Tattoo Ink and Permanent Makeup Labeling Guide

Association of Food and Drug Officials

Body Art Committee

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Introduction

The purpose of the Association of Food and Drug Officials – Body Art Committee Tattoo Ink and Permanent Makeup Labeling Guide is to assist with tattoo ink and/or permanent makeup labeling and answer questions about labeling requirements under the applicable regulations.

This document was created by the Association of Food and Drug Officials - Body Art Committee and as such, does not establish any legally enforceable responsibilities. Instead, this guide presents suggested information to include on tattoo ink or permanent makeup labels and other information that may be helpful to individuals and entities involved in the creation, use and regulation of tattoo ink or permanent makeup labels. Except when specific regulatory or statutory requirements are cited, the information presented in this document should be viewed only as recommendations by the Association of Food and Drug Officials - Body Art Committee.

Background

The inks used in intradermal tattoos, including permanent makeup, generally qualify as both "cosmetics" and "color additives." Under section 201(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 321(i)], the term "cosmetic" includes "articles intended to be . . . introduced into . . . the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance." Regulations that pertain specifically to cosmetics appear in Title 21 of the Code of Federal Regulations, Parts 700 (General), 701 (Cosmetic Labeling), 710 (Voluntary Registration of Cosmetic Product Establishments), 720 (Voluntary Filing of Cosmetic Product Ingredient Composition Statements), and 740 (Cosmetic Product Warning Statements). Under section 201(t) of the FD&C Act [21 U.S.C. § 321(t)], a "color additive" includes "a dye, pigment, or other substance . . . when added or applied to a . . . cosmetic, or to the human body or any part thereof, [that] is capable (alone or through reaction with other substance) of imparting color thereto." Color additives are subject to premarket approval under the Federal Food, Drug, and Cosmetic Act [see section 721 of the FD&C Act (21 U.S.C. § 379e)]. Regulations that pertain specifically, to color additives appear in Title 21 of the Code of Federal Regulations, Parts 70, 71, 73, 74, and 80. Cosmetic labels must also comply with the Fair Packaging and Labeling (FP&L) Act. Proper labeling helps consumers make informed decisions and helps public health officials investigate outbreaks.

Scope and Application

This guidance document is meant to assist industry, professionals, and regulators with compliance to U.S. laws and related regulations for tattoo ink or permanent makeup labeling of products in commercial distribution in the US. An additional checklist has been included at the end of this document to further assist in the assessment of the physical tattoo ink or permanent makeup label for required and suggested information.

Definitions

The following terms used in this document shall be defined as follows:

- **Adulterated** – A tattoo ink or permanent makeup that is contaminated, corrupted, debased, or made impure by the addition of a foreign or inferior substance or element.
- **Adverse Event –** Any health-related event associated with the use of a tattoo ink or permanent makeup that is adverse.
- **Batch** – A specific quantity of a tattoo ink or permanent makeup that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.
- **Body Art** – The application of tattooing and/or permanent makeup.
- **Body Artist or Practitioner** – Any person performing body art services whether licensed or not.
- **Color Additive –** A material which:
    - Is a dye, pigment, or other substance that is synthesized, extracted, isolated, or derived from a vegetable, animal, mineral, or other source.
    - When added or applied to a tattoo ink, permanent makeup or to the human body, it is capable of imparting color; unless the material is being used for something other than coloring.
    - The term "color" includes black, white, and intermediate grays.
- **Common Fractions –** A fraction that is expressed by a numerator and a denominator, not decimally. Examples: halves (1/2), quarters (1/4), eighths (1/8), sixteenths (1/16), or thirty-seconds (1/32).
- **Consumer Commodity –** A product customarily distributed for retail sale for use by consumers, including tattoo ink or permanent makeup.
- **Cosmetic –** A product and/or constituent raw ingredients, except soap, intended to be rubbed, poured, sprinkled, or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance.
- **Country of Origin –** The country in which tattoo ink or permanent makeup are formulated and or bottled.
- **Decimal Fractions –** The system of decimal numerical notation. A fraction whose denominator is a power of ten and the numerator is expressed by figures placed to the right of a decimal point.
- **Fair Packaging and Labeling Act –** Ensures 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 of 1938 –** Protects consumers from unsafe or deceptively labeled or packaged products by prohibiting the movement in interstate commerce or adulterated or misbranded food, drugs, devices, and cosmetics.
- **Incidental Ingredients –** Substances that have no technical or functional effect in the tattoo ink or permanent makeup but are present by reason of having been incorporated into the tattoo ink or permanent makeup as an ingredient of another tattoo ink or permanent makeup ingredient.
- **Information Panel –** Part of a label that is generally the back and side panels.

