



# This Title is Not Intended to Diagnose, Treat, Cure, or Prevent Any Disease: Why Sports Nutrition Products Should be Avoided

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I walked into a nutrition and health store in Palo Alto, California, as a customer was returning a bottle of exercise supplements. “It was giving me weird heart rates,” he told the sales associate. After refunding the customer, the associate asked him to check out a brand new supplement and its “advanced formula for working out.” The customer inspected the product and retorted, “These are not regulated by the FDA [U.S. Food and Drug Administration] or government, right?” The associate promptly replied, “Not by the FDA, thank God. If they did, we would never see them in our stores.”

The sports supplementation industry capitalizes on growing trends of self-medicating consumers seeking an “ideal” body type. Advertisements for sports nutrition products (SNPs) want us to believe the idealistic human figure is athletically built and completely toned. In the U.S., a quarter of adults aged 18 and over are estimated to take some form of sport supplement.<sup>1</sup> Furthermore, the U.S. is the largest market for sports nutrition with sales reaching \$6.7 billion in 2015.<sup>2</sup> McKinsey & Company analysts attribute market growth to an increased awareness for preventative care, the development of self-directed consumers, and targeted marketing campaigns.<sup>3</sup> These trends work together to pump wealth into the veins of sports nutrition companies worldwide.

A combination of factors culminates in the current state of affairs. First, lack of pre-market FDA regulation allows for a constant evolution of new products without governmental quality control. Secondly, millions of people are buying SNPs under the assumption that they’re safe. Finally, sly marketing tactics manipulate consumers with extreme claims and alluring packaging. To break this vicious cycle, people must realize the hidden dangers of SNPs through accessible resources that expose their inadequacy and the aberrant malpractice of their companies. These shortcomings are emphasized by the following section titles that incorporate the cautionary statements found on SNP labels. By addressing their regulation, safety, and

marketing, I am going to delve into why ceasing the purchase of SNPs is a wise choice to protect our health.

## **“This statement has not been evaluated by the Food and Drug Administration”: Untamed and Unregulated Products**

Why do SNPs remain unregulated? The FDA was established to protect the public against health hazards, pithily conveyed in their slogan, “Protecting and Promoting Your Health.”<sup>4</sup> However, there is a discrepancy between our presumptions and their principal obligations. The FDA’s regulatory power is limited due to the Dietary Health and Supplement Education Act (DHSEA) of 1994, which excludes “dietary supplements” (including SNPs) from food and prescription drug regulations.<sup>5</sup> Sports nutrition companies are thus responsible for their own evaluations of product safety and labeling before they reach the market.<sup>6</sup>

To clarify, selling adulterated or mislabeled products remains illegal, but sports nutrition manufacturers and distributors “are not required to get FDA approval before producing or selling” their products.<sup>6</sup> No groups or agencies need to test these products unless manufacturers pursue regulatory validation. A primary method of discovering contaminated or misbranded products are Adverse Event Reports that notify the FDA of believed malpractice within the sports nutrition market.<sup>6</sup> However, the FDA does not seek out violations of regulatory validation; existing ones are presented, and the FDA is responsible for operating retroactively.

Despite aforementioned deficiencies, there is still hope for the FDA’s proactive efforts concerning SNP regulation. In 2011, the FDA released a groundbreaking draft on industry guidance for “new dietary ingredients,” defined as those not used in supplements before 1994, when the DHSEA was enacted.<sup>7</sup> In a review of the industry guidance, Harvard Assistant Professor of Medicine Dr. Pieter Cohen affirms that “the proposed guidance clarifies the level of evidence the FDA would

use to assess safety," but he does not believe "the FDA has gone far enough" in regards to requiring companies to produce fresh and conclusive experimental data for the safety of new ingredients.<sup>8</sup> This new industry guidance would be a step towards additional pre-market regulation, but its implementation is hindered because the FDA is still working on revisions.

