The Ingredients *Column*

Speaking the Legal Lingo

by Irena James

If you have ever sold an anti-aging product or a product for acne-prone skin, chances are that, at some point, you have broken the law. Not because you sold these products, but because of the claims you made and the statements you used while closing the sale would most likely have been deemed as drug claims by the United States Food and Drug Administration (FDA).

Some of the first definitions aesthetics students are required to recite are those of a cosmetic and a drug. While it may seem like an unnecessary exercise, understanding these definitions is of utmost importance because they can have enormous implications in countless aspects of the skin care industry, from product line and manufacturer selection to marketing and branding efforts.

Do we sell cosmetics, drugs or cosmeceuticals?

In 1938, United States Congress defined cosmetics as articles (other than soap) intended to be rubbed, poured, sprinkled or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance. The most important aspect that a skin care professional needs to remember about this definition is that, as far as the FDA is concerned, cosmetics do not affect the skin past the stratum corneum and they should only produce temporary, surface, visible or textural changes.

A lot has changed since 1938. Advances in ingredient technology have inspired an abundance of treatment possibilities that go far beyond promoting attractiveness. Unfortunately, due to this archaic definition, product manufacturers are extremely limited in what they can share with customers regarding ingredients, especially when it concerns a mode of action that occurs below the stratum corneum.

Examples of cosmetics include: cleansers, toners, astringents, moisturizers, exfoliants, scrubs, masks, serums, body lotions, deodorants, balms, shampoos, conditioners, fragrance, lipstick, foundation and blush.

Drugs are articles (other than food) intended to affect the structure or function of the body of man or other animals; cure or mitigate disease. This means that drugs affect the skin under the stratum corneum, produce permanent changes, cure disease, and alter the structure or function of the skin.

Drugs detailed by FDA documents are called monographs. Monographs describe the type of drug, its function, active ingredients, and percentages as being recognized as safe and effective for various conditions. Manufacturing practices for production, as well as efficacy testing procedures performed prior to market launch and warnings, such as contraindications and allergic reactions, are also covered.

There are two types of drugs: over-the-counter (OTC) and prescription. OTC drugs may include acne preparations, skin bleaches, skin protectants, antiseptics, anti-inflammatories, antiperspirants, anti-fungals, and sunscreens, which include beach products, makeup and moisturizers with sunscreen. An example of a prescription drug would be Retin-A, one of the prescription forms of Tretinoin and vitamin A, a derivative used to treat acne and sun damaged skin.

Active ingredients or Action ingredients: How labeling requirements are different

A cosmetic product must be labeled according to cosmetic labeling regulations. Here are a few important aspects of cosmetic labeling requirements for an aesthetician to be aware of:

All ingredients must be listed in descending order of predominance, but ingredients included at one percent or below can be listed in any order.

Cosmetic ingredient names must match those found in the International Nomenclature of Cosmetic Ingredients (INCI) Dictionary.

Ingredient trade names cannot be listed on the ingredient panel, only International Nomenclature of Cosmetic Ingredients' names. For example, the peptide Argireline (trade name) must be listed by its International Nomenclature of Cosmetic Ingredients' name, Acetyl Hexapeptide-3. While Argireline may be used in marketing materials or even on the front panel of the product, it is illegal to include it in the ingredient list.

It is not acceptable to list common vitamin names such as vitamin C or vitamin A on the ingredient panel. Instead, a vitamin form represented by its chemical name must be listed on the panel. There are multiple forms of vitamin C used in skin care, each with a very distinct set of functions on the skin.

Ascorbyl palmitate will perform differently on the skin than tetrahexyldecyl acsorbate or magnesium ascorbyl phosphate. Not knowing which form of vitamin C is used in a product can cause serious issues and affect product results.

Plants and plant materials must be listed by their Latin binomial. It is important to recognize that there is a very good reason that the law requires manufacturers to use International Nomenclature of Cosmetic Ingredients' names for plants, which in most cases include the Latin binomial. For example, listing algae on the label does not give any information to the consumer as to which specific benefit the algae in their product will have. Algae can be purifying, hydrating, soothing or stimulating, depending on the species used for the extract or even the part of the plant used to extract the material. Algae (laminaria digitata) extract, algae (chlorella vulgaris) extract, and algae (ahnfeltia concinna) extract have a completely different affect on the skin – yet, if only algae extract is listed on the ingredient panel, a client would have no way of knowing which one of the three is in the product, therefore, no way of knowing how their skin will respond to the ingredient.

