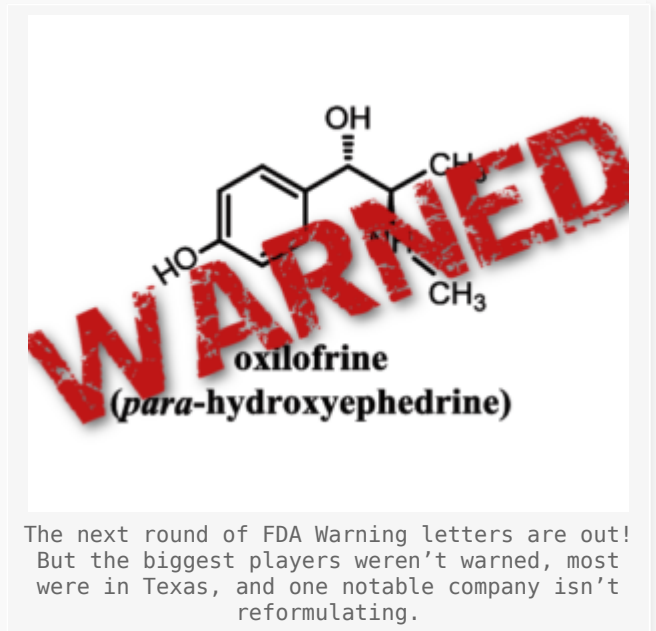


Methylsyneprine FDA Warnings, Hi-Tech Not Reformulating

written by Mike Roberto | April 7, 2016



On March 31, 2016, the FDA issued seven warning letters to supplement companies regarding **methylsyneprine**: since it does not meet the definition of a dietary supplement, it cannot be sold as one.[1]

Methyl-syneprine is also known as *oxilofrine*, *p-hydroxyephedrine*, and *1-Hydroxypholedrine*. It's a known banned substance in most sports due to its performance-enhancing properties.

The FDA states that it does not fit under the definition of a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of the preceding substances, per the 1994 DSHEA Act's requirement.[2]

Who received the warning letters?

Seven companies for eight products:

- Nutraclipse, Inc. – Thermo Bombs[3]
- Swagger Supps (Skyline Nutrition) – Miami Lean[4]
- Total Body Nutrition, LLC – Ephedra Free Tummy Tuck and Ephedra Free Shredder[5]
- Xcel Sports Nutrition, LLC – Leaner You[6]
- M4 Nutrition Companies, LLC – iBurn 2[7]

- **Line One Nutrition, Inc – Fat Burning Lean Pills**[8]
- **Chaotic Labz – Malice**[9]

Of note, Marc Lobliner's **MTS Nutrition** escaped without a warning letter, despite versions of their popular *Drop Factor* fat burner containing the ingredient.

Interestingly, one of these products, Line One Nutrition's Fat Burning Lean Pills, contains additional ingredients that the FDA dislikes and is battling Hi-Tech Pharmaceuticals over in court this year. It receives extra attention in Line One's letter.

Similarly, NutraClipse's Thermo Bombs also contain DMBA, also known as AMP Citrate, another ingredient that the FDA has warned against – and nobody's fighting those warning letters as its basis in nature is extremely weak, at best (it's only seen as a *vapor* from pouchong tea).

The inclusion of those ingredients may have accelerated the cases against those two products.

Based upon Another Pieter Cohen Study?

The FDA's investigation once again is aligned with the release of a Pieter Cohen study, published in Drug Testing and Analysis.[10]

Cohen has gone on the record stating that,

If a bottle contained a trace amount of oxilofrine, then the oxilofrine would be unlikely to pose a serious health risk.

However, if supplements contained prescription-doses of oxilofrine, then I would be extremely worried about the health effects. We would worry that high doses of oxilofrine would over-stimulate the heart, increase blood pressure and possibly lead to much more serious health problems.[11]

– Dr. Pieter Cohen

In his study, Cohen lists all products with the ingredient, and the doses found, so you can look at the study to see what products have it.

