) for 10 minutes.

(g) All disinfected non-electrical implements shall be stored in a clean closed cabinet or clean closed container.

(h) All disinfected electrical implements shall be stored in a clean area.

(i) Disposable and porous implements and supplies must be discarded after use or upon completion of the service.

(j) Product that comes into contact with the patron must be discarded upon completion of the service.

(k) Clean, closable storage must be provided for all disinfected implements not in use. Containers with open faces may be covered/closed with plastic wrapping. Disinfected implements must be kept in a clean closed cabinet or clean closed container and must not be stored with any implement or item that has not been disinfected.

(l) Lancets, disposable razors, and other sharp objects shall be disposed in puncture-resistant containers.

(m) All creams, lotions, wax, cosmetics, and other products dispensed to come in contact with patron's skin must be kept in clean, closed containers, and must conform in all respects to the requirements of the Pure Food and Drug Law. Any product apportioned for use and removed from original containers must be distributed in a sanitary manner that prevents contamination of product or container. Any product dispensed in portions into another container must be dispensed into a sanitized container and applied to patrons by means of a disinfected or disposable implement or other sanitized methods. Any product dispensed in portions not dispensed into another container must be used immediately and applied to patrons by means of a disinfected or disposable implement or other sanitized methods. No product dispensed in portions may be returned to the original container.

(n) As used in this Rule whirlpool or footspa means any basin using circulating water.

(o) After use by each patron each whirlpool or footspa must be cleaned and disinfected as follows:

(1) All water must be drained and all debris removed from the basin;

(2) The basin must be disinfected by filling the basin with water and circulating:

(A) Two tablespoons of automatic dishwashing powder and 1/4 cup of 5.25 percent household bleach to one gallon of water through the unit for 10 minutes; or

(B) Surfactant or enzymatic soap with an EPA registered disinfectant with bactericidal, tuberculocidal, fungicidal and virucidal activity used according to manufacturer's instructions through the unit for 10 minutes;

(3) The basin must be drained and rinsed with clean water; and

(4) The basin must be wiped dry with a clean towel.

(p) At the end of the day each whirlpool or footspa must be cleaned and disinfected as follows:

(1) The screen must be removed and all debris trapped behind the screen removed;

(2) The screen and the inlet must be washed with surfactant or enzymatic soap or detergent and rinsed with clean water;

(3) Before replacing the screen one of the following procedures must be performed:

(A) The screen must be totally immersed in a household bleach solution of 1/4 cup of 5.25 percent household bleach to one gallon of water for 10 minutes; or

(B) The screen must be totally immersed in an EPA registered disinfectant with bactericidal tuberculocidal, fungicidal and virucidal activity in accordance to the manufacturer's instructions for 10 minutes;

(4) The inlet and area behind the screen must be cleaned with a brush and surfactant soap and water to remove all visible debris and residue; and

(5) The spa system must be flushed with low sudsing surfactant or enzymatic soap and warm water for at least 10 minutes and then rinsed and drained.

(q) Every week after cleaning and disinfecting pursuant to Paragraphs (a) and (b) of this Rule each whirlpool and footspa must be cleaned and disinfected in the following manner:

(1) The whirlpool or footspa basin must be filled with water and 1/4 cup of 5.25 percent household bleach for each one gallon of water or EPA registered disinfectant with bactericidal, tuberculocidal, fungicidal and virucidal activity in accordance to the manufacturer's instructions; and

(2) The whirlpool or footspa system must be flushed with the bleach and water or EPA registered disinfectant solution for 10 minutes and allowed to sit for at least six hours; and

(3) The whirlpool or footspa system must be drained and flushed with water before use by a patron.

(r) A record must be made of the date and time of each cleaning and disinfecting as required by this Rule including the date, time, reason and name of the staff member who performed the cleaning. This record must be made for each whirlpool or footspa and must be kept and made available for at least 90 days upon request by either a patron or inspector.

(s) The water in a vaporizer machine must be emptied daily and the unit disinfected daily after emptying.

(t) The area where services are performed that come in contact with the patron's skin including treatment chairs, treatment tables and beds shall be disinfected between patrons.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; Eff. April 1, 2012.

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(a) Each cosmetic art shop and school must have antiseptics, gloves or finger guards, sterile bandages and other necessary supplies available to provide first aid.

(b) If the skin of the licensee or student is punctured, the licensee or student shall immediately do the following:

(1) Apply antiseptic and a sterilized bandage;

(2) Disinfect any implement exposed to blood before proceeding; and

(3) Put on disposable, protective gloves or a finger guard.

(c) If the skin of the patron is punctured, the licensee or student shall immediately do the following:

(1) Make available to the patron antiseptic and a sterilized bandage;

(2) Disinfect any implement exposed to blood before proceeding; and

(3) Put on disposable, protective gloves or a finger guard.

History Note: Authority G.S. 88B-2; 88B-4; 88B-14; Eff. April 1, 2012.