Supplement Manufacturer ABH Pharma INDICTED After Years of FDA Violations

written by Mike Roberto | January 20, 2020

Many consumers quickly glance at the label on a dietary supplement, blindly purchase it, and never question where it was made or if what's listed on the label is actually in the bottle. But what if you don't even know what you're buying? Has the product been tested to meet label claims, where is it manufactured, and how pure really is it?

After years of failed inspections, warning letters, meetings with the FDA, and recalls… ABH Pharma and their owner Mohammed Jahirul Islam have been *indicted* by the US Department of Justice

Regardless of the myths that surround the supplement industry of 'not being regulated by the FDA', this news story will change your mind. Because this one involves a *serious* indictment after plenty of warning letters, strikes, and failed audits.

FDA indicts major contract manufacturer in ABH Pharma

After years of playing "whack-a-mole" by sending warning letters to small brands, the FDA – and now the *Department of Justice* – have gone after the *root* of the supplement industry's biggest problem: **underhanded contract manufacturers**. These are the companies that are actually bottling the products, and we have long stated that they are a better "pinch point" for strict enforcement of current Good Manufacturing Practices.

On January 17th, 2020, a major contract supplement manufacturer under the names of **ABH Pharma**, **ABH Nature's Products**, and **Stocknutra.com** published a press release on BusinessWire issuing a **nationwide recall** on *all lots of dietary supplements manufactured and sold between January 2013 – November 2019*,[1] after

an indictment was posted in New York on December 26, 2019.[2,3]

Major offenses over several years

After numerous failed inspections, warning letters, and even meetings, the FDA and DOJ had finally had enough

The DOJ indictment, which names *Mohammed Jahirul Islam ("Islam")* as the owner of the three companies, alleges that their facilities distributed **adulterated and misbranded dietary supplements** and **unapproved and misbranded drugs**.[2] They signed a consent decree[3] forcing Islam to destroy all dietary supplements (and drugs) in their possession within 15 days, which has now also been posted on the FDA's website.[4]

The DOJ indictment report stated that ABH *failed 6 FDA audits* over the years, had *warning letters* dating back to 2012, *and* neglected to conduct at least one appropriate test for ingredient identity.[2]

The indictment itself (which is linked at the bottom of the DOJ's report web page) includes new infractions from a November 2018 inspection.[3] Such infractions include some egregious drug claims made on products they manufactured, such as *"Whey protein in the form of protein powder can help in reducing the symptoms associated with anxiety and depression"*.[3]

In addition, ABH Nature's products had a voluntary recall in June 2017 and January 2018 due to possible *salmonella* contamination.[3]

> *"As demonstrated by the consent decree, this Office and the FDA will work tirelessly to protect consumers who take dietary supplements, ensuring that manufacturers comply with good manufacturing practices and do not distribute unapproved and misbranded drugs in violation of the Food, Drug, and Cosmetic Act."*
>
> *– Richard P. Donoghue, U.S. Attorney for the Eastern District of New York[2]*

A long time coming

The indictment lists several inspections at the Defendants' Edgewood, NY facility, including inspections that occurred in or about July 2012, May 2013, August 2013, November 2016, and February 2018, on top of the most recent November 2018 inspection.

The FDA's warning letter from 2012 lists seven major cGMP (Current Good Manufacturing Practice) violations, such as adulteration, mislabeling, misbranding, failure to verify finished supplements, failure to monitor, and failure to follow control processes, and failure to qualify suppliers.[5]

The FDA even held regulatory meetings with Islam and his management team on March 23, 2017, in order to discuss previous deviations,[3] so this indictment was most certainly not out of the blue.

