



March 12, 2011 – Grand Rapids, MI

FDA Approved, Revisited

Last Saturday's message on FDA terminology as it relates to dietary supplements wasn't quite as clear as I thought; I base that on the questions you've asked and comments you've made. That's okay because I would rather take the time to be clear and get it right. In this message, I'll expand on each area. Here's the statement again from the FDA:

"The Food and Drug Administration does not have a regulatory definition of pharmaceutical grade for dietary supplements. Supplements are not required to be approved. Manufacturers are not required to submit safety or effectiveness data to the Agency."

Pharmaceutical Grade

As I said last week, there's no regulatory definition of pharmaceutical grade in the FDA lexicon, but it has been used by many supplement companies in recent years especially those who sell fish oil. Manufacturers know there's no legal definition for pharmaceutical grade, so what could they mean by that phrase?

The FDA does have the Dietary Supplement Current Good Manufacturing Practices (CGMP) rule published in the June 25, 2007, Federal Registry. This rule titled 21 CFR part 111 "requires people who manufacture, package, label, or hold a dietary supplement to establish and follow current good manufacturing practice to ensure the quality of the dietary supplement and to ensure that the dietary supplement is packaged and labeled as specified in the master manufacturing record." This document is over 200 pages long and describes in detail everything a manufacturer must do to comply in ensure product purity and accurate labeling (1).

Here's what I think: companies that follow CGMP rules feel their products are pharmaceutical grade as a result. Two problems with that: one, it's the law so every company that manufactures dietary supplements has to comply or get shut down until they comply. In effect, every dietary supplement would be considered pharmaceutical grade. Two, complying with the law doesn't mean that they're pharmaceutical grade because CGMP rules aren't the same as the rules governing pharmaceutical companies.

But let's go one step further. Some manufacturers may go beyond CGMP. They may test their products more often throughout the production process. They may use even more stringent rules for contaminants than the FDA requires. That's a good thing for us as consumers. We want to know that the products we're putting in our bodies are exactly what we think—no more and no less. But at the end of the day, it means they're excellent manufacturers that produce very high-quality products. That's important, but it still doesn't mean they're pharmaceutical grade.

Without a legal definition, the term "pharmaceutical grade" means only what people say it means, no matter how sincere and well-meaning they are. It reminds me of all those mugs that say, "World's Best Dad." You may have been totally sincere when you gave your father that mug, and you may believe it with all your heart, but that still doesn't make him unequivocally the world's best dad.

FDA Approved

As the statement from the FDA states, there are no FDA-approved dietary supplements. So why would manufacturers say something that isn't true? Again, I think it's the way they're interpreting another law: Generally Recognized As Safe (GRAS).

“Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act, any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.”

Dietary supplements are considered foods, not medications. As such, anything added to them must be GRAS. That includes vitamins, minerals, food colorings, preservatives, and other substances. But just because supplements contain GRAS ingredients doesn't mean they're approved by the FDA. I think you can see how much of a stretch that is. It's not even fuzzy—it's just plain untrue, because the FDA has never approved any supplement.

Being FDA-approved means that all types of safety data on the ingredient in test tubes, in animals, and finally in humans would have to be done. On the other hand, if something that will be added to food is approved for that purpose, the law says that type of testing is not required. Would the FDA-approved label mean that much to consumers to make it worth the enormous expense of doing all the testing required and jumping through all the other hoops to comply with the approval process? So far, no manufacturer has decided it is—so no supplement is FDA approved, even if all ingredients are Generally Recognized As Safe by the FDA.

The Bottom Line

I hope that this has clarified things for you if you are concerned about dietary supplements. I've also included the references to both sets of rules so you can check them for yourself if you like.

Words have meanings, especially when dealing with a government agency, and that's why I decided to spend time explaining this in a little more detail. While a term might make sense to you and me, we can't use it if it's inaccurate. I'm not recommending you go to war with anyone using those terms incorrectly, but I want you to know the real story and not be swayed by false claims when you're deciding which supplement to buy.

What are you prepared to do today?

Dr. Chet

References:

1. <http://1.usa.gov/gVfKKH>
2. <http://1.usa.gov/ec2NcW>

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