

Aromatherapy and FDA Compliance

May 22, 2024

By Michael H. Cohen

Aromatherapy uses natural plants and essential oils to promote beauty, health and well-being. According to Healthline, aromatherapy *“enhances both physical and emotional health.”* Aromatherapy has been used for thousands of years. Aromatherapy uses diffusers, inhalers, aromatic spritzers, body oils, lotions, facial steamers, cold and hot compresses, bathing salts, and other methods to help users smell the products and help the skin absorb the products. There are many different types of products.

Generally, the oils are not regulated by the FDA. The key factor that determines FDA regulation is whether the product is considered or advertised as a cosmetic or a drug.

FDA does not generally need to pre-approve cosmetic products or ingredients. There is an exception for color additives which must be approved for their intended use. This doesn't mean businesses that sell cosmetics have no responsibility to consumers. Businesses and individuals who market cosmetics must ensure the safety of their products. The FDA can still take action if the agency has *“reliable information showing that it is unsafe when consumers use it according to the directions in the labeling or in the customary or expected way.”*

Generally, cosmetic products that the FDA does provide information to the public about include:

- Aromatherapy
- Disposable Wipes
- EOS Lip Balm® Products
- Hair Products (Dyes, relaxers, removers, and cleansing products)
- Makeup
- Nail Products
- Soaps & Lotions (Soap makers' FAQs, anti-aging products, cellulite treatments, and more)
- Tanning Products
- Tattoos & Permanent Makeup

The FDA also has resources for cosmetic Ingredients.

FDA oversight of aromatherapy

You should also review how the FDA regulates aromatherapy with our experienced healthcare compliance lawyers. Generally, the FDA does not get involved with the preapproval of aromatherapy products that are considered cosmetics. The FDA will get involved if there is reason to believe aromatherapy products are being used as drugs.

FDA may review whether an aromatherapy product is a cosmetic or a drug based on the intended use of the product. FDA will review various factors such as claims about what the product can do for a user. The claims that FDA can review include the labels, websites, advertising, and marketing – and what consumers expect the product will do. FDA reviews aromatherapy products on a case-by-case basis.

According to the National Association for Holistic Aromatherapy, the most popular essential oils are:

- Clary Sage
- Cypress
- Eucalyptus
- Fennel
- Geranium
- Ginger
- Helichrysum
- Lavender
- Lemon
- Lemongrass
- Mandarin
- Neroli
- Patchouli
- Peppermint
- Roman Chamomile
- Rose
- Rosemary
- Tea Tree
- Vetiver
- Ylang Ylang

When aromatherapy is considered a cosmetic

FDA will likely consider that your product is a cosmetic if the intended purpose is to cleanse the body or make the person who uses the product more attractive. For example, perfumes and colognes that are used to make a person smell better will likely be considered cosmetics. Similarly, a shower gel will likely be considered a cosmetic because the purpose of the shower gel is to make the user cleaner.

Again, cosmetics do not require pre-approval by the FDA. However, the FDA can file an action against the makers, sellers, or marketers of a cosmetic if the FDA reasonably believes the aromatherapy product is not safe when users follow the directions on the label, *“or in the customary or expected way, or if it is not labeled properly.”*

When aromatherapy is considered a drug

An aromatherapy product may be considered to be a drug if the product is intended for therapeutic use. Examples of therapeutic uses include preventing or treating diseases and claims that a product can affect the function or structure of the body. FDA states that, for example, *“claims that a product will relieve colic, ease pain, relax muscles, treat depression or anxiety, or help you sleep are drug claims.”*

Other claims associated with aromatherapy that may lead the FDA to believe the product is a drug include claims that the aromatherapy product can treat asthma, insomnia, tiredness, depression, inflammation, menstrual issues, cancer, menopause, arthritis, and other conditions.

Just because an ingredient or fragrance comes from a plant doesn't mean the product can't be regulated as a drug.

FDA requires that drugs must be pre-approved by the FDA for safety and effectiveness before the drug can be marketed. You can learn more about how the FDA regulates drugs by reviewing its website and contacting our experienced healthcare lawyers.

WHEN WILL FDA LIKELY REGULATE YOUR PRODUCT AS AN OTC DRUG AND NOT A COSMETIC?

In today's video, we talk about when your product is likely to cross the line and be regulated by the federal Food & Drug Administration (“FDA”) as a cosmetic and not a prescription or Over the [...]

Can a product qualify as both a cosmetic and a drug?

Yes. Some products qualify as both cosmetics and drugs.

As an example, if a baby lotion is marketed with claims that the baby lotion *“both moisturizes the baby's skin and relieves colic”* that product would be both a cosmetic and a drug. The FDA will need to pre-approve the product as a drug and can regulate the product if the claims about the product's benefits and uses fail to protect consumers.

ARE THESE DRUG CLAIMS OR COSMETICS CLAIMS?

In today's video, we focus on anti-aging products to determine whether FDA will likely regulate your product as a drug instead of cosmetic.

Can an aromatherapy product be regulated outside the FDA?

Yes. The Consumer Product Safety Commission (CPSC) does regulate some fragrance products – including “air fresheners, scented candles, laundry detergents, and household cleansers.”

If an “essential oil” or other fragrance is “natural” or “organic,” doesn't that mean it's safe?

Products that come from plants aren't inherently safe. Essential oils and other aromatherapy ingredients may be *“toxic, irritating, or likely to cause allergic reactions when applied to the skin.”* The FDA provides the example that *“cumin oil is safe in food, but can cause the skin to blister.”* Some citrus oils that can be used safely in food may cause harm if they are applied to skin that has been exposed to the sun.

“FDA doesn't have regulations defining “natural” or “organic” for cosmetics.” The key requirement is that the product must be safe. Healthcare providers can learn more by reviewing the following FDA sites “Organic Cosmetics” and “FDA's Poisonous Plant Database.”

How are advertising claims about aromatherapy products regulated?

Generally, the FDA regulates the labeling of cosmetics and drugs. Advertising claims are regulated by the [Federal Trade Commission](#).

Aromatherapy oils and products may be regulated by the FDA if the products are considered drugs because the companies that make and market the oils and products make therapeutic claims – such as that the aromatherapy products can treat cancer. Many marketing claims may be considered therapeutic even if the claims are made by other individuals and companies. Aromatherapy oils and products may also be subject to FDA oversight, if the claims about substances may endanger the safety of the consumers who use or apply the oils and products according to the labels or expected usage. Aromatherapy products may also be subject to FTC oversight.

Medical companies and medical practices should [contact](#) Cohen Healthcare Law Group, PC to discuss their aromatherapy products to review whether FDA or FTC oversight may be required. Our [experienced healthcare attorneys](#) advise medical businesses and medical practices about healthcare compliance laws and regulations.

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