

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

Small Businesses & Homemade Cosmetics: Fact Sheet

The questions and answers below are based on questions we frequently receive from people who are new to the cosmetics business, and our responses to them. This information is intended to help you get started. We've also included links for learning more on each topic. Before you send a question to FDA, please check here. You may find the answer.

1. Does FDA regulate cosmetics?

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1. Does FDA regulate cosmetics?

Yes. FDA regulates cosmetics under the [Federal Food, Drug and Cosmetic Act \(FD&C Act\) \(/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/FDCAActChapterVICosmetics/ucm2016708.htm\)](http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/FDCAActChapterVICosmetics/ucm2016708.htm). Under this law, cosmetics must not be adulterated or misbranded. For example, they must be safe for consumers under labeled or customary conditions

of use, and they must be properly labeled. Any color additives they contain must be approved for the intended use, and some must be from batches certified in FDA's own labs. Packaging and labeling must not be deceptive. If you manufacture or market cosmetics, you have a legal responsibility for the safety and labeling of your products.

If your cosmetics are marketed to consumers on a retail basis, such as in stores, or by mail order (including online), or by personal sales representatives (for example, door-to-door sales), they also must meet ingredient labeling requirements under the [Fair Packaging and Labeling Act \(/RegulatoryInformation/Legislation/ucm148722.htm\)](#).

To learn more, see "[Resources for You: Industry \(/Cosmetics/ResourcesForYou/Industry/ucm2005224.htm\)](#)" and "[Cosmetics: Guidance and Regulations \(/Cosmetics/GuidanceRegulation/ucm2005160.htm\)](#)," where you will find overviews of the laws, links to the laws and regulations themselves, and more.

2. Do I need to have my cosmetic products or ingredients approved by FDA?

The law does not require cosmetic products and ingredients, except for [color additives \(/For-Industry/ColorAdditives/ColorAdditivesinSpecificProducts/InCosmetics/ucm110032.htm\)](#), to be approved by FDA before they go on the market. However, cosmetics must not be adulterated or misbranded. This means that they must be safe for consumers when used according to the labeling, or as people customarily use them, and they must be properly labeled. To learn more, see [Key Legal Concepts: Interstate Commerce, Adulterated, and Misbranded \(/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074248.htm\)](#).

With the exception of color additives and [ingredients that are prohibited or restricted by FDA regulations \(/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm\)](#), you may use any ingredient in your cosmetic, as long as it does not cause the product to be adulterated in any way. You are legally responsible for making sure your cosmetics are safe and properly labeled, in compliance with all the laws and regulations that apply to them.

Remember, however, that not all "personal care products" are regulated as cosmetics under U.S. law. For example, some are regulated as drugs. If your product is a drug under U.S. law, it must meet the requirements for drugs, such as premarket approval.

3. How do I know if my products are regulated as cosmetics, and not as drugs or some other product category?

A product's intended use is determined by factors such as claims made for the product, consumer expectations, and certain ingredients. A product is a cosmetic if it is intended for uses such as cleansing the human body, making a person more attractive, or changing a person's appearance. Here are some examples of products marketed as cosmetics:

- Makeup
- Moisturizers
- Hair dyes, permanent waves, straighteners, and removers
- Perfumes and colognes
- Nail care products

If a product is intended to affect the way a person's body works, or to treat or prevent disease, it's a drug, but sometimes it is both a cosmetic and a drug depending on its claims. Drugs must meet different requirements.

Some "personal care products" are regulated by FDA as medical devices or as dietary supplements, while others, including some soaps, are regulated by the Consumer Product Safety Commission. Here are some resources to help you learn more:

