Inside Cosmeceutical Marketing Claims

Dermatologists and their patients may wonder what makes a product "dermatologist tested" or "clinically proven." Here's what you need to know.

BY LESLIE BAUMANN, MD

Roughly 25 years since Albert Kligman, MD introduced the term "cosmeceutical," the category has never been officially recognized with a true, legal definition, and this category of products remains largely unregulated.[1] The United States Food and Drug Administration (FDA) allows personal care products to be classified as a drug, cosmetic, or both (such as antidandruff shampoos or moisturizers with SPF), and cosmeceutical formulations remain in the loophole.

Although many trusted manufacturers have emerged in the cosmeceutical realm and a number of formulations have proven their clinical merit, the lack of official oversight leaves room for doubt, especially for those that make extraordinary claims. Most reputable formulators test both their main ingredients and their finished products through *in vivo* trials, but these tend to be small and are rarely published in the peer-reviewed literature. In this setting, then, how should dermatologists and their patients assess cosmeceutical claims?

PRODUCT CLAIMS

The fact that the cosmeceutical "class" is not regulated does not indicate that the field is without standards and good practices. Of course, some formulators can circumvent these, but their products are unlikely to succeed and their brand will probably not gain traction. With this in mind, dermatologists evaluating product claims should be aware that many of the common "claims" on labels have a consistent meaning from brand to brand or manufacturer to manufacturer. Following is a review of common terms, their meanings, and the typical evidence used to support the marketing.

Lightening. Lightening claims in the US are addressed in the OTC monograph. Lightening can be assessed with any combination or single method of evaluation, including bioinstrumentation, clinical expert assessment, or consumer questionnaire. Clinical studies typically include dermatologist assessments of overall fairness, overall evenness, and instrumental measurements for luminosity and L*a*b* values from chromameters. Image analysis for pigmented spots can be done on high-resolution images, and dark marks can be followed for size and intensity compared to nearby skin.

Brightening. There are multiple approaches for assessing "brightening" effects. Often this is done via clinical evaluation, with dermatologists grading brightness on a scale (for example, from very dull/not bright to very bright/no dullness) over the course of treatment. Results may also be obtained through measurement of luminosity from chromameter or image analysis.

TAKE HOME TIPS

The fact that the cosmeceutical "class" is not regulated does not indicate that the field is without standards and good practices. Dermatologists evaluating product claims should be aware that many of the common "claims" on labels have a consistent meaning from brand to brand or manufacturer to manufacturer. Even when products are tested by a company, the study may be conducted under unrealistic conditions or with such tight controls that it is unlikely that a consumer's actual use will produce similar effects. Still, well-formulated products can confer benefits. "Clinically proven" claims, supported by research and development studies with independent dermatologists, are very strong indicators of potential product efficacy.

Hypoallergenic. No standard definition of hypoallergenicity has been established, and each company defines this in its own way. Common methods of evaluation include human repeated insult patch testing (HRIPT) of about 100 to 200 subjects, cumulative irritation testing (smaller panel), and sometimes photoreactivity testing, depending on the product type.

Allergen-free. Again, no standard definition has been established; each company defines this in its own way and is not required to do testing. Generally, "allergen-free" means at least that the formulation contains no fragrances on the EU's "List of Substances Which Cosmetic Products Must Not Contain Except Subject to Restrictions and Conditions Laid Down" or other materials commonly known as allergens. Some companies will use HRIPT for allergy testing.

Unscented/Fragrance-free. Companies can call a formulation "fragrance free" when their products are free of common fragrance ingredients (especially those most frequently associated with allergic sensitivity) or have not added a traditional fragrance for the specific purpose of providing a scent to the product. However, "fragrance free" does not always mean that a fragrance has not been added. Fragrance subcomponents or botanicals may be incorporated for a primarily cosmetic or preservative effect and, at the same time, happen to provide a scent or pleasant odor to a product. If the "fragrance" serves a primary function other than a scent (such as a preservative), then the company need not consider the ingredient a fragrance.

