

# Cosmeceuticals—OTC/ Prescription/Professional

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In the previous chapters we identified the structure and function of the three distinct layers of the skin and discussed options for treating visible skin aging and certain diseases of the skin. In these next few chapters, we will be delving into various differences between over-the-counter (OTC) cosmetics, pharmaceutical products and professional cosmeceutical skin care formulations. These include federal and state regulations as well as active ingredients and their formulation into finished, marketed products.

## **Topical Product Regulatory Issues**

As mentioned previously, one significant element that has risen in prominence to help off-set the financial costs and improve profitability of a medical practice is the addition of esthetic services. One of the many challenges today is finding the balance between the fiscal bottom line and providing patients with the most cost effective care possible. This usually includes the offering of services provided by numerous light and/or laser devices with esthetic treatment regimens, fillers, and injectible neuromodulators to treat facial wrinkles. Additionally, professional cosmeceutical products should be offered for daily use to further improve visible results and maximize benefit of in-office procedures. Optimal results are achieved with a plan between client and skin care professional, working together as a “team.” Since home care treatments make up a large percentage of a patient’s skin care program time, the skin care professional must have thorough knowledge of available options. Confidence in a well-formulated product line will then have the greatest positive impact. Because you, as the licensed skin care professional, are providing recommendations within your office, it is

absolutely crucial to have a full understanding of which products are safe and effective and how to integrate them into your practice. Since clientele trust your recommendations, you must strive to become an expert regarding all aspects of skin care, including products you sell.

Estheticians and other skin care professionals are often asked these common questions from clients: What is the difference between a “professional” skin care cosmeceutical versus a brand one can find OTC at a drug or department store? Is there really a notable difference in formulations, or is it all about celebrity endorsement, fancy marketing and pretty pictures? Can one get superior results with drugstore cosmetic brands, or will results be better using professional cosmeceuticals? All too often, consumers fall under the spell of cosmetic company marketing and advertising claims, and will spend a lot of money on expensive OTC cosmetics that don’t really go beyond “feeling” or “smelling” good.

The US Food and Drug Administration (FDA) recognizes two distinct categories of products that affect skin conditions and diseases: pharmaceuticals and cosmetics. Pharmaceutical ingredients are used in medicines that claim to treat specific diseases and conditions. They are available by prescription through a physician, nurse practitioner or physician assistant with a supervising doctor. Topical pharmaceuticals are drugs that penetrate through the stratum corneum barrier into the epidermis to have a measureable effect on the structure and function of the skin, and to reverse the disease state. FDA approval requires proof of effectiveness by double-blind randomized prospective controlled clinical trials in hundreds of people. The study should be conducted by an independent research group to prevent bias, even though it is paid for by the company sponsoring the drug. Product development costs usually exceed \$230 million and take seven to 12 years for approval of a single prescription drug by this New Drug Application (NDA). Safety and stability studies of the products must be completed prior to the final (phase III) clinical trials.

A group of nonprescription ingredients in FDA over-the-counter (OTC) drug monographs stipulate that the use of ingredients at specific concentration ranges can be claimed to treat specific diseases, thus are OTC medicines. These include 2% salicylic acid for acne and 3% for psoriasis, 1% zinc pyrithione for dandruff shampoo, and 2% sulfur for psoriasis and acne. Companies selling these types of OTC drugs can advertise that they treat certain diseases just as prescription products can. A product must not make the treatment of a disease claim if it does not fit under an OTC monograph nor was approved by the FDA as a new drug. OTC drugs have relatively few side effects and are sold without a prescription. These types of ingredients include certain sunscreens, acne,

dermatitis, dandruff and psoriasis treatments, skin protectants, topical anesthetics, and warts removers. Standardized labeling is a mandatory requirement for these types of ingredients called drug facts labels, and are usually found on the outer box or actual product packaging. This labeling clearly indicates how to use the product and what condition the product treats. Also included in the drug facts labeling are possible side effects and contraindications.

Cosmetics are defined by the FDA as “...articles intended to be applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance...”<sup>1</sup> Skin care products that are marketed under the cosmetics category do not require a prescription and are not required to prove their marketing claims nor have any safety studies. Very low concentrations of FDA OTC monograph ingredients such as 0.4% salicylic acid fit in this category, and do not need to be listed separately on ingredient labels.

Cosmetic topical products may cite “scientific studies” of the ingredients used in their product formulations in order to give the impression their product is safe and effective. However, formulation of ingredients, especially the exotic active ones, is usually difficult. Licenses or notifications to any regulatory agency are not required to formulate, manufacture and/or distribute cosmetic products, even though a Cosmetic Safety Board does handle complaints about complications with products.