- [Aromatherapy \(/Cosmetics/ProductsIngredients/Products/ucm127054.htm\)](http://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm127054.htm)
- [Consumer Product Safety Commission \(http://www.cpsc.gov/\)](http://www.cpsc.gov/)
- ["Cosmeceutical \(/Cosmetics/Labeling/Claims/ucm127064.htm\)"](http://www.fda.gov/Cosmetics/Labeling/Claims/ucm127064.htm)
- [Cosmetics Q&A: Personal Care Products \(/Cosmetics/ResourcesForYou/Consumers/ucm136560.htm\)](http://www.fda.gov/Cosmetics/ResourcesForYou/Consumers/ucm136560.htm)
- [Dietary Supplements \(/Food/DietarySupplements/ucm2006892.htm\)](http://www.fda.gov/Food/DietarySupplements/ucm2006892.htm)
- [Is It a Cosmetic, a Drug, or Both? \(Or Is It Soap?\) \(/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm\)](http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm): To learn more about these product categories, including how FDA determines a product's intended use.
- [Soap \(/Cosmetics/ProductsIngredients/Products/ucm115449.htm\)](http://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm115449.htm)
- [Warning Letters Highlight Differences Between Cosmetics and Medical Devices \(/Cosmetics/ComplianceEnforcement/WarningLetters/ucm081141.htm\)](http://www.fda.gov/Cosmetics/ComplianceEnforcement/WarningLetters/ucm081141.htm)

4. What do I need to know about using color additives in cosmetics?

A color additive, other than coloring materials intended for use as coal-tar hair dyes, must be approved by FDA for the intended use. These are listed in regulations called "listing regulations." Some may be used only if they are from batches certified in FDA's own labs. Here are some resources to help you learn more:

- [Color Additives and Cosmetics \(/ForIndustry/ColorAdditives/ColorAdditivesinSpecificProducts/InCosmetics/ucm110032.htm\)](http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditivesinSpecificProducts/InCosmetics/ucm110032.htm) — An overview
- [Color Additives Permitted for Use in Cosmetics \(/Cosmetics/Labeling/IngredientNames/ucm109084.htm\)](http://www.fda.gov/Cosmetics/Labeling/IngredientNames/ucm109084.htm) — A quick-reference table, with links to the listing regulation for each of these color additives
- [Color Additive Regulations \(/Cosmetics/Labeling/IngredientNames/ucm109084.htm\)](http://www.fda.gov/Cosmetics/Labeling/IngredientNames/ucm109084.htm) — For links to the color additive regulations themselves

5. Do I need to register my cosmetic firm or product formulations with FDA?

FDA encourages both domestic and foreign cosmetic firms to register their establishments and file their product formulations with our Voluntary Cosmetic Registration Program (VCRP), but participation in this program is voluntary. Participating in the VCRP does not indicate FDA approval, and no registration number is required to import cosmetics into the United States. In fact, the VCRP will only accept information on cosmetics that are already on the market in this country.

If, however, your products are drugs, or both cosmetics and drugs, they must meet the requirements for drug registration. Similarly, importers of cosmetic ingredients that are also classified as food products must meet the registration requirements of the **[Bioterrorism Act of 2002 \(/RegulatoryInformation/Legislation/ucm148797.htm\)](#)**.

6. Can I manufacture cosmetics in my home or salon?

It's not against the law to manufacture cosmetics in your home. Keep in mind, however, that it's your responsibility to manufacture products in an environment that will not cause them to become adulterated.

FDA does not have regulations specifying good manufacturing practices (GMP) for cosmetics. However, "**[Good Manufacturing Practice \(GMP\) Guidelines/Inspection Checklist \(/Cosmetics/GuidanceRegulation/GuidanceDocuments/ucm2005190.htm\)](#)**" is a list of factors an FDA investigator will look at during an inspection. We have posted this list of GMP guidelines to alert firms to some factors to keep in mind when planning their manufacturing conditions and procedures. Even if you are manufacturing your products in your home or salon, these guidelines will help you keep your process and your products safe.

Here are some of the ways in which a cosmetic can become adulterated:

- Color additive violations: Misuse of color additives makes a product adulterated.
- Prohibited and restricted ingredients: Violating the restrictions on the use of these substances makes a cosmetic adulterated.
- Packaging: The composition of its container may make the contents "injurious to health."
- Microbial contamination: Cosmetics are not required to be sterile, but microbial contamination can pose a health hazard, making a product adulterated. (See "How must I test my products and ingredients?")
- Other contaminants: Unwanted substances from a number of sources may adulterate a product.
- Any other problem that could make the product unsafe for consumers when they use it according to directions on the label, or as it is customarily used. (See the **[FD&C Act, Section 601 \(/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAAct/ChapterVICosmetics/ucm2016708.htm\)](#)**)

7. Can I label my cosmetics "natural" or "organic"?

The same requirements for safety and labeling apply to all cosmetics, no matter what their source. This includes, for example, making sure that all your labeling is truthful and not misleading.