Very interesting that many of the products that state they have the ingredient had **none detected!**

Table 1. Information provided on the label and actual oxlofine content in 27 brands of dietary supplements

Code #	Product name (manufacturer)	Label description of oxlofine [labelled quantity of oxlofine/serving]	Claim provided on label	Serving size listed on label	Maximum recommended daily dose listed on label	Number of other ingredients listed on the label**	Average weight per tablet or capsule (mg)	Measured amount (mg/serving size)	Measured amount (mg/maximum recommended daily dose)**
D517364	HyperDrive® 3.0 (ALR Industries)	methylsyneprhine	hardcore diet and energy aid	1 capsule	4 servings	7	751.8	61	250
D517381	Shredder (TBN Total Body Nutrition)	methyl syneprhine	a killer ABS formula	1 capsule	3 servings	11	735.1	75	220
D517360	Fastin® (Hi-Tech Pharmaceuticals)	methylsyneprhine HCl	pharmaceutical-grade weight loss aid for optimal diet and energy	1 tablet	4 servings	7	830.4	48	190
D517367	Lean Pills™ (Line One Nutrition)	methyl syneprhine	fat burning	1 capsule	4 servings	6	501.9	25	98
D517383	Tummy Tuck (TBN Total Body Nutrition)	methyl syneprhine	a killer ABS formula	1 capsule	3 servings	11	702.6	15	44
D517355	Methyl Drive™ 2.0 (ANS Advanced Nutrition Systems)	methylsyneprhine	powerful thermogenic rush	1 capsule	1 serving	6	712.7	35	35
D517357	Drop Factor™ (MTS Nutrition)	methylsyneprhine HCl	thermogenic powerhouse	2 capsules	2 servings	14	671.7	16	33
D517359	Exile (AmericanMuscle Sports Nutrition Company)	methyl syneprhine	euphoric weight loss	1 capsule	3 servings	20	750.4	8.4	25
D517356	China White 25 Ephedra (Cloma Pharma Laboratories)	methylsyneprhine	energy, thermogenesis, alertness, fat burning	1 tablet	2 servings	12	1124.5	11	23
D517376	Phenadrine™ (APS)	Acacia rigidula extract leaves (methylsyneprhine)	world strongest diet and energy aid	1 capsule	3 servings	5	671.6	3.8	11
D517363	Hypercor™ (Ket-a-lyst Nutraceuticals)	methyl syneprhine HCl	metabolic formula	3 capsules	2 servings	30	772.5	0.60	1.2
D517372	MethylDrene™ 25 Ephedra Elite stack (Cloma Pharma Laboratories)	methylsyneprhine [20 mcg]	super intense-hardcore version	1 capsule	2 servings	15	735.8	0.025	0.050
D517373	Miami Lean (Skyline Nutrition)	methylsyneprhine HCl [10 mg]	fat burner	1 capsule	2 servings	29	754.1	0.010	0.020
D517379	Eliminator X (Rok Hard Body Sports Nutrition)	methyl syneprhine	maximum strength formula	2 capsules	1 serving	9	521.2	0.0003	0.0003
D517385	Ultimate Burn (Schwartz Laboratories)	methylsyneprhine HCl [25 mg]	the ultimate thermogenic fat burner	2 capsules	3 servings	19	670.7	ND	ND
D517369	Matria-Xtreme (iOne Body Nutrition)	methyl-syneprhine HCl [8 mg]	fat loss formula	3 capsules	1 serving	10	708.6	ND	ND
D517358	Ephedra X (Oxol sports nutrition)	methyl syneprhine	advanced weight loss formula	1 capsule	2 servings	6	781.9	ND	ND
D517362	FireStorm™ (GE Pharma)	methyl syneprhine	hardcore thermogenic	1 capsule	2 servings	11	485.2	ND	ND
D517365		methyl syneprhine	thermogenic fat burner	1 capsule	2 servings	9	575.5	ND	ND