In addition, some ingredients, such as preservatives like phenoxyethanol, background wax odors from long chain/paraffins, or unfragranced sunscreens, are not considered fragrances in any sense, but they do have an odor and can cause problems in fragrance-allergic patients.

"Unscented" typically is reserved specifically to describe formulations that have no detectable odor, but the product may have a "masking" fragrance incorporated to cover background odor. Unscented does not mean that no fragrance has been added.

Clinically Tested. Typically, these products have indeed been investigated through some form of clinical testing, but the test could be a simple 48-hour patch test for irritancy. There are no rules about how many subjects or the type of trial required for a formulation to be considered "clinically tested," and it is not always clear whether the finished formulation was tested or only components. When a product is described as "clinically tested," each word is carefully chosen (e.g., clinically tested "technology" or clinically tested "formula") to offer clarity to the attentive reader.

Clinical testing is distinct from more ordinary "consumer" testing, which could include focus groups and simple patient use questionnaires. Clinical tests are typically run with scientific/medical experts, using an approved protocol, specified statistical analysis, and enough subjects to provide statistical significance, based on the study design. The new sunscreen monograph allows for as few as 10 subjects per panel for SPF. Other types of assessments (moisturization, anti-acne, etc.) would typically use more subjects, perhaps from 30 to 100.

Clinically Proven. "Proven," according to the National Advertising Division of the Council of Better Business Bureaus (NAD), requires two similar well-controlled clinical studies to make this claim. This is the standard for the major television networks with regard to broadcast advertising of a product. The Office of Broadcast Standards & Practices reviews ads and the data to support any claims before accepting them for broadcast. If there has been just one study, the wording might be limited to clinically "shown" or "tested." Sometimes, one study on the "technology" and another study on the final formulation will satisfy the network's requirements for "clinically proven."

Despite attempts at rigor, the "clinically proven" claim can be unclear for consumers, as they are unable to determine if it was only the ingredient or the actual final formulation that is clinically "proven." Furthermore, the advertising regulation does not apply to package labeling. If only the ingredient was clinically proven, the wording usually is carefully crafted (e.g., "with an ingredient that has been clinically proven to X").

WHAT'S IN A MONOGRAPH?

A monograph is a listing of active ingredients that, when used at the concentration range allowed in the monograph, can be included in product claims. Claim language pre-approved by the FDA is allowed on a monograph product without supplying additional proof. Generally, companies are required to follow the wording provided in the monograph for its claims. However, additional claims can be added provided they are non-OTC, such as "moisturizes," "cleans," "brightens," etc.

For example, for acne products, companies must have an approved monograph active ingredient such as benzoyl peroxide (BPO), salicylic acid, or sulfur, and within the approved range. Companies are not required to test this formulation for acne benefit, provided they meet the range requirement. However, they cannot mix acne actives or other monograph actives; a formulation could not contain PBO and UV screens and make a claim to treat acne and confer SPF without undergoing FDA review and approval.[1]

1. Kessler, DA. Federal register. Rules and regulations, acne. 1991; 56(159): 41020.

LABELING IMPLICATIONS

Even though companies may perform extensive research on cosmeceuticals, their findings generally remain unpublished—providing several implications.

1. Dermatologists do not have easy access to this scientific evidence and are unable to evaluate the efficacy of the numerous products making it to market. Physicians are taught to practice evidence-based medicine, but without evidence, have little reason to believe that any of these products are efficacious. Consequently, the medical establishment dismisses these products as useless when such formulations may, in fact, offer potential benefits to patients.
2. Consumers may become confused by marketing. With little guidance, consumers try products and likely feel disappointed with the lack of results. In addition, they are left to operate under the false assumption that you get what you pay for—that is, the more expensive the product, the more likely it is to be effective. This can lead to a general distrust of the entire cosmetic dermatology field.
3. Internal research circumvents the peer review process. Peer review has long been considered essential to validate the research findings of scientists. It is difficult to have confidence in the results of a study that has not been subjected to the peer review process.