- **Intended Use –** The directed or prescribed use for a product determined from the statements made on a product's label or labeling.
- **Label –** Any display of written, printed, or graphic matter on the immediate package of any article, or any such matter affixed to any consumer commodity or affixed to or appearing on a package containing any consumer commodity.
- **Labeling –** All labels, inserts, risers, display packs, leaflets, promotional literature, or any other written, printed, or graphic information distributed with the product.
- **Lot** – A batch, or a specific identified portion of a batch, having uniform character and quality within specified limits; or a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits.
- **Lot Number, Control Number, or Batch Number** – Any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of product or other material can be determined.
- **Misbranded** – Label, labeling or package is misleading in any way.
- **Net quantity –** The weight or mass, measure, or numerical count.
- **Package** – Any container or wrapping, not including shipping containers or wrappings, in which any tattoo ink or permanent makeup, of any size, is enclosed for use in the delivery or to retail purchasers.
- **Permanent Makeup –** A tattoo, whether permanent, semi-permanent, or temporary, by someone other than a licensed physician, which includes but is not limited to eyebrows, eyelids, lips and other parts of the body for beauty marks, hair imitation, lash enhancement or areola repigmentation. This includes any procedures referred to as, but not limited to, "Permanent cosmetic", "microdermapigmentation", "micropigment implantation", "microblading", "dermagraphics", or "cosmetic tattooing" and for the purpose of these rules has the same meaning as "tattoo".
- **Principal Display Panel** – Part of a label that is most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for retail sale. Usually, it is the front panel of the label of the outer package, if there is an outer package.
- **Professional –** Licensed tattoo and/or permanent makeup artist.
- **Sterile –** A state of being free from viable microorganisms.
- **Tattoo/Tattooing –** Any method of placing ink or other pigment into or under the skin or mucosa by the use of needles or any other instruments used to puncture the skin, resulting in permanent or temporary colorization of the skin or mucosa. This includes all forms of permanent makeup.
- **Tattoo Ink –** A color additive (dye, pigment, lake, or other substance) combined with a carrier that is used in tattooing and permanent makeup.
- **Trade Secret** – 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.
- **Ultimate Purchaser** – The last U.S. person who will receive the goods in the form in which it was imported. If the goods are destined for a U.S. based processor where they will undergo a substantial transformation, then that processor or manufacturer is considered the ultimate purchaser.

- **Use By Date** – The date by which the label of a tattoo ink or permanent makeup states that the product must or should be used by.

Labeling Requirements

A label may consist of more than one panel. It may consist of a front panel, side panels, and a back panel. The following are requirements when creating a label, whether it is a principal display panel or an information panel (FP&L Act, 15 U.S.C. 1453).

- The size of each panel must be large enough to provide sufficient space for prominent display of the required information (21 CFR 701.2 (a)).
- The style and size of letters should be at least the required minimum size and be easily readable. The minimum size requirements are (21 CFR 701.2 (a)):

Section/Content of Labeling	**Font Size**
Ingredients	• 1/16 of an inch. • 1/32 of an inch. if labeling surface is less than 12 square inches
Net Contents	• 1/16 of an inch if principal display panel is less than 5 square inches. • 1/8 of an inch if principal display panel is between 5 and 25 square inches • 3/16 of an inch if principal display panel is between 25 and 100 square inches.
Warnings	• 1/16 of an inch.
All Others	• Reasonable related to panel size

- The background contrast must be sufficient to make the required label statements conspicuous and easily readable (21 CFR 701.2 (a)).
- The required statements must not be obscured by vignettes, other designs, or by crowding with other printed or graphic matter (21 CFR 701.2(a)).
- All words, statements, and other information required in the Federal Food, Drug, and Cosmetic Act should be on the label or labeling in English. If the label or labeling contains any representation in a foreign language, the required statements must also appear on the label or labeling in English (21 CFR 701.2 (b); Tariff Act of 1930, 19 U.S.C. 1304).

Principal Display Panel

The principal display panel is the part of the label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel needs to be large enough to accommodate all of the required label information (FP&L Act, 15 U.S.C. 1453; 21 CFR 701.2).

The information that must be on the principal display panel is:

- Product Name
- Identity
- Warning Statement for any Product with Unsubstantiated Safety (740.10 Warning)
- Declaration of Net Quantity of Contents.

