

BUSINESS AND LEGISLATION

Labeling Aromatherapy Products for Retail Sale

by Marie Gale



There is a vast difference between aromatherapy products developed for, and used in, massage therapy or other therapies and aromatherapy products for retail sale. The difference is not in the product itself, but in the manner in which it is regulated at a state and federal level. Once a product is entered into “commerce,” it falls under the jurisdiction of the Federal Trade Commission (FTC). If it is considered or marketed as a food, drug or cosmetic, it falls under the jurisdiction of the Food and Drug Administration (FDA).

The Federal Trade Commission (FTC), through the authority of the Fair Packaging and Labeling Act (FPLA), sets the standard for the labeling of all consumer commodities. A consumer commodity, as defined by the FPLA, includes:

“any food, drug, device, or cosmetic ... and any other article, product, or commodity of any kind or class which is customarily produced or distributed for sale through retail sales agencies or instrumentalities for consumption by individuals, or use by individuals for purposes of personal care or in the performance of services ordinarily rendered within the household, and which usually is consumed or expended in the course of such consumption or use.”

The difficulty with labeling aromatherapy products is that a single product could be identified, for regulatory purposes, as a food, drug, cosmetic or household product based solely on the use of the product and/or the claims made about the product. It is important to understand that the claims made about the product are not just those on the product label itself, but also those claims made in any material accompanying the product, including website text, and may also include claims made in any advertising about the product.

Consider lavender (*Lavandula angustifolia*) essential oil. If lavender essential oil (*Lavandula angustifolia*) were to be used in a diffuser for its pleasant fragrance, it would be a household product, but if a claim of “curing insomnia” were to be made, it would be a drug. If it were intended to be added to salad dressing and consumed (unlikely, but possible), it would be a food. If it were to be applied to the skin through massage as a topical blend in almond (*Prunus amygdalus*) oil because the fragrance is “nice”, it would be a cosmetic, but if applied to the skin as an anti-bacterial, it would be a drug.

The key, then, in labeling an aromatherapy product for retail sale, is determining the use or application of the product and the intent or claims made about the product.

Household Products

Household products are ones that are not intended to be used on the body and include aromatherapy products such as; room sprays, candles and essential oil diffusers. Providing there are no drug claims, there are virtually no restrictions on these products other than safety considerations (e.g. for burning candles).

Drugs and Drug Claims

The FDA defines a drug as: “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease,” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals” [FD&C Act, sec. 201(g),(1)]

Based on this definition; many of the traditional, anecdotal, or even proven qualities of essential oils commonly used in aromatherapy fall under

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the class of drug claims. To make a statement that a room spray contains lavender (*Lavandula angustifolia*) essential oil “which helps you sleep” or a topical treatment contains “anti-bacterial” tea tree (*Melaleuca alternifolia*) essential oil, renders the product a drug in the eyes of the FDA.

In order for a drug to be sold in the United States, it must have premarket approval by the FDA for the intended use (following a very strict, detailed, time-consuming and expensive process), or be included in a specific, approved monograph for the intended use for over-the-counter (OTC) drugs. It also must be manufactured in accordance with drug manufacturing regulations in an approved facility. A product for which drug claims are made, and which is not approved by the FDA, is subject to enforcement actions by the FDA.

Cosmetics

The FDA defines a cosmetic as: “*articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance*” [FD&C Act, sec. 201(i)].

Typical cosmetics are lotions and creams, bath products, make-up and hair products. Massage oil, provided no drug claims are made, is considered a cosmetic in that it is “promoting attractiveness” or “beautifying,” but not actually altering physical function or structure.

Traditionally, perfumes or fragrance products applied to the body are considered cosmetics by the FDA. In the eyes of the FDA, aromatherapy products are another version of a perfume – unless claims are made that imply the, “diagnosis, cure, mitigation, treatment, or prevention of disease,” or a change to the function or structure of the body.

Cosmetics are overseen by the FDA, but do not require approval in advance of being marketed. Facilities manufacturing cosmetics do not need to be approved or registered with the FDA, (although there is a Voluntary Cosmetic Registration Program administered by the FDA).

Mental and Spiritual Well-Being

The area of mental and spiritual well-being is not explicitly addressed by the FDA. Aromatherapy products which promote spiritual well-being could, for the sake of argument, be considered to be “beautifying” or “promoting attractiveness,” as spiritual well-being on the inside creates beauty and attractiveness on the outside.

Certainly there are drugs approved for the prevention, cure, or mitigation of mental “diseases,” and an aromatherapy product that specifically claimed to relieve symptoms of, say, ADHD (Attention deficit-hyperactivity disorder), would be considered a drug.

However, claims of improving mental focus, relaxation or calmness – all of which might affect the symptoms of ADHD, but are more in the realm of mental and spiritual well-being – are less clearly defined by the FDA. The FDA states on their website, that the agency will, “make judgments on a case-by-case basis.”

Product Labeling Requirements

The type of product, as determined by the use of the product and/or the claims made about the product, establishes the requirements for the content of the label on the product.

Under the Fair Packaging and Labeling Act, the label on any consumer commodity must contain:

- 1. Name of the item**
- 2. Net Contents (including metric measurements)**
- 3. Name and Address (of manufacturer or distributor)**

Therefore, all aromatherapy products, regardless of what they are, how they are used or what claims are made, must have the three items above on the product label.

For cosmetics, the FDA, which is responsible for implementing and enforcing the FPLA requirements as applied to foods, drugs and cosmetics, requires:

- 4. Declaration of ingredients (in descending order of predominance)**

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Finally, for drugs, there are additional approval and label requirements which can be found on the FDA website (www.fda.gov).

As an additional note, there are specific requirements as to placement of these four items on the label, required font sizes based on the container size, and the way the net contents are displayed. There are also some alternatives to listing all ingredients in descending order of predominance and specifications on how to handle "blended" ingredients (such as infusions or tinctures) which are added to the final product. Details are available on the FDA website.

In Summary

When preparing labels for aromatherapy products to be sold in a retail environment, always include the name of the product, name and address of the manufacturer or distributor, and the net contents of the package. Include the ingredient declaration if the product is to be applied to the body in any way. Carefully consider the type of claims that are being made about the product, and determine if any of the statements being made should be revised

or removed in view of how they might affect the regulatory authority over the product.

Aromatherapy, in its many forms, is a valuable alternative or adjunct to established forms of treatment. Introducing aromatherapy products into retail channels can help make the benefits of aromatherapy available to a wider public audience. When aromatherapy products are correctly labeled, they will withstand the scrutiny of the FDA and stay on the market to the benefit of all consumers.

About Marie Gale

Marie Gale is the author of Soap and Cosmetic Labeling: How to Follow the Rules and Regs Explained in Plain English and Good Manufacturing Practices for Soap and Cosmetic Handcrafters. She has been a member of the Handcrafted Soapmakers Guild since 1999 and is Past President of the HSMG (2004-2009). Marie currently resides on her family's ranch in southwest Oregon. **To learn more about Marie**, please visit: www.mariegale.com



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