

Are Anti-Aging Claims Drug Claims or Cosmetics Claims?

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In today's video, we focus on anti-aging products to determine whether FDA will likely regard your product as a drug instead of a cosmetic, which where you wanted to be.

Hi, I'm Michael H. Cohen, founding attorney of Cohen Healthcare Law Group. It's a sunny day, it's really me, and the glasses are photogray. We've helped lots of clients just like you, navigate the health and wellness industry through the legal requirements.

Let's talk about the Intended Use Doctrine. FDA determines that the intended use of a product could make it a drug, it looks to the labeling. And "labeling," under the federal Food, Drug & Cosmetic Act (FDCA) will mean "all labels and other written, printed, or graphic matter (1) on any article or any of its containers or wrappers, or (2) accompanying such article." In other words, "labeling" includes everything on the website, such as the blog, the product name, all the marketing.

Everything is "labeling."

Worse (for you), this "intended use" doctrine gives FDA broad enforcement discretion. FDA can look at everything you've put out about the product and say, hey, this sounds like a drug to us. That's the intended use, gleaned from the totality of the contents.

Next, FDA gives particular scrutiny to some kinds of products, for example, Weight loss. The market is flooded with weight loss products whose claims go too far, and if you get to the end of this video, I guarantee you'll lose two inches off your waist! That is, if you simultaneously engage in caloric restriction, read the fine print please.

Okay, weight loss products, big problems for the FDA and the FTC.

Now, you can't look to what other companies are doing as evidence that they are successfully beyond enforcement scrutiny. Lots of people out there, not everyone gets caught. People are doing things, sometimes it takes years, but it can happen and it does happen.

So, enough about weight, let's talk about wrinkles. And there are some fine lines here, pardon the pun. If a product is intended to make lines and wrinkles less noticeable, simply by moisturizing the skin, the FDA will likely regard the product as a cosmetic. Similarly, makeup or "primers" intended to make the signs of aging less noticeable just by hiding them, are also considered, cosmetics.

But products intended to affect the structure or function of the body, such as skin, are regulated as drugs. Note, if they're not

applied topically to the skin, and are machines, they might be considered medical devices. So, for example, if a product is intended to remove wrinkles or increase the skin's production of collagen, it's likely a drug or a medical device.

Put another way, FDA emphasizes that products that are merely "intended to make people more attractive" generally are cosmetics. FDA states that its concern is with claims "that involve supposed effects on the structure or function of the skin." Sound familiar? That's part of the definition.

Remember that drugs and medical devices are much more expensive to bring to market, and the regulatory burden is much higher, so it's better if you can tame your claims to keep your product in the regulatory bucket of a cosmetic—assuming you can do this without sacrificing too much marketing power.

And that's where legal strategy comes in, as FDA lawyers we enjoy working with language, our goal is to help you choose marketing claims that won't likely make the FDA bull charge at you, yet will also waive the flag sufficiently for marketing so that you'll gain market share.

Along these lines, we'd like to refer you to other materials on our Healthcare & FDA blog that talk about ten ways you can unwittingly end up making an implied disease claim for your product.

Thanks for watching. Please [contact us](#) with your questions, comments. We have helped hundreds, thousands of healthcare companies just like you, market their products, navigate the legal and regulatory boundaries. We look forward to working with you on the journey to your success!

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