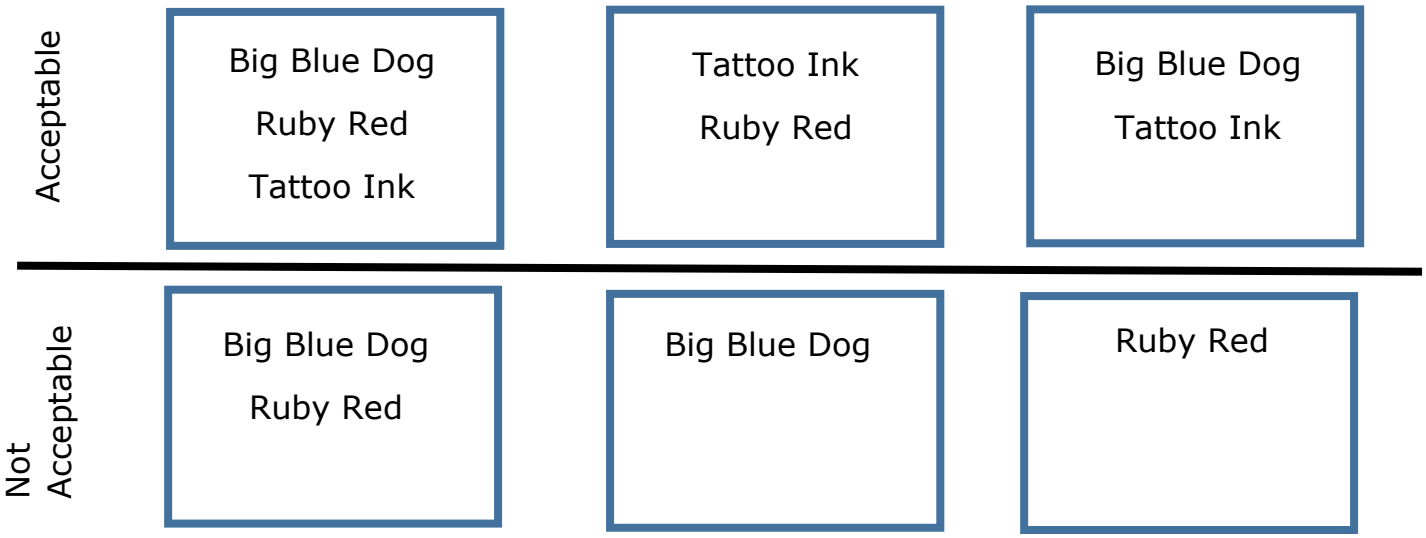
The area of the principal display panel should be:

- Rectangular package: one entire side (21 CFR 701.10 (a))
- Cylindrical or nearly cylindrical package: 40% of the height x circumference (21 CFR 701.10 (b))
- Any other shape of package: 40% of total package surface, excluding top, bottom, neck, shoulder, and flanges (21 CFR 701.10 (c))

Product Name

The common or usual name must be on the label (21 CFR 701.10). “Tattoo Ink” or “Permanent Makeup Ink” is an acceptable name. Having only the brand name without a description of the product, however, is not acceptable.

Examples (all examples are best practice):



Identity Labeling

The identity statement can be expressed in terms of the common or usual name, a descriptive name, or when the nature of the product is obvious, a fanciful name (FP&L Act 15 U.S.C. 1453). It may also be expressed in the form of an illustration.

The statement of identity should be in bold type on the principal display panel, a size reasonably related to the most prominent information on the panel, and in line parallel to the bottom of the package (21 CFR 701.11).

Warning Statement for any Product with Unsubstantiated Safety (740.10 Warning)

A tattoo ink or permanent makeup that's safety has not been adequately substantiated must have the following statement conspicuously placed on the principal display panel, or it is considered misbranded (FD&C Act Sec 602; 21 CFR 740.10):

Warning – The safety of this product has not been determined

This statement must be in bold type, on contrasting background, and may not be less than 1/16 of an inch in height (21 CFR 740.2).

The safety of a tattoo ink or permanent makeup 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 will not cause harm or injury to consumers when used under customary conditions (21 CFR 740.10 (b)).

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

Declaration of Net Quantity of Contents

The net quantity of contents should be separately and accurately stated in a uniform location within the bottom 30% of the label parallel to the base on which the package rests, using the most appropriate units of both the customary inch or pound system of measure and the SI metric system (FP&L Act, 15 U.S.C. 1453; 21 CFR 701.13).

The contents should be expressed in terms of weight, measure, numerical count, or a combination of numerical count and weight or measure (21 CFR 701.13).

The print must be legible, bold face type, and in distinct contrast to the background and other material on the label. The type size is determined by the area of the principal display panel.