Dermatologist Tested. This claim conjures images of a dermatologist applying a lotion to the face, assessing it as cosmetically acceptable, and subsequently approving the formulation. While "dermatologist tested" generally means much more than this, the claim is highly variable.

Often if a formulation is "dermatologist tested," a dermatologist has reviewed the clinical study and signed off on it, but he or she may have simply reviewed the formula or a study report. The doctor may or may not be involved in the conduct of the study and/or analysis of results.

Nonetheless, this claim is usually based on a specific clinical trial with a protocol, and the final formula sold in stores has been tested. Panel size depends on the company, but the general rule is a minimum of 30 subjects for claims of efficacy. In this case, a certified dermatologist signs off and oversees the testing. However, this is not required to make the claim "dermatologist tested."

Dermatologist Approved. This claim only requires one dermatologist to approve the product in some fashion, perhaps based on an assessment of safety, efficacy, or just a brief review of ingredients. Typically, a small company doing infomercials may just use one dermatologist, who may also be its consultant or a stock holder in the company. Larger companies typically sample four or five independent dermatologists with data to be reviewed, depending on the claim and the size of the company. This wording is not as common as "dermatologist recommended," which is typically based on a questionnaire that is sent to many dermatologists.

"…Appearance of Wrinkles." A common claim for nonprescription skin care products is that they improve the appearance of wrinkles. Companies could use bioinstruments (e.g., fringe projection, image analysis), an expert grader, or a consumer study with questionnaire to support this claim. Normally, only a drug product, like tretinoin, for example, can make claims of actually reducing wrinkles and not simply minimizing their "appearance." For cosmetic products, this claim is typically supported by dermatologist *in vivo* or photographic assessment of subjects at the end of the trial compared to baseline. A higher hurdle of "versus placebo" or "versus vehicle" may be used to further support efficacy. Sometimes silicon replicas of the treated area are taken before and after and then analyzed.

Lifting. There are three primary methods for demonstrating "lifting": bioinstrument (change in volume based on imaging software), expert grader, or consumer questionnaire. Live grading can sometimes be done split-face, if subjects are symmetrical, or 3D imaging can be employed and used for grading of lifting. Sometimes calculations can be done on the images to measure the appearance of visual lifting in millimeters.

Smoothing. Smoothing can be measured in many ways, but it can also be as simple as an ingredient claim along with feedback from consumers and investigators. In a clinical study, dermatologist-assessed improvements in tactile roughness would support smoothing. 3D imaging or replicas could also support this claim or provide additional visual documentation. Consumer self-assessment can be helpful, with a claim such as, "In a clinical study, subjects noticed smoother skin after X weeks." While some companies use clinical trials with imaging systems as proof, others could use consumer (sensory) feedback only.

Firming. Expert assessment and/or subject self-assessments are typically used to document firming. Some instrumental measures have been applied, such as ballistometry, but few publications are available on this method. Sometimes firming is based solely on an ingredient claim with no actual testing performed.

Anti-aging. Anti-aging claims are often based on an ingredient claim. Often a consumer or expert grading is included. SPF is shown to prevent premature aging/photodamage,

FTC GUIDELINES ON PRODUCT ENDORSEMENTS

The Federal Trade Commission (FTC) recently introduced several changes to its "Guides Concerning the Use of Endorsements and Testimonials in Advertising," which covers endorsements by consumers, experts, organizations, and celebrities, as well as the disclosure of important connections between advertisers and endorsers.

Advertisements that feature a consumer and suggest his or her experience with a product or service is typical when that is not the case will be required to clearly disclose the results that consumers can generally expect. Since the guidelines were last drafted in 1980, advertisers can no longer simply include a disclaimer such as "results not typical."