Drug labeling

Over-the-counter drugs must be labeled according to OTC drug regulations, including Drug Facts labeling. For example, the drug ingredients must be listed alphabetically as Active Ingredients, followed by cosmetic ingredients, listed in descending order of predominance as Inactive Ingredients. Sunscreens, acne medications containing benzoyl peroxide or salicylic acid 0.5 to 2%, and hyperpigmentation treatments containing hydraquinone are all examples of OTC drugs that require this pattern of identifying active and inactive ingredients on their labels.

As far as the FDA is concerned, an active ingredient is always a drug. Therefore, ingredients that perform in cosmetics should be referred to as performance or action ingredients.

Cosmeceuticals

Coined in 1979, the term cosmeceutical originally described a drug with cosmetic benefits. A true example of a cosmeceutical is a topical tretinoin prescription known by various brand names, such as Retin-A, Renova, or Avita, that are used for treating acne, fine wrinkles, and hyperpigmentation.

Today, cosmeceutical is a marketing term that applies to a cosmetic with high performance or clinical benefits. Ingredients commonly advertised as cosmeceuticals are peptides, various forms of vitamin C, vitamin A, a slew of antioxidants and even some aggressive exfoliating agents. It is important to remember that, since the FDA does not recognize the term cosmeceutical, a manufacturer can call out any of the ingredients featured in their product as a cosmeceutical as long as they determine that the data supports the claim.

According to the FDA, cosmetics with drug-like activity are drugs. Cosmetics claiming to alter the structure or function of the skin must be approved by the FDA as a new drug, which would still be a pharmaceutical, not a cosmeceutical.

What the FDA does not do

FDA registration is voluntary for cosmetic manufacturers, but the FDA does inspect facilities to make sure they are good manufacturing practices (GMP) compliant. The FDA will not approve or certify skin care products, cosmetics, or the development and manufacturing facilities themselves, so claims such as FDA approved lab should raise a red flag and be met with suspicion.

What is your intention?

Considering the legal implications of drug and cosmetic definitions, it is crucial for aestheticians to understand exactly how they most frequently break the law by making statements about the benefits of the products they sell and treatment procedures they perform. Whether these claims are made on treatment menus, product brochures or website pages, the person or brand making them can be held liable if the FDA deems them drug claims.

It is the seller's intent regarding a product's efficacy, not the product itself, that determines how the product will be classified by the FDA. If you claim that your cosmetic product stimulates collagen, repairs wounds and clears acne, the FDA could send you a regulatory letter citing a violation and ask you to cease using these claims, threatening fines and further action. Failure to comply with federal and state regulations can also nullify product liability insurance and other insurances.

Cosmetic claims should be visual, textural, surface and temporary. You can tell consumers how their skin will look or feel or what they will experience, but not how the product or ingredients work in the skin or cells.

As an aesthetician, when making cosmetic claims feel free to tell your clients that their skin will feel less sensitive, lines will appear smoother, or that the skin will seem healthier-looking and younger-acting.

However, never say cosmetics are healing or anti-aging. Do not describe a product as a "face lift in a jar" or say it is "just like Botox" under any circumstances. Certainly do not claim that a product cures anything, regenerates collagen or other tissue, or removes wrinkles.

While you may know how a product affects the body's structure or function, due to current FDA regulations, you cannot relay this to your client. Until Congress establishes a new definition of cosmetics, we are all confined to these restrictions.

Irena James, director of custom product development and education for YG Laboratories, has educated generations of students and industry peers on skin care ingredients, treatment protocols and brand development. Irena's versatile experience in the skin care industry spans over 20 years, during which she worked as an aesthetician, educator, territory sales manager and director of business development in the EU. She is an assistant instructor at the UCLA Extension Cosmetic Sciences Program and a member of BIW and the Society of Cosmetic Chemists.