Area of Principal Display Panel	**Font Size (minimum)**
Less than 5 square inches	At least 1/16 of an inch
Between 5 and 25 square inches	At least 1/8 of an inch
Between 25 and 100 square inches	At least 3/16 of an inch

If the product is in liquid form, the statement should be in terms of fluid measure. If the product is in solid, semisolid, viscous, or a mixture of solid and liquid, the statement should be in terms of weight (21 CFR 701.13).

Weight should be in terms of pounds and ounces while fluid measure should be in terms of US gallon and quarts, pint, and fluid ounce subdivisions. It should express the volume at 68 deg. F (20 deg. C) (21 CFR 701.13).

The declaration may contain common or decimal fractions which should be reduced to the lowest common terms (21 CFR 701.13).

The declaration should not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the tattoo ink or permanent makeup in the package; for example, "full quart" (FP&L Act, 15 U.S.C. 1453).

Examples (all examples are best practice):

- A declaration of 1 ½ pound weight should be expressed as "Net wt. 24 oz. (1 lb. 8 oz.)", "Net wt. 24 oz. (1 1/2 lb.)", or "Net wt. 24 oz. (1.5 lb.)"
- A declaration of three-fourths pound avoirdupois weight should be expressed as "Net wt. 12 oz."
- A declaration of 1-quart liquid measure should be expressed as "Net contents 32 fl. oz. (1 qt.)"
- A declaration of 1 ¾ quarts liquid measure should be expressed as "Net contents 56 fl. oz. (1 qt. 1 ½ pt.)" or "Net contents 56 fl. oz. (1 qt. 1 pt. 8 oz.)" but not in terms of quart and ounce such as "Net contents 56 fl. oz. (1 qt. 24 oz.)"

Information Panel

The information panel needs to be large enough to contain the mandatory information.

The information panel must include:

- The Directions for Safe Use
- Warnings (if any)
- Name and Place of Business
- Ingredient Declaration
- Any Other Information.

Directions for Safe Use

Adequate directions for safe use must be included (21 CFR 1.21).

Examples (all examples are best practice):

- "Shake well"
- "Do not dilute"
- "Ink should be kept within a defined temperature range (insert range) to ensure product integrity"

Warnings

The label of a tattoo ink or permanent makeup product should have a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product (21 CFR 740.1).

Examples (all examples are best practice):

- "This product may harmful to your health or may cause an allergic reaction."
- "Do not use on women who may be pregnant"
- "Keep out of reach of children"
- "Not to be reused – discard any leftover ink"
- "Ink should not be used if the seal is broken"

The warning statement(s) must appear on the label prominently and conspicuously as compared to other words, statements, or designs, so that it is likely to be read and understood by the consumer.

The lettering must be in bold type on contrasting background and in no case be less than 1/16 of an inch (21 CFR 740.2).

Name and Place of Business

The label in package form needs to have the name and place of business of either the manufacturer, packer, or distributor conspicuously (21 CFR 701.12). The purpose of this is so the consumer can identify and communicate with at least one of the three.

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 applicable wording.

The name of the firm must be the corporate name and the address of the principal place of business. The business address must include the street address, name of the city and state and zip code (21 CFR 701.12).

Imported products, including tattoo ink or permanent makeup that are formulated or bottled in another country, must have the country of origin declared in English on the label conspicuously. The purpose of this is so that the ultimate purchaser, body artist or practitioner knows the country of origin. The body artist or practitioner may or may not be the ultimate purchaser. (Tariff Act of 1930, 19 U.S.C. 1304)

Examples include "Made in China" and "Made in Mexico".

Ingredient Declaration

Declaration of ingredients except flavor, fragrance, and trade secret ingredients should be listed in descending order of predominance.

If one or more ingredients is accepted as exempt from public disclosure pursuant to the procedure established in 21 CFR 720.8 (a), instead of label declaration of identity the phrase "and other ingredients" may be used at the end of the ingredient declaration.

The declaration should be prominent and conspicuous, so it is easy to read (21 CFR 701.3). The minimum sizing should be:

- Letter height: 1/16 of an inch.
- Exceptions:
    - If total labeling surface area is less than 12 square inches: 1/32 of an inch.
    - Information panel: 1/32 of an inch.
    - Firmly affixed tag, tape, or card: 1/32 of an inch

A tattoo ink or permanent makeup ingredients should be identified in the declaration of ingredients by one of the following (21 CFR 701.3):

- The established name as specified in 701.30
- The name adopted for the ingredient as listed in:
    - PCPC-wICID (Web Based International Cosmetic Ingredient Dictionary and Handbook) https://www.personalcareconcil.org/member-industry-resources/winci-web-based-ingredient-dictionary
    - PCP-ICID (International Cosmetic Ingredient Dictionary and Handbook, 15th Ed. 2014)
    - CTFA (Cosmetic, Toiletry, and Fragrance Association, Inc.) Cosmetic Ingredient Dictionary
    - United States Pharmacopeia
    - National Formulary
    - Food Chemicals Codex
    - USAN and the USP dictionary of drug names
    - FDA Substance Registration System Nomenclature
- The name generally recognized by consumers.
- The chemical or other technical name or description.