"Expert" endorsements—such as those provided by a dermatologist—also require listing the expertise the spokesperson possesses and how that expertise aids in evaluating product features or characteristics. Evaluations must include product testing to support the claims. When based on a comparison, the comparison must be included in the expert's evaluation and the expert must conclude that the product is at least equal overall to the competition. When the impression of "superiority" is expressed, the expert must have found the product superior to others with respect to features.

The revised Guides also add new examples to illustrate that payments or free products between advertisers and endorsers must be disclosed (i.e., bloggers paid to write a review or celebrity endorsements while on a talk show). Likewise, if a company refers in an advertisement to the findings of a research organization that conducted research sponsored by the company, the advertisement must disclose any connection between the advertiser and the research organization.

The Guides are administrative interpretations of the law intended to help advertisers comply with the FTC Act; they are not binding law themselves.

—PD Staff

1. Federal Trade Commission 16 CFR Part 255. Guides Concerning the Use of Endorsements and Testimonials in Advertising. October 15, 2009; 74: 198.
2. FTC Publishes Final Guides Governing Endorsements, Testimonials. http://www.ftc.gov/opa/2009/10/endortest.shtm

and new label revisions allow SPF products to make this claim. However, typically the anti-aging product companies tout "anti-aging" effects based on ingredients other than UV screens. For example, AHAs and vitamin A derivatives are popular in "anti-aging" formulations.

Non-comedogenic. This claim is not officially defined, although industry practice suggests the use of comedogenicity patch testing on the upper back with between 10 and 20 subjects, based on the modified Kligman method. Cyanoacrylate follicular biopsies may be reviewed under a microscope.

Pore Reducing. The appearance of a reduction in pore size may be assessed by dermatologist reviewers/graders *in vivo* or with photographic comparisons. Images can also be assessed with bioinstrumentation such as the software used in the Visia system by Canfield that evaluates change in pore size. However, effects on pore size are often self-assessed by subjects on a questionnaire.

Deep Cleaning. No standard definition has been established, but a number of approaches have been presented. A standard material can be applied to the skin and allowed to equilibrate. Then a standardized washing procedure can be applied. Typically, a new cleansing product or device is compared to either one of or all of the following: a competitor, water alone, bar soap, or an older formulation. The amount of material left behind can be quantified using laboratory instruments. For depth, tape stripping can be employed, and to show reduction of sebum, a sebumeter can be used. Assessment of "cleanliness" may also be made by consumers or expert graders.

Plumping. This is a frequent claim on lip cosmetics. Dermatologist assessment of lip volume, plumpness, color, or shape can be used. Subject self-assessment can be important, as subjects sometimes say they "feel" the plumpness. Digital imaging has been used and graded by experts, and advanced 3D imaging techniques can even allow quantification of volume changes. Plumping may simply be an ingredient claim, based on incorporation of ingredients that cause an increase in blood flow and thus temporarily increase the size of the lips.

Volumizing. This is a common claim for eye cosmetics and a potentially tricky one. Any coating on the eyelash will increase the volume based on the volume equation $\prod r^2h$, so a doubling of the hair shaft radius will quadruple the volume (i.e., a 400 percent increase in the volume of the lash). Most often, photo assessments are completed, but there are no regulations on the number of subjects needed to establish a plumping effect.

BUYER BEWARE

Perhaps somewhat skeptically, cosmetic company insiders have noted that the most reliable claim on a package is the product size, as this can be objectively measured. Any other claims can be exaggerated based on limited or non-product-specific data or, in rare cases, based on nothing at all. Even

ORGANIC OR NATURAL?

