Board Member Spotlight

Deconstructing Cosmetic Claims

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In today's competitive environment claims may be the difference between a product you can't keep on the shelves and one you wish never made it off the formulator's bench. The problem is claims are regulated by the FTC and labeling is regulated by the FDA, so you have two regulators assessing two very different sets of risks. The FTC is concerned that your claims are supported by data, or in other words, truthful. The FDA is concerned that you are first and foremost not making a "structure-function," or drug claim, and that the labeling of ingredients, net contents and any mandatory warnings statements are correct.

There are many different types of claims; some can get you in trouble, although many cannot. There is puffery, defined as what the average consumer would consider a statement of exaggerated praise, for example, the tag line "feel like a woman." There are formulation claims like "contains aloe." These are the claims that present very little risk.

Then there are product performance claims for both safety and efficacy. Safety related claims can present only slight risk, provided you do the testing required. Safety based claims include claims like "hypoallergenic, allergy tested, ophthalmologist tested and dermatologist tested." Efficacy claims tend to more product benefit specific "wrinkle reduction" for example. These claims present a risk that increases as claims become more aggressive. At present there is no definitive regulatory guidance on acceptable claims in the U.S., as there is in many other jurisdictions. Additionally, there is no regulatory guidance regarding study design, so industry standards have been developed primarily through legal challenges and FTC decisions. Provided you are not making a drug claim in the U.S. or an illegal claim in the rest of the world, you need to validate, or support your claim with evidence, typically in the form of scientific data.

Safety based claims by far carry the least risk, as the methodology for these claims have been around for a long time and enjoy acceptance worldwide. The primary safety test is the human repeated insult patch test or HRIPT. There are several claims that are commonly made from a simple HRIPT; allergy tested, clinically test, dermatologist tested if the study is conducted under the auspices of a dermatologist and hypoallergenic based on a study of two hundred subjects without a reaction. Unfortunately, not every product category can be tested by RIPT. Products that contain known irritants, regimes of products, products for specific parts of the body and products for specific market segments are not good candidates for HRIPT.

When an HRIPT is not feasible, the next method usually employed would be a safety in-use study or an SIU. The study design of most SIU's is usually a four-week period where the product is used as the study sponsor intends to sell the product with periodic evaluations for reactions. The advantage of SIU's is that they are typically conducted by physicians allowing for physician based claims like ophthalmologist tested, or pediatrician tested and additional information can be gathered by adding a questionnaire to the study.

The final area of claims is efficacy testing. There are as many study designs as there are claims, so study design is of primary importance. The first question to be answered is:

1. What claim do you want to make?
2. What instrumentation is available for that claim?
3. How many subjects are needed to support the claim?
4. How long does the study have to run?

Once you know what claim or claims you want to make based on the product's profile, you can check if there is instrumentation to measure the parameter for your claim. Instrumentation allows you to make a quantitative or objective claim, such as "75% decrease in wrinkles." If there is no instrumentation available or you choose not to go to the expense, there are subjective claims typically supported by questionnaire. A subjective claim would be, "75% of the subjects saw a decrease in wrinkles." You should be aware that even if you have good statistically significant objective support you still need to show clinical relevance, as in the above example, seeing the decrease in wrinkling.

The number of subjects necessary is more difficult to approximate, as it depends on how well your product works. The better your product works, the greater the improvement seen, so fewer subjects will be needed to reach statistical significance to support your claim. The study duration should be significantly longer than the time it should take for your product to reach peak effect.

Finally, it is important that whoever is in charge of your claim support study be well informed regarding industry standard study design and instrumentation.