FDA has not defined the term "natural" and has not established a regulatory definition for this term in cosmetic labeling.

FDA also does not have regulations for the term "organic" for cosmetics. The U.S. Department of Agriculture (USDA) regulates the use of the term "organic" for agricultural products under the National Organic Program (NOP). If you have questions about the use of the term "organic," contact **[USDA \(http://www.ams.usda.gov/AMSV1.0/nop\)](http://www.ams.usda.gov/AMSV1.0/nop)**. Answers to some common questions about "organic" cosmetics are available on our website under "**['Organic' Cosmetics \(/Cosmetics/Labeling/Claims/ucm203078.htm\)](#)**."

Don't use terms such as "natural" as part of an ingredient statement, because ingredients must be listed by their common or usual names, without additional description.

And remember, choosing ingredients from sources you consider "organic" or "natural" is no guarantee that they are safe. You are still responsible for making sure your ingredients are safe when used according to the labeling, or as they are customarily used, no matter what kinds of ingredients you use.

8. Must I test my products and ingredients?

FDA does not have a list of tests required for any particular cosmetic product or ingredient, but you are responsible for ensuring that your product is safe when it is used according to labeled directions, or in the way it is customarily used.

Newcomers to cosmetic manufacture sometimes think that because they have used a product themselves with no apparent problems, or because the ingredients are "natural," "organic," or "botanical," the product must be safe. This assumption is not correct.

9. Using available safety data

You can use safety data that's already available on individual ingredients and on products whose formulations are similar to yours. Here are some examples:

- Cosmetic ingredient suppliers often have safety data on their products.
- Safety data may be published in scientific journals (sources include PubMed, at <http://www.ncbi.nlm.nih.gov/pubmed>, and TOXNET, at <http://toxnet.nlm.nih.gov/>).

The **Cosmetic Ingredient Review** (<http://www.cir-safety.org/ingredients>) (CIR) website has information on the safety of cosmetic ingredients that they have reviewed. (CIR is an industry-funded panel of scientific and medical experts who review the safety of cosmetic ingredients. FDA participates in CIR meetings, but does not vote, and we may agree or disagree with CIR conclusions. However, we do take CIR reviews into consideration when we evaluate cosmetic ingredient safety.)

10. Doing additional testing

You may also need to do toxicological testing to fill in any gaps in the information that's available. Toxicology or other testing methods may be necessary to determine the safety of each ingredient and the finished product. Animal testing is not a specific requirement for marketing a cosmetic; however, whatever testing you rely on should be scientifically sound.

As a government agency, FDA does not provide referrals for private testing labs. However, you may find useful resources under "**Trade and Professional Associations of Interest to the Cosmetics Industry** ([/Cosmetics/ResourcesForYou/Industry/ucm077669.htm](http://www.fda.gov/Cosmetics/ResourcesForYou/Industry/ucm077669.htm))."

And don't forget microbiological safety. Cosmetics do not have to be sterile, but they must not contain any harmful microorganisms, and the number of aerobic microorganisms per gram must be low. To learn more, see "**Microbiological Methods for Cosmetics** ([/Food/FoodScienceResearch/LaboratoryMethods/ucm073598.htm](http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm073598.htm))."

Many factors can affect how your product may become contaminated, including use by consumers, such as dipping one's fingers into a jar. If you do not have the technical expertise to determine the best way to ensure that your product is protected from contamination, you may want to work with a consultant.

For more information on substantiating the safety of cosmetics, see "[Product Testing \(/Cosmetics/ScienceResearch/ProductTesting/ucm2005153.htm\)](http://www.fda.gov/Cosmetics/ScienceResearch/ProductTesting/ucm2005153.htm)."

11. Can I use a Post Office (P.O.) box or website for the address on the label?

A post office box or website address is not adequate for this labeling requirement.

The FD&C Act requires cosmetic labels to identify the name and place of business of the manufacturer, packer, or distributor. By regulation, this includes the street address, city, state, and ZIP code, although you may omit the street address if your firm is listed in a current city or telephone directory. You may use the main place of business instead of the actual place where the cosmetic was manufactured, packed, or distributed, unless such a statement would be misleading.

