Michael O'Grady 3/14/16

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

Soap: FAQs

FDA often receives questions from soap makers about how their products are regulated. Here is information to help small-scale soap producers understand the laws and regulations they need to know about.

How are traditional soaps and synthetic detergents different?

Ordinary soap is made by combining fats or oils and an alkali, such as lye. The fats and oils, which may be from animal, vegetable, or mineral sources, are degraded into free fatty acids, which then combine with the alkali to form crude soap. The lye reacts with the oils, turning what starts out as liquid into blocks of soap. When made properly, no lye remains in the finished product. In the past, people commonly made their own soap using animal fats and lye that had been extracted from wood ashes.

Today there are very few true soaps on the market. Most body cleansers, both liquid and solid, are actually synthetic detergent products. Detergent cleansers are popular because they make suds easily in water and don't form gummy deposits. Some of these detergent products are actually marketed as "soap" but are not true soap according to the regulatory definition of the word.

What's the regulatory definition of soap?

Whether a product is a "soap" in the traditional sense, or is really a synthetic detergent, helps determine how the product is regulated. So, let's take a look at how "soap" is defined in FDA's regulations;

To meet the definition of soap in FDA's regulations, a product has to meet three conditions:

1. **What it's made of**: To be regulated as "soap," the product must be composed mainly of the "alkali salts of fatty acids," that is, the material you get when you combine fats or oils with an alkali, such as lye.
2. **What ingredients cause its cleaning action:** To be regulated as "soap," those "alkali salts of fatty acids" must be the only material that results in the product's cleaning action. If the product contains synthetic detergents, it's a cosmetic, not a soap. You still can use the word "soap" on the label.
3. **How it's intended to be used**: To be regulated as soap, it must be labeled and marketed only for use as soap. If it is intended for purposes such as moisturizing the skin, making the user smell nice, or deodorizing the user's body, it's a cosmetic. Or, if the product is intended to treat or prevent disease, such as by killing germs, or treating skin conditions, such as acne or eczema, it's a drug. You still can use the word "soap" on the label.

You can read the entire regulation at **21 CFR 701.20 (http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr;sid=f5791fef5cbf087716dfdc085c835078;rgn=div6;view=text;node=21%3A7.0.1.2.11.3;idno=21;cc=ecfr)**.

How are different "soap" products regulated?

- **If your product meets the regulatory definition of soap**, it's regulated by the **Consumer Product Safety Commission (http://www.cpsc.gov)** (CPSC), not by FDA. Please direct questions about requirements for these products to CPSC.
- **If it's a cosmetic,** it's regulated by FDA. Neither the product nor its ingredients need approval by FDA, except for any color additives it contains. It is your responsibility to make sure your product is safe for consumers when it is used as intended, and to make sure it is properly labeled. You don't need to register your company or file your product formulations with FDA, although we do encourage you to participate in our **Voluntary Cosmetic Registration Program (/Cosmetics/RegistrationProgram/default.htm)**. To learn more, see "**Fact Sheet for Small Businesses and Homemade Cosmetics (/Cosmetics/ResourcesForYou/Industry/ucm388736.htm)**," and the resources listed on that page.
- **If it's a drug**, it's regulated by FDA. It must comply with the regulations (called "monographs") for certain categories of non-prescription drugs or requirements for new drug approval or. You will need to register your firm and list your products with FDA. For more information, you can contact FDA's Center for Drug Evaluation and Research (CDER), Division of Drug Information, Small Business Assistance, at **CDERSmallBusiness@fda.hhs.gov (mailto:CDERSmallBusiness@fda.hhs.gov)**.
- **If it's both a cosmetic and a drug**, it must meet the requirements for both cosmetics and drugs. To learn more, see "**Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?) (/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm)**."

What if my ingredients are "natural" or "organic"?

The laws and regulations that FDA enforces do not have definitions for "natural" or "organic." The same requirements apply to your product no matter whether the ingredients are plant, animal, mineral, or synthetic. It's important not to assume that using only ingredients from plants will make your products safe. To learn more, see "**'Organic' Cosmetics (/Cosmetics/Labeling/Claims/ucm203078.htm)**" and "**Product Testing (/Cosmetics/ScienceResearch/ProductTesting/default.htm)**."

Resources for You

- **FDA Taking Closer Look at 'Antibacterial' Soap (/ForConsumers/ConsumerUpdates/ucm378393.htm)**
- **Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?) (/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm)**
- **Bad Reaction to Cosmetics? Tell FDA (/ForConsumers/ConsumerUpdates/ucm241820.htm)**

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