As an alternative to listing all ingredients in descending order of predominance, ingredients may be grouped listed in the following manner (21 CFR 701.3):

- Ingredients, other than color additives, present at a concentration greater than 1%, in descending order of predominance; followed by
- Ingredients, other than color additives, present at a concentration of not more than 1%, without respect to order of predominance; followed by
- Color additives, without respect to order of predominance.
- Ingredients specified in the not more than 1% category may be included with those specified in the greater than 1% category of this section and listed in descending order of predominance.

When declaring colors, the name of the color should be identified in addition to the C.I. number, as to provide the most information to the consumer. In the ingredients declaration, if using the C.I. number, it shall follow the color name in parentheses, which can be seen in the examples below.

Examples (all examples are best practice):

Ingredients: Distilled Water (58), Glycerin (8), D&C Red No. 6 (C.I. 13578)(5), Titanium Dioxide (C.I. 77891)(4), Witch Hazel (3), D&C Orange No. 10 (C.I. 57887)(2)	Ingredients: Distilled Water, Glycerin, Witch Hazel, D&C Red No. 6 (C.I. 13578), Titanium Dioxide (C.I. 77891), D&C Orange No. 10 (C.I. 57887)

Color additives added sometimes for color matching are listed after the declaration of other color additives and after the phrase “May contain”.

Incidental ingredients that are present in a tattoo ink or permanent makeup at insignificant levels and that have no technical or functional effect in the tattoo ink or permanent makeup are not required to be declared on the label or labeling.

Other Suggested Information

Federal law does not require identification of a lot or batch. However, it is in best interest of the manufacturer to include a lot and/or batch number on the label. If a package does not contain a lot or batch number, then the entire production of that tattoo ink or permanent makeup would be considered a lot. For example, if there was a recall of a specific tattoo ink or permanent makeup, the entire lot would be subject to recall; if there is no lot number recorded, the entire production of that tattoo ink or permanent makeup would need to be recalled.

It is advised to limit the size of batches by assigning a lot number on a routine basis. This will allow the linking of adverse events to specific lots, therefore improving the investigation of adverse events as well as potentially limiting the amount of product affected.

Additionally, use by dates or date coding are not required by law but are recommended to be on the label because it is the responsibility of the manufacturer to make sure that the products are safe. Stability testing is recommended to establish use by dates.

Having a use by date:

- Is recommended if the product deteriorates over time, creating a possible safety issue.
- Can serve as a batch ID.
- Can decrease/prevent packages from being reused.

Placement of Information on Labels

Outer Package (or label if sold as a single bottle) as in a multilevel packaging configuration or set of tattoo inks or permanent makeup (21 CFR 701.10, 21 CFR 701.13).

Principal Display Panel	**Information Panels**
Name of Product	Directions for Safe Use
Identity	Warnings (if any)
740.10 Warning	Name and Place of Business
Net Quantity of Contents	Ingredient Declaration
	Other Suggested Information

An Inner Package (if packaged in an outer package) is an individual bottle of tattoo ink or permanent makeup that is part of a set. If tattoo ink or permanent makeup is sold as part of a set, then the individual bottles should state that they are not packaged for individual resale.

Front Panel	**Information Panels**
Name of Product	Directions for Safe Use
	Warnings (if any)
	Name and Place of Business
	Net Quantity of Contents
	Other Suggested Information

Exemptions from Labeling Requirements

A shipment or delivery of a tattoo ink or permanent makeup is exempt from labeling requirements during interstate commerce and time of holding if:

- The tattoo ink or permanent makeup in the shipment or delivery is going to be traded, processed, labeled, or repacked in substantial quantity at an establishment other than where originally processed or packed.

A shipment or delivery of a tattoo ink or permanent makeup is exempt from labeling requirements during interstate commerce and time of holding if the person who introduced the shipment or delivery into interstate commerce (21 CFR 701.9):

- Is the operator of the establishment where the tattoo ink or permanent makeup is going to be processed, labeled, or repacked.
- Is not the operator and there is a written agreement that:

- Is signed by both the person who introduced the shipment and the operator of the establishment
- Has the address of both parties
- Contains specifications for the processing, labeling, or repacking of the tattoo ink or permanent makeup in the establishment to ensure that the product will not be adulterated or misbranded during processing, labeling, or repacking.
- Is provided to both parties and retained for at least two years after the final shipment or delivery of the tattoo ink or permanent makeup from the establishment.