The word “cosmeceutical” is not categorized by the FDA, but it is a term used by skin care professionals, physicians and skin scientists to define a product that fits the niche between a pharmaceutical and a cosmetic. It is used in the professional skin care arena to describe a product that actually has measurable biological action in the skin, like a drug, but is regulated as a cosmetic since it claims to affect appearance. The formula need not technically prove efficacy or safety, even when it contains an active ingredient that may impact skin conditions like extrinsic aging. Cosmeceuticals are available without a prescription and should be marketed with claims based on appearance of the skin; i.e. “reduces *the appearance of* wrinkles.”

Medicinal Herbs are plants classified as “food stuffs.” The FDA does not regulate “food stuffs” that are ingested or applied to membranes. Herbal ingredient-based products that are clinically effective are the result of complex but targeted product development. The multiple variables ranging from environmental harvesting to trans-stratum corneum delivery means that no herbal product can ethically claim efficacy and safety without clinical trials, conducted by independent researchers, using the complete ingredient formulation.<sup>2-4</sup>

Cosmetics advertising is not managed by the FDA, but by the Federal Trade Commission (FTC) and is different from cosmetics labeling. It should not be misleading and the company must be able to substantiate the claims made in marketing pieces. Consumers will find many of the same catch phrases when reading an advertisement for skin care: “Dermatologist-Tested,” “Clinically Proven,” “Clinical Studies show that ...,” “Clinically Tested.” While these words may sound impressive, remember that no regulatory definition for any of these phrases exists. As a skin care professional, you must interpret this language with caution, especially when trying to choose a skin care line that works best for your practice and clientele.

The Fair Packaging and Label Act requires an ingredient listing for every cosmetic product retailed to consumers. Since cosmetic companies aren’t regulated by the FDA and required to prove efficacy claims, the special active ingredient touted in the formula must only appear somewhere on the ingredient list. All the ingredients in the product are listed in order, from most weight to least weight, so if you see that “active” on the last half of the list (usually alphabetically) it is likely to be a very tiny percentage (less than 1%) of that specific ingredient.<sup>1</sup> Keep in mind that formulations often do not necessarily need a high percentage of active ingredient in order to have efficacy in the skin because it is the total mix of actives plus the base that make an effective topical formulation. Moreover, many prescription ingredients are potent enough to work at 0.01% to 1.0% concentration. When a cosmetic product cites clinical study claims, it is up to you to ask at least these questions:

- What was tested—an individual ingredient or the finished formulation?
- How was it tested, in vitro (in a test tube or petri dish, in an ideal laboratory environment), or was it tested in vivo (on living human skin) as a patch or as a clinical study of a complete body site, i.e. face?
- Were the studies double-blind controlled, which means the product you are being asked to sell was compared against a) placebo (product base) without the active; b) against an approved prescription product; or c) a change from baseline? If the study is conducted by an independent research group, the FDA considers the study valid and unbiased even if paid for by the cosmetic company owner.
- Was it studied on the appropriate body site, i.e. face, for a product to modulate extrinsic aging?
- Was the number of participants large enough to determine statistical significance? This measure of probability is what determines whether it

really works. If the result in the clinical trial is reproduced 95% of the time the trial is run, then the FDA says the product works. This is known as a p-value of  $<0.05$  ( $p < 0.05$ ). Likewise, if this probability is not achieved, then it is not an effective product.

The gold standard for clinical testing of pharmaceuticals or cosmeceuticals is double-blinded, prospective controlled, randomized human clinical trial against placebo or an approved prescription product, conducted by an independent research group using the finished product. Interestingly, while 73% of women polled said it is important to have “younger looking skin,” the “vast majority of topical products promise youth but lack clinical evidence of producing the desired skin,” notes dermatologist Leslie Baumann.<sup>5</sup>

It is important to note that many single ingredients that test very well in in vitro testing actually have no function in human skin when mixed into a formulation—yet skin care professionals and consumers believe the anecdotal evidence from in vitro studies. As well, many cosmetic companies that cite clinical study results will not *provide* clinical study documentation. A number of these companies will conduct an in-house study on employees and claim the study is “on file.” Obviously, the validity is questionable. Because it is not a requirement by the FDA, rare is the cosmetic or cosmeceutical company that tests complete formulations (beyond a single ingredient) and then offers full studies for the public to see. You will sometimes find peer-reviewed cosmetic formulation studies in dermatology or cosmetic surgery journals or presented as posters at refereed meetings, which lends more credibility to the testing process. For example, only 30% of the poster exhibits applied for at the American Academy of Dermatology are selected to present at the annual meeting after review by a panel of dermatologists.<sup>3</sup>

In these current times, clinical studies on finished formulations tested on human faces should become the norm and not be the exception. Cosmeceutical companies that cannot provide clinical study efficacy or safety data are not providing skin care professionals with the best treatment for their patients. Interpreting clinical studies will be addressed further in the next chapter.

Because many consumers “self-diagnose” when choosing a skin care product to try from a drug or department store, OTC products sold at these types of venues must be manufactured to minimize risk of problems with the product. Big cosmetic companies cannot afford to have masses of consumers with reactive issues from using highly active products—so often a skin care product will