



An FDA-Listed Drug Isn't an FDA-Approved One

By Lauren Streicher, MD

Open a magazine or scroll any website and you're likely to be bombarded with a plethora of products that promise to remove wrinkles, tighten your vagina, cure incontinence, or ensure orgasmic ecstasy. It's a wonder that anyone has anything but perfect skin, fail proof bladders, and a fabulous sex life, at least if you believe the testimonials that accompany these ads.

But in truth, most of these products haven't gone through any kind of testing process to ensure that what they claim actually happens.

"How can that be?" you ask, "when virtually all of these devices and products have an FDA (U.S. Food and Drug Administration) seal?"

The answer is: An FDA-*listed* drug doesn't equal an FDA-*approved* drug. Despite the reassuring blue FDA logo, these are not [FDA-approved products](#). They're simply cleared, listed, or registered by the FDA.

Which Products Must Be FDA Approved?

It's the FDA's job to establish not only that a prescription drug or medical device works but also that its benefits outweigh its risks. The road to approval for an FDA-approved – not FDA-listed – drug is arduous.

The average time it takes for a drug to get to your pharmacy is 15 to 25 years and requires millions of dollars for research, development, and trials. The FDA doesn't test these drugs; they simply review the testing process used by the pharmaceutical or device company.

Most drugs never make it to the gate. But the only drugs or devices that are required to go through the process are those prescription products and medical devices that are used to treat specific medical conditions.

When FDA-Approved Drugs Are Used 'Off Label'

Sometimes drugs are prescribed to treat conditions that weren't FDA-approved uses, and that can be okay. Use of drugs in ways other than how they were originally intended is known as "off-label" prescribing, and it's something every doctor does. When your doctor prescribes a drug off-label, it doesn't mean that the drug is illegal, or that it won't work, but simply that it's being used to treat

something other than what it was developed and originally intended for.

Every birth-control pill has been FDA-approved to prevent pregnancy. But 30 percent of birth control prescriptions are legitimately written for reducing menstrual cramps, treating endometriosis, or decreasing heavy bleeding, and these are all off-label reasons.

FDA-Cleared Products Aren't FDA-Approved Drugs

The FDA-cleared, -listed, or -registered products are in a completely different category than FDA-approved ones. According to the FDA website, the three levels of products that require FDA clearance

1. **Class 1 products** are those that have essentially no risk and require no regulation (think dental floss).
2. **Class 2 products** require some regulatory control of safety and effectiveness. Condoms fall into this category.
3. **Class 3 products** are for medical use (a heart valve, for instance), potentially high risk, and require full FDA approval prior to use.

But many Class 2 devices are eligible for "FDA-clearance" if they're similar to a device that the FDA has already deemed safe and effective. This is true even if the new device is intended to be used for different purpose, and even if the original device was approved many years ago. With this loophole, an FDA-cleared product is likely to be safe, but doesn't necessarily do what it claims to do.

What's an FDA-Registered or FDA-Listed Product?

The final category, and the most troublesome, is the one designated FDA-registered or FDA-listed drugs or devices. Devices and drugs that manufacturers claim are about wellness and fitness, rather than treating a specific medical condition, don't require a prescription. They also don't need to go through the FDA approval process. For example, a device that claims to [tighten the pelvic floor](#) but markets itself as treating [incontinence \(a medical condition\)](#) would need to be FDA cleared. A similar device that claims to "enhance intimacy" only needs to be FDA registered.

Many claims are simply an impressive triumph of marketing over science.

In the case of FDA-registered products, the company that makes the product, and their marketers, determine what language is used, and yes, what the device claims to do. No scientific studies are required, and no scientific studies are performed, since it's not in a company's best interest to do so. Why would a company spend millions of dollars (scientific studies are expensive) on a study that proves that their invention doesn't actually eliminate wrinkles?

Similarly, the FDA doesn't regulate vitamins, herbs, or other [dietary supplements](#), which is why so many products claim to simply "promote" health as opposed to treating a specific illness.

False Claims on Airborne, Not an FDA-Approved Drug

One product that got nailed was [Airborne](#), a product originally marketed as a supplement that would ward off the common cold. Since Airborne was marketed as a supplement and fell under the [Dietary Supplement Health and Education Act of 1994 \(DSHEA\)](#), the manufacturer legally could make claims without any FDA oversight, as long as there were no "disease" claims for the product.

But, because colds are a specific medical illness and the manufacturer presented NO credible scientific evidence that Airborne prevented colds, a 2008 class action suit by the nonprofit [Center for Science in the Public Interest](#) resulted in a [\\$23.3 million settlement](#). Airborne now only claims to "provide immune support" and "boost your immune system," whatever that means. No matter, millions buy it year still believing it will ward off the common cold.

This is only one of the hundreds of products that line pharmacy shelves and bombard people with promises. If you are confused, you're not alone. And it doesn't help that many products will say they're FDA approved, when in fact they are simply listed. So, a healthy skepticism is appropriate. And when in doubt, a visit to the [FDA website](#) is in order.

PHOTO: Getty Images

Last Updated: 5/31/2016

Important: The views and opinions expressed in this article are those of the author and not Everyday Health. [See More](#)

The Latest in Women's Health