A shipment or delivery that is exempt from labeling requirements becomes invalid if (21 CFR 701.9):

- The tattoo ink or permanent makeup in the shipment or delivery is adulterated or misbranded when removed.
- The person who introduced the shipment or delivery into the interstate commerce refuses to make a copy of the required agreement available for inspection.

Professional Use Labeling

Tattoo ink or permanent makeup that is marketed solely for use by professionals may say "for professional use only" on the label. If the ink is only sold to and used by professionals, then it is exempt from having the ingredient declaration on the label. However, if the tattoo ink or permanent makeup is also made available for sale and use to non-professionals in any way, it is no longer exempt, and it must contain the ingredient declaration on the label (FP&L Act).

Misbranding

A tattoo ink or permanent makeup is considered misbranded if the labeling (FD&C Act, Sec 602):

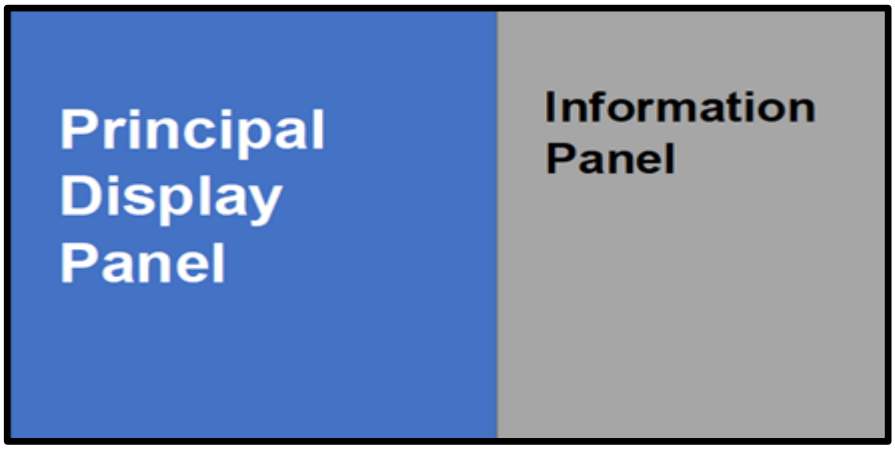
- Is false or misleading.
- Has a false or misleading representation with respect to another cosmetic or a food, drug, or device.
- Does not include the name and place of business of the manufacturer, packer, or distributor.
- Does not include an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.
- Does not have all of the required information on the label or labeling in a way that it can be understood by the ordinary individual under customary conditions of purchase and use.
- Of the package is misleading.
- Or packaging is in violation of an applicable regulation.

Labeling of a tattoo ink or permanent makeup shall be deemed to be misleading if it has a label that is deceptive or has a material fact that is not revealed on the label.