Interest in what are perceived to be the healthiest skin care product ingredients has risen steadily over the last two decades, spurring the emergence of terms such as "organic," "natural," "naturally derived," and "botanical," but these terms are fraught with considerable confusion:

Organic. Certifying products as "organic" is a current trend. However, one should be wary of the organic label and understand the differences in the various certifications. In 2005, the US Department of Agriculture enacted new organic standards for skin and body care products. Accordingly, a product labeled as "organic" contains at least 95 percent organic ingredients; one that is "made with organic ingredients" contains at least 75 and up to 94 percent organic ingredients. These standards are derived from the organic food standards, and prohibit the use of synthetic preservatives and most chemical processing of ingredients. Organic personal care products such as skin cleansers are therefore derived from organically grown plant products, rather than conventionally grown plants, synthetic chemicals, or petroleum byproducts. In order to meet this standard, they also exclude or minimize ingredients that could be considered potentially harmful to people, animals, waterways, or the environment.

Natural, Naturally Derived, Botanical. These terms have no legal definition. Products that are labeled as "natural" may or may not be organic. These products contain ingredients of plant origin but can also contain chemicals intended to act as preservatives or to improve its texture. In addition, "naturally derived" ingredients often are plant-derived ingredients that have been improved upon in the laboratory. For example, active soy is derived from soybeans, but the estrogenic components have been removed in the laboratory. Sales of products that claim to be organic, natural, naturally derived, or botanical have soared in recent years. There are several effective botanical products on the market but, unfortunately, consumers may miss out when enticed by copycat generic products with similar ingredients and packaging. The order of ingredients, pH, and temperature at time of addition of ingredients are all patented trade secrets that influence a product's efficacy.

when products are tested by a company, the study may be conducted under unrealistic conditions or with such tight controls that it is unlikely that a consumer's actual use will produce similar effects. A product may make a claim for improvement in wrinkles, for example, after 51 percent of consumers report a self-assessed benefit, which translates to roughly a 50/50 chance of a given consumer seeing benefit.

Still, well-formulated products can confer benefits. "Clinically proven" claims, supported by research and development studies with independent dermatologists, are very strong indicators of potential product efficacy. In addition, a television ad on one of the three major networks that states "clinically proven" is a good indicator of product benefit. Brand name products with strong research and development organizations are most likely to carry these claims. Patients should be cautious with generic store brands that state "compare to X product…" These products are selling off of the reputation of the "innovator" and are unlikely to have done any studies. They may contain the same ingredients as another brand, but the manufacturing process is rarely duplicated exactly to result in an identical final product. The generic product can only be assumed to have the same efficacy if its final formulation has been clinically proven.

For reliability, consumers should consider the history and reputation of the company selling the product and note the efficacy claimed. In general, the larger corporations will do clinical research and testing that can verify claims, since their competitors are likely to challenge any false advertising. Smaller companies are less likely to be scrutinized and therefore can more easily operate under the radar screen and get away with less scrupulous claims.

LOOKING AHEAD

The main reason there are so many ethical debates in the cosmetic dermatology world is that there are just so many opportunities to make money and some of these opportunities walk the ethical tightrope. Claims are not clearly defined and rarely objectively determined. Dermatologists and their patients are best served by an objective, organized approach to product evaluation. It is especially important that physicians who dispense products understand the science of formulations and their claims. There is nothing wrong with a practice enhancing revenues through dispensing—as long as it is done ethically, responsibly, and with the patients' best interests in mind. The preservation of the patient's trust and of the sanctity of the physician–patient relationship should be placed on par with patient welfare as highest priorities. ■

Dr. Baumann has performed research trials for over 50 pharmaceutical and cosmetic companies and serves on the advisory boards of many.

Leslie Baumann, MD is CEO of Baumann Cosmetic & Research Institute in Miami Beach, FL. Her books include Cosmetic Dermatology: Principles and Practice (McGraw-Hill, 2002) and The Skin Type Solution (Bantam Dell, 2006).

1. Kligman A. Cosmeceuticals: do we need a new category? Cosmeceuticals, edited by Elsner P, Maibach H. New York, Marcel Dekker Inc., 2000; 1.