Impending recalls

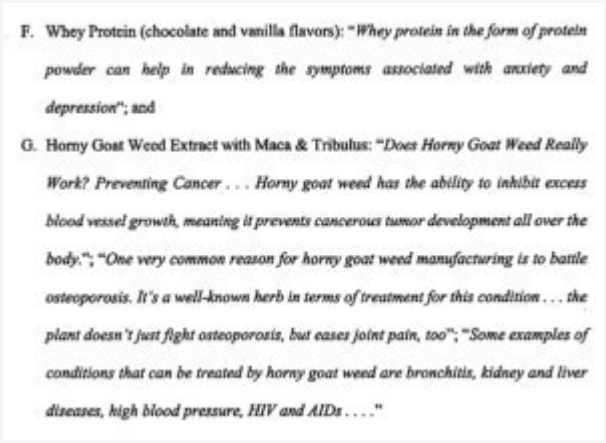
This is a *massive* deal considering the list of over *800* supplement brands for whom ABH produced supplements. Any products that made it to market are subject to recall.

To see the full list of supplement companies *potentially* involved in this recall check out the pdf below:

See the **ABH Customer List** (archived here from BusinessWire)

Note that the list above allegedly includes companies that ordered just a *single* lot from ABH (many of which never made it to market), as explained below.

Defrauded customers?



F. Whey Protein (chocolate and vanilla flavors): "*Whey protein in the form of protein powder can help in reducing the symptoms associated with anxiety and depression*"; and

G. Horny Goat Weed Extract with Maca & Tribulus: "*Does Horny Goat Weed Really Work? Preventing Cancer . . . Horny goat weed has the ability to inhibit excess blood vessel growth, meaning it prevents cancerous tumor development all over the body.*"; "*One very common reason for horny goat weed manufacturing is to battle osteoporosis. It's a well-known herb in terms of treatment for this condition . . . the plant doesn't just fight osteoporosis, but eases joint pain, too*"; "*Some examples of conditions that can be treated by horny goat weed are bronchitis, kidney and liver diseases, high blood pressure, HIV and AIDs . . . .*"

These are just a couple of the egregious drug claims made by ABH Pharma.[3]

To make matters worse, we've received first hand reports that they allegedly

defrauded several companies by *withholding* products and/or money from them. Therefore, multiple brands included on this list may have never shipped products from them or only worked with them for a small period of time before moving on to another manufacturer.

Long story short, *just* because a company is on the above list doesn't mean that their current product offerings are mislabeled or adulterated. However, we'll do our best to stay updated with relevant recalls that *do* occur.

What consumers can do about this…

This should be taken very seriously since it involves a large time frame, widely-used manufacturer and hundreds of supplement companies.

Consumers are being recommended to check the list of companies who sell products manufactured by ABH Pharma to see if they issue a recall in the near future. You may also wish to contact those brands, and many may put out statements on social media. With that information, you will be able to decide if the product needs to be returned to the company or properly disposed of.

ABH is supposed to be contacting all of its customers/distributors over email to request a return of all recalled products. If anyone has any questions, they should email recall@abhnutra.com. Also, if you ever have an adverse reaction, you can report it to the *FDA's MedWatch Adverse Event Reporting* program by completing and submitting a report linked here.

> *"A lot of people say the industry is not regulated, this is a perfect example of how testing, proving label claims for strength, purity, and composition is a requirement by the law. And if you don't do it, you'll eventually be caught."*
>
> *-Benjamin Kane, PricePlow Co-Host*

Final Thoughts: Stay tuned for more information…

We've covered this topic in the past with

NutraBio's Mark Glazier, who explains that Supplements *are* regulated, going over the laws on our YouTube channel.

Before you completely write off the supplement industry, just know there are a ton of great manufacturers and companies doing the right thing, and many incredible certification programs and third-party lab tests available. However, there are bad apples, and for years, we've called on the FDA to enforce their laws at the *manufacturing* level, not just at the brand level.

Despite the bad news, this type of enforcement is the only kind that can *work*, and we're happy to see the FDA and DOJ joining forces to properly level the playing field rather than play "whack a mole" with one-off brands who aren't the ones doing the actual manufacturing.

