

\$8 Million Worth of Jack3d and OxyELITE Pro... Down the Drain

written by Mike Roberto | July 17, 2013



Earlier this week, the FDA reported that **USPLabs has destroyed a whopping \$8 million worth of Jack3d and OxyELITE Pro.**[1] The pre workout supplement and fat burner are USP's flagship products, but have been under FDA scrutiny for over a year due to their use of their stimulant content.

The destruction occurred on July 2, 2013 at the company's warehouse in Dallas, TX, which we can only imagine was a sad, sad day in USPLand.

This comes as a moderate surprise in the never-ending FDA saga – Exactly three months ago, we broke the news that USPLabs was halting production. Apparently, they still had quite the stockpile, which has been selling at the online stores listed on our Jack3d and OxyELITE Pro pages.

Distribution of remaining stock leads to FDA “Detainment”

It was that decision made months ago – to keep selling what was left in stock – that got USP into its next pot of hot water.[2] The FDA, which disagrees with USPLabs' stance on the products, issued a *detainment order* for the products and asked USP to destroy them.

We can only imagine what the issuance of a “detainment order” is... but one thought that comes to mind is a team of DEA agents with loaded AK's pounding the doors in...

According to the FDA's regulations,

*Administrative detention provides a means through which **FDA can hold adulterated or misbranded food** and prevent it from reaching the marketplace, thus further enhancing FDA's*

ability to ensure the safety of food for U.S. consumers.[3]

Emphasis ours. See source [3] for more information on detainment, which was brought to you courtesy of the Bioterrorism Preparedness and Response Act of 2002.

Get it while you can...



Fans who use it properly – Get it while you can...

While casual consumers have long thought that these products were illegal and unavailable, the opposite is actually the truth.

That said, with \$8 million worth of the supplements now off the table, the existing stock will certainly dwindle far faster than expected or hoped. So if you are a fan who *follows the label and dosing instructions*, now is definitely the time to stock up. Once it's gone, it's *really* gone this time.

GNC Under Similar Fire

GNC has been on USP's side the entire time, which has brought the ire of the FDA as well. Federal prosecutors procured authorization from two state judges to seize over 3,000 cases worth of Jack3d and OxyELITE products from their warehouses in Pittsburgh and Anderson, SC.[4]

GNC's spokesman, Greg Miller, believes that their seizure was retaliation for their public backing of USPLabs over the past year:

"Given this situation, it is hard to view this action as anything other than a biased agency action against GNC in retaliation for GNC's stance on [the stimulant]."

– Greg Miller, GNC Spokesman

That basically covers the news component of this post. Now it's time for some subjective analysis and a recap of the situation in whole:

Were the FDA's actions even legal?

Before I go any further, allow me to note that I am not a lawyer, nor is any employee of mine. We are not affiliated with USPLabs in any way, shape, or form. This site does not physically sell *any* products, nor do we warehouse or distribute them.

That said, let's take a look at the following points:

1. The stimulant was not outright banned by FDA using their own rulemaking procedures.

The FDA's director of dietary supplement programs has merely stated that "*We don't want consumers using the products. We think they present a risk to public health*".[5]

There are surely plenty of things the FDA doesn't "want", and plenty of things they "think". But that does not make a law. That does not make a *fact*.

And the fact is, the stimulant has *never been proven* to be the stimulant that has caused anybody health problems when used properly per the label. That is the truth.

But it gets far hairier than that.

In fact, the above points really don't mean much in the legal scheme of the situation. The process went something like this:

1. USPLabs claims the stimulant is a natural constituent of *geranium Pelargonium graveolens*.

The FDA claims that it is not compliant under DSHEA, as several studies haven't found the stimulant in other geranium plants, and the organization did not see proper procedure in the studies that USPLabs references.

Because of this, the FDA claims that it cannot be marketed as a *dietary supplement*.

2.



Does it, or doesn't it contain it? Depends on who you ask and where they get it from...

It's currently extremely ambiguous as to **who carries the burden of proof**.

The FDA says "No, you prove it." USP says "Here's proof. You prove that it isn't." The FDA says "That proof isn't good enough. Here's some other geranium plants that *don't* have it."

This game can go on forever no matter how powerful your science is – because there is a *massive* variance in *any* plant's constituent content. Based upon what region it's in, the exact genetic lineage, the soil conditions, the hydration status, temperature control, etc etc.. the plants all behave differently.

So, as it stands to the FDA – and that's what is currently the "law" being enforced – **it is not illegal, but it is illegal for use as a dietary supplement**, due to the lack of NDI (new dietary ingredient) paperwork that they find acceptable.

2. **There is no NDI on it.. Because it was sold before 1994**

Patrick Arnold undoubtedly brought it to the market, as it had been sold by Eli Lilly from the 1940s up through the 1980s (the FDA's own words)[6]

Since it had been sold before 1994, it was exempt from requiring NDI according to the FDA's regulations.[7]

But was Eli Lilly using it as a *supplement*? Maybe not, but *geranium oil* was. So let's get into that..

3. **Geranium Oil is GRAS (Generally Regarded as Safe) Exempt**

And by extension, all of geranium oil's constituents are exempt as well.[8]

Again, we come back to the argument – **does it come from any geranium oil?**

And again, we come to the question of the burden of proof.

4. **Are Jack3d and OxyELITE Pro adulterated or misbranded?**

The products contain 1,3 Dimethylamylamine HCL, and their labels state it as such.

But are they misbranded as *supplements*? That is where the FDA stands.

So in the end, it all really comes down to whether or not this stuff is truly natural, and in the FDA's eyes, there's never been proof beyond the shadow of a doubt.

It's just one nasty, long legal case, and this post has probably touched upon 10% of it. It's all in a very gray area in terms of the laws, and it was getting to the point where it simply wasn't worth fighting for.

This gray area is the current battleground, and one that USPLabs helped to push.

..But what was USP going to do?

At this point, after this whole mess, it was just time to let go. If USP fought this one, things likely would have gone down like this:

1. Spend \$2-3 million fighting the FDA in courts and funding more third-party studies on geranium Pelargonium graveolens, with a high probability of losing anyway.
2. Enrage the FDA, bringing on other "witch hunts" and "random inspections" that would likely yield several financial sanctions, based upon bylaws that you and I could hardly imagine.
3. Bring further bad press

Since USP was done manufacturing the products anyway, it was time to call it a loss. To our knowledge, they had really never been fined much, so let's consider this \$8M destruction their final fine and call it a day.

Fighting in the gray area – Respect to USP



Many casual fans have claimed USP should have done more to fight the FDA. They certainly could have done this – the detainments can last only 30 days maximum (while authorities determine to press charges or take further actions), which gave them a chance for a final fight.

But what you need to realize is that they were the *only* company to stand up for their rights (and the industry in general), and went 1000X further than any other company did when the violations came out in spring of 2012. They stepped into what they knew was a gray area, and at least held the line.

They deserve respect for their fight, and have done nothing but take it on the chin in terms of negative mainstream press and lost revenues. In a way, they kept the FDA at bay and forced them to work within the confines of *their own laws*. This pushback has provided a sort of balance to the ambiguous laws the industry works within.

It kills me to say it, but it is time to let Jack3d and OxyELITE Pro rest in peace.

The good news? The Jack3d Advanced Formula is here, and despite the lack of the stim, it's pretty good. See our review for more info.

References

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