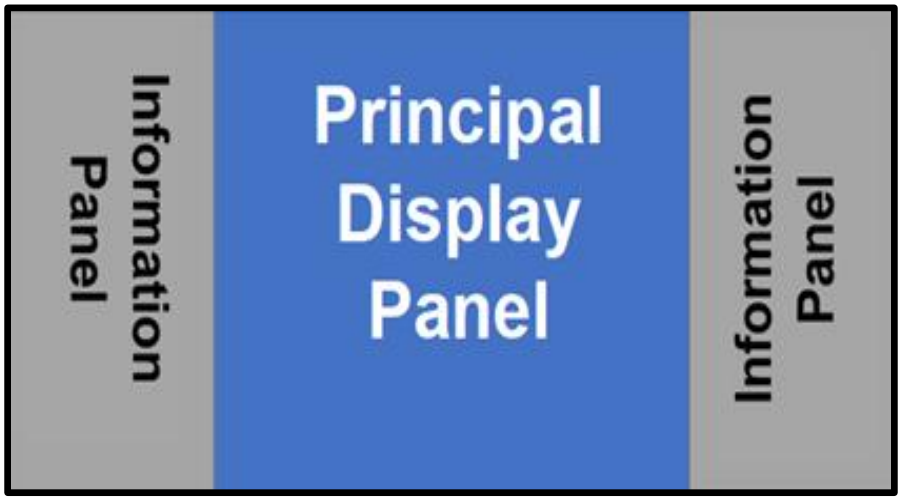
Examples of Labels

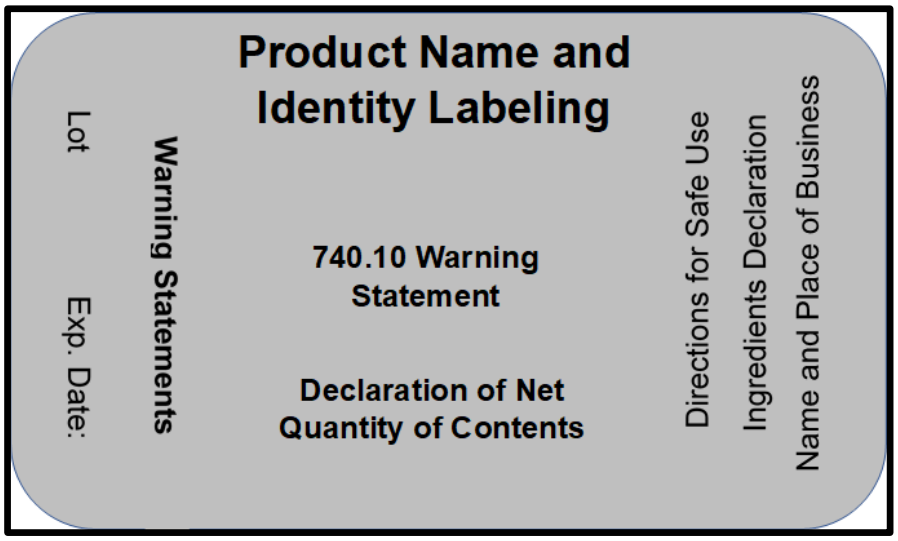
These example labels are best practice examples.

Label Layout Example 1



Label Layout Example 2





Appendix I – Checklist

General Label Requirements		
Compliance (Y/N)	**Citation**	**Description/Notes**
	21 CFR 701.2	**General Labeling Requirements**
	a(1)	All required information is on the label and is displayed under customary conditions of purchase.
	a(2), a(3), a(4), a(5)	Label is large enough for all required information.
	a(6)	Style and size of letters is at least the minimum size and is easily readable. (Size requirements listed in each section).
	a(6)	Background contrast allows for label statements to be conspicuous and easily readable.
	a(6)	Required statements are not obscured by vignettes, other design, or by crowding with other printed or graphic matter.
	b	All words, statements, and other required information must be on the label and labeling in English.

Principal Display Panel Requirements		
Compliance (Y/N)	**Citation**	**Description/Notes**
	21 CFR 701.10	**Principal Display Panel Size**
	a	Rectangle package: principal display is one entire side.
	b	Cylindrical/nearly cylindrical package: principal display panel is 40% of the height x circumference.
	c	Any other shaped package: principal display panel is 40% of the total container surface (excluding top, bottom, neck, shoulder, and flanges).

Compliance (Y/N)	Citation	Description/Notes
	21 CFR 701.11	**Identity Labeling**
	a	On the principal display panel.
	b	In terms of the common name/usual name/descriptive name.
	c	In bold type.
	c	Letter size is reasonably related to the most prominent information on the panel.
	c	In line and parallel to the bottom of the package.
	21 CFR 740.10	**Warning Statement for any Product with Unsubstantiated Safety**
	a	Has safety been substantiated for cosmetic use for every ingredient? If not, then this statement is on the principal display panel: "Warning – The safety of this product has not been determined".
	21 CFR 740.2	**Conspicuousness of Warning Statements**
	a	In bold type.
	a	Letter size is at least 1/16 of an inch in height.
	21 CFR 701.13	**Declaration of Net Quantity of Contents**
	a	Expressed in terms of weight, measure, numerical count, or a combination of numerical count and weight or measure.
	a	Cosmetic in liquid form? Statement is in terms of fluid measure.
	a	Cosmetic is solid/semisolid/viscous/mixture? Statement is in terms of weight.

Compliance (Y/N)	Citation	Description/Notes
	21 CFR 701.13	**Declaration of Net Quantity of Contents**
	b	Statement in weight? Statement in terms of avoirdupois pound and ounce.
	b	Statement in fluid measure? Statement in terms of the U.S. gallon and quart, pint, and fluid ounce.
	d	Common fractions being used? Reduced to lowest terms.
	d	Decimal fraction being used? No more than two decimal places.
	e	Located on the principal display panel(s).
	f	Appears as a distinct item and is separated from other printed label information.
	f	Does not include any terms that exaggerate the amount in the container. Ex: “full quart”.
	f	Within the bottom 30 percent of the label.
	f	In line and parallel to the base on which the package rests.
	g	Accurately reveals the quantity in the package.
	h	In bold type.
	i(1)	Label size less than 5 sq. inches? Letter size at least 1/16 of an inch in height.
	i(2)	Label size between 5 and 25 sq. inches? Letter size at least 1/8 of an inch in height.
	i(3)	Label size between 25 and 100 sq. inches? Letter size at least 3/16 of an inch in height.
	i(4)	Label size more than 100 sq. inches? Letter size at least 1/4 of an inch in height.