We will be adding more information as this major story unfolds and companies start to speak out. PricePlow has contacted ABH and some of the companies on the above list to get their comments and find out more details. There will be plenty more to share, so make sure you are subscribed to PricePlow's supplement news alerts and follow us on social media to our take on this topic!

Mark Glazier (NutraBio) and Brent Laffey (Armada Nutrition) Discuss

Brent Laffey of Armada Nutrition and Mark Glazier of NutraBio came on to discuss this indictment and how we all can improve this industry, whether you're a manufacturer of dietary supplements, brand owner, or retailer:

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Statements from Supplement Companies

The following companies have issues statements regarding this situation:

- **Nutrex Research**

  On **January 24, 2020**, Nutrex Research published a statement indicating that only *three* lots of their CLA 180ct supplement were manufactured at ABH Nature's Products in January of 2018. The lots are as follows:

  - Lot #0116119
  - Lot #0117179
  - Lot #0117594

Read **Nutrex Research's Statement** (PDF) or watch their explanation on IGTV below:

View this post on Instagram

□ In light of a national recall of products made by ABH Nature’s Products, Inc.; □□ ABH Pharma, Inc.; and Stocknutra.com Inc., for failing to meet current good manufacturing practice regulations that has affected over 800 companies. We at Nutrex Research, Inc. want to reassure you that our company has not manufactured or sold any of those businesses’ products cited, with the exception of one limited, single production run in January 2018:□□ □□ CLA 180ct with the following Lot Numbers: □□ Lot#0116119□□ Lot#0117179□□ Lot#0117594□□ □□ Consumers who bought CLA 180ct with these specific lot numbers can return the unused portion for a full refund.□□ □□ No other Nutrex branded products were ever made by these companies or are part of this recall.□□ □□ In our nearly 20 years in business, our priority has always been focused on manufacturing and distributing the highest quality products for our customers’ specific

needs.□□ □□ Sincerely,□□ Jens Ingenohl□□ President/CEO□□ Nutrex Research, Inc.□□ □□ If you have any questions or concerns, please give us a call at (407) 359-0734 or email us at info@nutrex.com.□□ Go to this link to view the statement: https://bit.ly/36qqalL

A post shared by Nutrex Research *(@nutrexresearch) on Jan 24, 2020 at 10:50am PST*

The above section will stay up-to-date as information develops.

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References

1. *"ABH NATURE'S PRODUCTS, INC, ABH PHARMA, INC., and STOCKNUTRA.COM, INC. Issues Nationwide Recall of All Lots of Dietary Supplement Products"; BusinessWire; January 17, 2020; https://www.businesswire.com/news/home/20200117005507/en/*
2. *Marzulli, John; "District Court Orders Three Long Island Companies and Their Owner to Stop Distributing Adulterated and Misbranded Dietary Supplements and Unapproved and Misbranded Drugs"; United States Department of Justice; Eastern District of New York; December 26, 2019; https://www.justice.gov/usao-edny/pr/district-court-orders-three-long-island-companies-and-their-owner-stop-distributing*
3. *United States District Court, Eastern District of New York; "Consent Decree of Permanent Injunction"; December 23, 2019; https://www.justice.gov/usao-edny/press-release/file/1230056/download*
4. *United States Food and Drug Administration; Recalls, Market Withdrawals, & Safety Alerts; "ABH NATURE'S PRODUCTS, INC, ABH PHARMA, INC., and STOCKNUTRA.COM, INC. Issues Nationwide Recall of All Lots of Dietary Supplement Products"; January 21, 2020; https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/abh-natures-products-inc-abh-pharma-inc-and-stocknutracom-inc-issues-nationwide-recall-all-lots*
5. *United States Food and Drug Administration; "Warning Letter NYK-DO 2013-2: ABH Nature's Products, Inc. 10/24/12"; October 24, 2012; https://wayback.archive-it.org/7993/20171115100918/https://www.fda.gov/ICECI/EnforcementAct*

ions/WarningLetters/2012/ucm375464.htm