If you use the distributor's address, you must use a phrase such as "Distributed by" or "Manufactured for," followed by that firm's name and place of business. The name of the firm must be the corporate name. See the regulation on name and place of business at [21 CFR 701.12 \(http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=79073513f7ba6a05126c6da0aa85c460&r=PART&n=21y7.0.1.2.11.3.1.1\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=79073513f7ba6a05126c6da0aa85c460&r=PART&n=21y7.0.1.2.11.3.1.1).

12. Where can I learn more about labeling requirements?

We can respond to specific labeling questions, but cosmetic labeling is not subject to premarket approval by FDA. It's your responsibility to make sure your labeling meets all requirements.

Here are some useful resources:

- [Cosmetic Labeling and Label Claims \(/Cosmetics/Labeling/Claims/UCM2005200.htm\)](http://www.fda.gov/Cosmetics/Labeling/Claims/UCM2005200.htm): An overview to help you get started
- [Cosmetic Labeling Guide \(/Cosmetics/Labeling/Regulations/ucm126444.htm\)](http://www.fda.gov/Cosmetics/Labeling/Regulations/ucm126444.htm): For step-by-step help that answers many common questions
- [Cosmetic Labeling Regulations \(/Cosmetics/Labeling/Regulations/ucm126440.htm\)](http://www.fda.gov/Cosmetics/Labeling/Regulations/ucm126440.htm): For links to the full text of the regulations that apply to cosmetic labeling

Some cosmetic labeling requirements are regulated by other federal agencies. For example, the [U.S. Federal Trade Commission \(http://www.ftc.gov/\)](http://www.ftc.gov/) regulates claims of "Made in USA." Other country of origin labeling is regulated by [U.S. Customs and Border Protection \(http://www.cbp.gov/\)](http://www.cbp.gov/) (see "Chapter 13-Country of Origin Marking").

You may wish to work with a labeling consultant. FDA, as a government agency, does not provide referrals to private consultants. You may, however, find useful resources under "[Trade and Professional Associations of Interest to the Cosmetic Industry \(/Cosmetics/ResourcesForYou/Industry/ucm077669.htm\)](http://www.fda.gov/Cosmetics/ResourcesForYou/Industry/ucm077669.htm)" and "[Cosmetic Trade Publications \(/Cosmetics/ResourcesForYou/Industry/ucm077674.htm\)](http://www.fda.gov/Cosmetics/ResourcesForYou/Industry/ucm077674.htm)."

13. What local requirements are there for starting a cosmetics business?

You will need to contact your state and local authorities for that information. The **Small Business Administration (<http://www.sba.com/>)** also can help.

14. Do I need to get a license from FDA to manufacture or market cosmetics?

FDA does not license cosmetics firms. However, state or local authorities may require licensing or have other requirements you need to know about. You will need to contact your state or local authorities directly. Again, the **Small Business Administration (<http://www.sba.com/>)** may be able to help.

15. Where can I find more information on FDA requirements I need to know about?

See "**Resources for You: Industry ([/Cosmetics/ResourcesForYou/Industry/ucm2005224.htm](http://www.fda.gov/Cosmetics/ResourcesForYou/Industry/ucm2005224.htm))**" for a list of resources for members of the cosmetics industry, large and small. You will find information on labeling, color additives, imports, exports, other agencies you need to know about, links to the laws and regulations, and more.

<p>Resources for You More in Industry (/Cosmetics/ResourcesForYou/Industry/default.htm) <ul style="list-style-type: none"> • Get Email Updates (/AboutFDA/ContactFDA/default.htm) </p>
<p>Go to the FDA Consumer Information Site: /Cosmetics/ResourcesForYou/Industry/ucm435978.htm (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)</p>
<p>Importers & Exporters: Fact Sheet (/Cosmetics/ResourcesForYou/Industry/ucm388732.htm)</p>
<p>Salon Professionals: Fact Sheet (/Cosmetics/ResourcesForYou/Industry/ucm388738.htm)</p>
<p>▶ Small Businesses & Homemade Cosmetics: Fact Sheet (/Cosmetics/ResourcesForYou/Industry/ucm388736.htm)</p>