Currently, a company's credibility can be verified mainly through the optional regulation it seeks, such as by reliable third-party testing groups which are free from conflicts of interest and are further accredited by external organizations.<sup>9</sup> A prime example is the National Science Foundation (NSF), recognized by the U.S. Anti-Doping Agency (USADA) and major league sports associations. The foundation uses the NSF/ANSI 173 standard, which is "the only standard currently available for evaluating dietary supplements" such as SNPs.<sup>9</sup> The NSF investigates product adulteration and crosschecks labels against contents to provide high-quality safety information for consumers. Unfortunately, there are only 623 SNPs certified by the NSF compared to thousands that are not.<sup>10</sup>

Being aware of a trustworthy testing source is helpful, and so is the ability to research the track record of individual companies. The FDA's previously mentioned reporting service keeps track of adverse events such as possible company malpractice and potentially harmful products and makes this information publicly available to consumers.<sup>11</sup> A major drawback is the system's reactionary nature; substantial reports on newly marketed supplements are unlikely. Nonetheless, scanning a company's FDA track record could provide helpful information to facilitate informed decisions before purchasing a product.

### **"Consult with your physician before using this product": What You See is Not What You Get with SNPs**

Unfortunately, many SNPs end up adulterated or mislabeled, and third-party studies quantify the scope of harmful substances on the market. For example, in 2008, Dr. Hans Geyer and colleagues analyzed the composition of 634 SNPs from 13 countries for the presence of potentially dangerous substances not represented on the label.<sup>12</sup> Almost one in five products were contaminated with anabolic steroids.<sup>12</sup> In

2006, a similar study by Baume et al. concluded that contaminated products "could lead to several and unintentional consequences on morphological appearance and behavior. Depending on the time period of the treatment, these psychological and physiological effects could be dangerous and irreversible for the consumer."<sup>13</sup> One in five companies makes billions of dollars by selling hazardous products to millions of people, which is doubtlessly cause for concern.

Moreover, it is also vital that consumers understand even "good" SNPs do not have consistent scientific bases for effectiveness. The FDA requires companies to notify them if their product contains ingredients not marketed before 1994, when the DHSEA was enacted. For post-1994 "new ingredients," companies are allowed to use past findings from scientific literature to demonstrate the benefits of the components in their product.<sup>6</sup> Unfortunately, the referenced literature could have studied a different dosage or delivery method making it difficult to assess product effectiveness in humans. Furthermore, the FDA acknowledges that "there is no authoritative list of dietary ingredients that were marketed in dietary supplements before October 15, 1994," which means companies decide if they will submit a "new ingredient" notification or not.<sup>6</sup> Again, we see that regulatory responsibility belongs to the companies themselves.

The shocking outbreak of acute non-viral hepatitis (non-contagious liver inflammation) in Hawaii in 2013 exemplifies the hazards of seemingly unadulterated SNPs. Described by Johnston et al. as "one of the largest statewide outbreaks of dietary supplement-associated hepatotoxicity," this spate of life-threatening liver problems was linked with ingestion of OxyELITE Pro™, a weight loss and energy supplement created by USPlabs®.<sup>14</sup> Deplorably, two patients required liver transplants and one patient died as a result.<sup>14</sup> State investigators screened the product in conjunction with the FDA and confirmed, "analysis found consumed products were consistent with labeled ingredients [of OxyELITE Pro™]" with no evidence of overdosing reported.<sup>14</sup>

Yet one ingredient, aegeline, worried the FDA. They deemed it a "new dietary ingredient" and issued USPlabs® a warning letter to cease product distribution because the company failed to provide safety infor-

mation for aegeline before selling OxyELITE Pro™.<sup>15</sup> As previously stated, there is no definitive list for new dietary ingredients, but on November 17, 2015, the U.S. Justice Department indicted six USPLabs® executives for involvement in the adulteration of OxyELITE Pro™ with “synthetic” stimulant drugs: 1,3-dimethylamylamine (DMAA) and aegeline.<sup>16</sup> Relatedly, the USADA warns that no regulatory body can test for all substances, and it is difficult to analyze adulterated products with the continuous evolution of synthetic “designer drugs.”<sup>19</sup> During the study conducted by Johnston et al., researchers could not pinpoint which ingredient caused the non-viral hepatitis, but recently aegeline was linked to the disease outbreak.