Table 1. Continued

Code #	Product name (manufacturer)	Label description of oxlofine [labelled quantity of oxlofine/serving]	Claim provided on label	Serving size listed on label	Maximum recommended daily dose listed on label	Number of other ingredients listed on the label**	Average weight per tablet or capsule (mg)	Measured amount (mg/serving size)	Measured amount (mg/maximum recommended daily dose)**
D517366	Incineration (EN Energized Nutrition)	methyl syneprhine HCl	fat loss and detox complex	2 capsules	1 serving	14	651.5	ND	ND
D517371	Burn™ (M4 Nutrition Company)	methylsyneprhine	extro-potent fat burner	1 capsule	2 servings	16	700.9	ND	ND
D517377	MethylDrene™ 25 Ephedra ECA stack with cayenne and ginger (Cloma Pharma Laboratories)	methyl syneprhine	fat burning formula	2 capsules	2 servings	25	658.4	ND	ND
D517380	Burn™ (Pinnacle Sports Nutrition)	methyl syneprhine	rapid fat loss accelerator	2 capsules	1 serving	9	700.9	ND	ND
D517382	Thermolombs (NutraClipse Premier Sports Supplements)	methylsyneprhine	accelerates metabolism (body recomposition agent)	1 capsule	2 servings	11	695.9	ND	ND
D517384	Noiner 8 (Twisted Genetix)	methyl syneprhine	advanced fat burner	1 capsule	2 servings	9	600.3	ND	ND
D517386	Ultra Fire (Live 4 Life Health)	methyl syneprhine	thermogenic metabolic booster	1 capsule	2 servings	8	538.1	ND	ND
D517387	Burn-FX (Tokkyo Nutrition)	methylsyneprhine	weight loss	2 capsules	2 servings	8	771.2	ND	ND

ND, not detected.
* Figure S3 has photographs of labelled ingredients.
** The calculated amount was rounded to two significant figures.

The amounts of methylsyneprhine found in the supplements stating it on the label. Honest truth here? We're more upset about those who said it *is* on the label yet didn't have any, than those who put it in there.[10] Note: Click on the image to zoom in. With this image, you may need to right-click on it and select "Save Link as" to save the big one.

Industry Comments: Hi-Tech is NOT Reformulating

We reached out to a few companies for public comment. There are two different approaches.

Marc Lobliner, founder of MTS Nutrition and executive of TigerFitness.com, whose fat burner Drop Factor previously contained the ingredient stated

Drop Factor has already been reformulated to avoid any

issues and the new version is out within a couple weeks!

– Marc Lobliner, MTS Nutrition

We'll be on top of that new formula when we are allowed to publish it.

On the other hand, Jared Wheat of Hi-Tech Pharmaceuticals stated that the **Hi-Tech Family is not reformulating** away from methylsyneprine. They claim that they have already received the FDA's blessing on one of their methylsyneprine-containing products (likely Fastin) after ephedrine was banned and they were looking for approval on a legal replacement. Per Wheat, they've been legally selling it for 13 years and aren't stopping now.

Basis in nature?

While one study goes so far to say that *"Methyl-syneprine is purported to occur in nature, does not occur in bitter orange extract, and is of synthetic origin in this product and other products that have been marketed,"*[12] that doesn't preclude it from being in other plants. Bitter orange is simply the most common place to find *regular* syneprine.



This Southern Texan plant, *Acacia Rigidula*, contains some incredible fat burning and mood-enhancing compounds. We wouldn't at all be surprised if methylsyneprine was one of them, given that it has nearly everything else.

For instance, molecules extremely similar (if not the same) as methylsyneprine have been found in nature. One study showed that *R-(-)-β-O-methylsyneprine* is naturally-occurring,[13] and that drags us into the argument about the specific wording of DSHEA, which one could argue is unconstitutionally vague in such cases.

We also wonder if someone looked hard enough, would we find methylsyneprine in *acacia rigidula*? After all, everything else seems to be found in that plant.

On the flip side, other large organizations, such as Steve Mister of the Council

for Responsible Nutrition (CRN), have stated that including the ingredient is “*blatant illegal activity*”.[14]

We’re not sure how far this battle will go (if anywhere at all), but we’re almost certain that Hi-Tech Pharma would fight any warning letter they received. This will almost definitely leave the ingredient in a gray area, and smaller supplement companies who use it will have some tough decisions to make moving forward.

PricePLOW chimes in

In our opinions, the *bigger* crime here are those who potentially lied about having it in their products, yet none was found. We can argue the legality of the ingredient itself all the way to the Supreme Court – but **there’s no arguing the illegality of *not including something*** that you say you’re including.