Information Panel Requirements		
Compliance (Y/N)	**Citation**	**Description/Notes**
	21 CFR 1.21	**Failure to Reveal Material Facts/Directions for Safe Use**
	a(2)	Has statement(s) about what can happen when using product. Ex. Directions for safe use.
	21 CFR 740.1	**Establishment of Warning Statements**
	a	Has a warning statement to prevent a health hazard that may be associated with the product.
	21 CFR 740.2	**Conspicuousness of Warning Statements**
	a	In bold type.
	a	Letter size is at least 1/16 of an inch in height.
	21 CFR 701.12	**Name and Place of Business of Manufacturer, Packer, or Distributor**
	a	Specifies the name and place of business of the manufacturer, packer or distributor.
	b	Is the manufacturer, packer or distributor a corporation? Use actual corporate name. The name of the particular division can go before or behind the corporate name.
	b	Is the manufacturer an individual, partnership, or association? Use the name under which the business is conducted.
	c	Using a name different than the person who manufactured the product? Have qualifying statement revealing connection. Ex. "Manufactured for _____", "Distributed by _____", or any other wording that expresses the facts.

Compliance (Y/N)	Citation	Description/Notes
	21 CFR 701.12	**Name and Place of Business of Manufacturer, Packer, or Distributor**
	d	Street address (unless in a current city directory or telephone directory).
	d	City.
	d	State.
	d	Zip code.
	21 CFR 701.3	**Designation of Ingredients**
	a	States the name of each ingredient in descending order of predominance (fragrance or flavor may be listed as fragrance or flavor).
	b	Letter size is at least 1/16 of an inch in height.
	c	Ingredients are identified by one of the following: 1. The established name as specified in 701.30. 2. The name adopted for the ingredient as listed in: a. PCPC-wICID (Web Based International Cosmetic Ingredient Dictionary and Handbook). b. PCP-ICID (International Cosmetic Ingredient Dictionary and Handbook). c. CTFA (Cosmetic, Toiletry, and Fragrance Association Inc.) Cosmetic Ingredient Dictionary. d. United States Pharmacopeia. e. National Formulary. f. Food Chemicals Codex. g. USAN and the USP dictionary of drugs. h. FDA Substance Registration System Nomenclature. 3. The name generally recognized by consumers. 4. The chemical or other technical name or description. *Color is declared using the color name in addition to the C.I. number.

Compliance (Y/N)	Citation	Description/Notes
	21 CFR 701.3	**Designation of Ingredients**
	f	Instead of listing ingredients in descending order of predominance, ingredients can be listed as follows: 1. Ingredients (other than color additives) present at a concentration greater than 1% in descending order of predominance. 2. Ingredients (other than color additives) present at a concentration of less than 1 % without respect to order predominance. 3. Color additives without respect to order predominance.
	g	Have a color additive that was added for color matching purposes? Include with the phrase "may contain" after the declaration of other color additives.
*Reference to a website for designation of ingredients does not satisfy labeling requirements. *		

Label Content Exempt if "For Professional Use Only"	
	Ingredient Declaration but only if not sold at retail.

Suggested Best Practice Content	
	Lot and/or batch number.
	Use by date.

Suggested Best Practice Examples	
Directions for Safe Use:	
	Shake well.
	Do not dilute.
	Ink should be kept within a defined stability range (insert range) to ensure product integrity.
Warnings:	
	This product may be harmful to your health or may cause an allergic reaction.
	Do not use on women who may be pregnant.
	Keep out of reach of children.
	Not to be reused – discard any leftover ink.
	Ink should not be used if the original seal is broken.

References

Code of Federal Regulations Title 21. Retrieved from https://www.ecfr.gov/cgi-bin/text-idx?SID=3ee286332416f26a91d9e6d786a604ab&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl

Fair Packaging and Labeling Act. Retrieved from https://www.ftc.gov/enforcement/rules/rulemaking-regulatory-reform-proceedings/fair-packaging-labeling-act

Federal Food, Drug, and Cosmetic Act of 1938. Retrieved from https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/FederalFoodDrugandCosmeticActFDCAct/default.htm

Food & Drug Administration (FDA) Cosmetic Labeling Guide. Retrieved from https://www.fda.gov/downloads/Cosmetics/Labeling/UCM391202.pdf

Tariff Act of 1930. Retrieved from https://www.law.cornell.edu/uscode/text/19/chapter-4