This case study brings us back to the NSF. With the NSF/ANSI 173 standard, the foundation assures “a dietary supplement contains the ingredients claimed on the label, either qualitatively or quantitatively, and that it does not contain specific undeclared contaminants.”<sup>17</sup> However, synthetic and newly evolving ingredients can elude current scientific analyses, such as in the case of aegeline. Additionally, the NSF and other organizations do not check the validity of products’ claims, an astonishing fact that Dr. Cohen confirmed when I reached out to him for comment. In fact, “no one tests for efficacy of supplement products,” he said, “given the current regulatory environment, consumers are not able to obtain accurate information about [the claims of] supplements on store shelves.”<sup>18</sup> This account is not meant as an attack on reputable organizations, rather a sobering realization that billions of dollars are spent on products that modern science has difficulty proving safe and effective for humans.

### **“Please Read the Entire Label Before Use”: Unreasonable Promises and Exploitative Marketing**

Millions of people are buying SNPs in pursuit of fitter bodies. With regulatory ignorance and a lack of a convincing body of evidence, negligent supplement companies manipulate the public’s understanding in attempts to exploit desires to improve health. SNP marketing targets consumers’ aspirations, openly illustrated by the advertisements and images they use. The most obvious examples are photographs of hyper-fit men and women emblazoned on product labels or advertising campaigns. In *Visual Persuasion: The Role of Images in Advertising*, University of Penn-

sylvania Professor Paul Messaris notes, “photographs supply crucial documentation, without which an ad can lose much of its power to convince the viewer.”<sup>19</sup> Though a simple strategy, images of perfectly toned individuals juxtaposed with a company’s products visually influence a consumer to link them together.

Beyond graphics, companies market and label their products primarily through structural and functional claims focused on beneficial effects.<sup>6</sup> For most dietary supplement claims, U.S. law “does not require the manufacturer or seller to prove to FDA’s satisfaction that the claim is accurate or truthful before it appears on the product.”<sup>20</sup> As resources permit, the FDA will monitor supplement labels after a product has entered the market.<sup>20</sup> This level of labeling autonomy and the extrapolation of scientific data mentioned in the first section allow companies to make bold claims about how their products work. For example, a sports supplement could state it “supports extreme muscle building power,” or “promotes maximum energy performance.” Eloquent diction is entertaining to read — sometimes highly enticing — but the devil is often in the details, and the details are in the asterisks associated with SNP claims. The fine print of SNPs provides disclaimers that the FDA has not evaluated claims and the products are not meant to diagnose, treat, cure, or prevent any disease.<sup>6</sup> The asterisk is a symbolic reminder hidden in plain sight that SNPs have not been rigorously tested for their safety and efficacy within the human body. The alluring statements of SNPs capture attention and intrigue as intended, but desires for a better body fall prey to their often misleading promises.

### **Calling for a Culture Shift**

Resources providing insight into the safety and efficacy of SNPs indicates a lack thereof. Absence of appropriate regulation, unfounded scientific claims, and exploitative marketing perpetuate a vicious cycle that makes SNPs dangerous to consumers. Even though research clearly exposes the dangers of SNPs, people will inevitably still purchase them. SNPs are a growing billion-dollar industry, and they are marketed as a shortcut to fitness. At the very least, consumers should minimize the potential for harm by evaluating sports nutrition companies and their products through resources such as FDA records

and NSF regulation. Third-party testing can identify “safer” SNPs, but synthetic additives can still evade toxicity analyses. No resource can protect you from all malpractice, no organization tests for product efficacy, and there is no guarantee that SNPs work. As individuals, we have the freedom to choose our nutrient sources. Rejecting the use of these products is a safe and smart option, because we can threaten our health by using SNPs for the sake of it.

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