What other products contain Methyl-Synephrine / Oxilofrine?

First, the Hi-Tech Family products that we know will *not* be reformulated:

- **ALR Hyperdrive 3.0 (contained the second-highest dose found at 61mg)**

ALR Hyperdrive 3.0 – Deals and Price Drop Alerts

Get Price Alerts

Get Hyperdrive 3.0 Price Alerts Get ALR alerts Get Fat Burners price drops

Also get hot deal alerts

No spam, no scams.

Disclosure: PricePLOW relies on pricing from stores with which we have a business relationship. We work hard to keep pricing current, but you may find a better offer.

Posts are sponsored in part by the retailers and/or brands listed on this page.

- **Hi-Tech Pharmaceuticals Fastin (48mg found)**

Hi-Tech Pharmaceuticals Fastin – Deals and Price Drop Alerts

Get Price Alerts

Get Fastin Price Alerts Get Hi-Tech Pharmaceuticals alerts Get Fat Burners price drops

Also get hot deal alerts

No spam, no scams.

Disclosure: PricePlow relies on pricing from stores with which we have a business relationship. We work hard to keep pricing current, but you may find a better offer.

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• **APS Phenadrine (3.8mg found)**

APS Phenadrine – Deals and Price Drop Alerts

Get Price Alerts

Get Phenadrine Price Alerts Get APS alerts Get Fat Burners price drops

Also get hot deal alerts

No spam, no scams.

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So if you're a fan of this ingredient, you can be confident that it'll still be around for quite some time.

And then the rest of them, which may or may not be reformulating:



- **Total Body Nutrition – Shredder** (this product had the highest dose found at 75mg)
- **ANS (Advanced Nutrition Systems) – Methyl Drive 2.0**
- **MTS Nutrition – Drop Factor** (reformulating!)
- **American Muscle Sports – Exile**
- **Cloma Pharma Labs – China White 25**
- **Kat-a-lyst Nutraceuticals – Hypercor**
- **Cloma Pharma Labs – MethylDrene 25 Ephedra Elite Stack**
- **Rok Hard Body Sports Nutrition – Eliminator X**

The rest on the list had ND, meaning *Not Detected*.

Not listed is Gold Star Infrared, which we've recently written about too, due to its inclusion of Kigella-based stimulant, DMHA.

What's with the FDA's Selective Action?



There are quite a few products named in the Cohen study that contain this ingredient, yet several of these companies were not warned.

We're not sure why the FDA was so selective about it – and Hi-Tech wasn't the only company left off that list. Our *guess* is that this has been a “top-up” investigation that didn't make it all the way to the upper echelons of the FDA.

For instance, note that four of the seven warning letters sent were to Texas-based companies, and another in nearby Arkansas. Not a single one of them was from west of Texas, so perhaps this was based upon a regional FDA employee's work.

NutraIngredients may have the quote that answers that question:

Commenting on this discrepancy, Marianna Naum, PhD, strategic communications and public engagement staff in the Office of Foods and Veterinary Medicine at the FDA, told us: “FDA's action provides regulated industry with a clear message regarding the status of methyl synephrine: no firm can now remain under the illusion that methyl synephrine is a dietary ingredient. Preparing a Warning Letter takes time and resources, and products frequently come on and off the market, so the agency works hard to strike the right balance. If FDA waited to act until we were certain we had addressed every marketed product, we wouldn't ever be able to issue these warning letters.”[15]

Most of the companies who received letters are extremely small and their products aren't even found on the most major retailer websites. So perhaps the FDA is starting small and working their way up.

The above article cited is titled *Sen McCaskill: "We shouldn't be relying on Cohen et al to ensure industry is acting responsibly"*. Senator McCaskill is pushing for stronger enforcement for the FDA and not needing reactively rely upon third parties in order to take action.

So now what?

What next? Who knows.

Given the "selectivity" of the FDA here, our guess is that this started with a regional agent, and we aren't sure if they will pursue things further.

The FDA's enforcement behavior has been sporadic at best, always leaving us with more questions than answers. There are at least a few politicians pushing hard for more enforcement, so we may be seeing changes around here.

But we also write that every six months and nothing ever seems to happen, so it'll probably be business as usual, at least until after this election cycle.

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