UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA)
V.	Criminal No. 19-CR-30041-MGM
RYAN M. STABILE,)
Defendant)

GOVERNMENT'S SENTENCING MEMORANDUM

The defendant knew what he was doing was illegal, and he did it anyway. He knew what he was selling was highly addictive, and he sold it anyway. After being told to stop selling Tianeptine over and over again, the defendant was defiant. He continued to start new companies and register new websites, and he continued smuggling the dangerous drug into the United States. The defendant profited on his customers' addictions, earning at least two million dollars along the way.

On September 7, 2023, the defendant pleaded guilty pursuant to a plea agreement to a three-count indictment charging him with conspiracy in violation of 18 U.S.C. § 371, and introduction of misbranded drugs with intent to defraud or mislead in violation of 21 U.S.C. §§ 331(a) and 333(a)(2). The United States of America, by Joshua S. Levy, Acting United States Attorney for the District of Massachusetts, respectfully requests that the Court order the following sentence: *incarceration for 48 months; a fine within the Guidelines sentencing range unless the Court finds the Defendant is not able, and is not likely to become able, to pay a fine; a mandatory special assessment of \$300; and forfeiture of \$1,833,922.13, as set forth in the plea agreement.*

I. Factual Background

The facts of this case are set forth more fully in the Probation Department's February 6,

2024 Presentence Investigation Report ("PSR") and summarized herein. PSR, ¶¶ 15-46. The defendant owned a company named Supplements for Work ("S4W"), which sold nootropics, a class of drugs and supplements claiming to enhance mood and cognitive functioning. *Id.*, ¶ 15. The defendant operated S4W through several websites, where he sold various forms of Tianeptine to online customers. *Id.* The defendant knowingly and intentionally sold tianeptine to customers for their personal use, even though his websites displayed disclaimers that sales of tianeptine were for research purposes only and not intended for human consumption. *Id.*, ¶ 16. The defendant smuggled Tianeptine in multi-kilogram quantities from China, divided and repackaged it, and sold it on his websites in 5-, 10-, and 20-gram quantities, for between \$54.95 and \$174.95. *Id.*, ¶¶ 24, 28. Through his illegal smuggling and distribution of Tianeptine on the internet, the defendant earned at least \$1,833,922.13. *Id.*, ¶ 16; Financial Analysis Chart of S4W Tianeptine Sales, attached hereto as Exhibit A.

The investigation into the defendant's crimes began when U.S. Customs and Border Protection ("CBP") intercepted and seized four packages during the approximately two-week period between December 20, 2017 and January 3, 2018. PSR, ¶ 19. Those packages contained approximately 4.2 kilograms of Tianeptine and were shipped to the defendant's employee from a Chinese company. Id., ¶¶ 19-20. The defendant, in an effort to have CBP release the packages, wrote a petition stating that the Tianeptine was for research and development purposes only and instructed his employee to send it to CBP. Id., ¶ 21.

After executing a search of the employee's home and interviewing the employee, Food and Drug Administration ("FDA") Office of Criminal Investigations Special ("FDA-OCI") Agent William Hughes ("SA Hughes") made two undercover buys (on May 15 and 17, 2018) of Tianeptine from the defendant's websites. *Id.*, ¶¶ 32-34. The FDA Laboratory confirmed that

both packages contained Tianeptine. Id.

On June 13, 2018, FDA-OCI agents executed a search warrant on the S4W warehouse in Los Angeles and found tianeptine in various types of packaging and weights, along with shipping and packaging labels bearing the S4W company name and logo. *Id.*, ¶ 34; *see* Photographs from June 13, 2018 Search of S4W Warehouse, attached hereto as Exhibit B. During the search, SA Hughes interviewed the defendant, who stated, among other things:

- (1) He created S4W in June 2017 and ran it through his websites. S4W sold Tianeptine and other supplements.
- (2) He and his team purchased Tianeptine from China.
- (3) His profit margin was 50 percent.
- (4) He believed Tianeptine was legal, though he knew CBP had seized several shipments of Tianeptine.
- (5) He was aware of tianeptine-related overdose deaths in Michigan. He was aware that Michigan had classified tianeptine as a Schedule II drug as a result of the overdose deaths. For this reason, S4W did not ship tianeptine to Michigan.
- (6) He had employees in Texas and Massachusetts who received shipments of Tianeptine from China on behalf of S4W. He also had several P.O. Boxes. He did this because his Chinese contact suggested that he have multiple addresses to receive the Tianeptine.

PSR, ¶ 35. When SA Hughes pressed the defendant further on why he would have multiple receipt locations, the defendant ended the interview and left. *Id*.

Evidence seized from the warehouse, along with e-mails and correspondence produced in response to search warrants revealed that the defendant ran S4W, knew tianeptine was illegal, and made efforts to circumvent CBP's detection. For example, On October 11, 2017, the defendant sent

an e-mail to his Chinese supplier stating that he was "desperate for tianeptine" because "customer demand is high." Id., ¶ 36. The defendant went on to give his supplier instructions on how to evade detection by CBP. Id. He stated:

Your sender name on the address should be different, because I believe CBT [sic] will open packages when they see that they are from your company.

Use a name and not a business as the sender.

. . .

If you're sending a small amount, please declare it as food with customs. Other tianeptine vendors do this by wrapping the tianeptine in food packaging. I suggest you get a large candy and empty it out so the bags of tianeptine will it [sic] inside of it.

Using this method, you do not pay a tariff tax of goods shipped for commercial use. Customs will not bother to open your package. but i [sic] they do, all they will find is bags of powdered candy. This is a method you can use to ship up to 1kg of tianeptine sodium, sulfate, or free acid at a time.

. . . .

Id.

SA Hughes interviewed other S4W employees, who stated, among other things, that: (1) S4W imported between ten and fifteen kilograms of Tianeptine per month; (2) S4W sales averaged \$250,000 per month; (3) 95 percent of S4W's profits were from Tianeptine sales; (4) The defendant knew S4W was selling Tianeptine not for research and development purposes but for personal consumption; (5) The defendant knew that some of S4W customers had become addicted to Tianeptine; and (6) S4W did not sell Tianeptine to Michigan customers because Michigan had banned Tianeptine. *Id.*, ¶¶ 38-40.

The defendant continued to smuggle Tianeptine into the United States from China even after the search of the S4W warehouse. One of the defendant's employees continued to receive email correspondence from the defendant's Chinese supplier even after the employee had left S4W, and she provided those e-mails to SA Hughes. *Id.*, ¶ 39; *see* Oct. 2018 Stabile E-mails with

Chinese Supplier, attached hereto as Exhibit C. The e-mails showed that the defendant continued placing regular orders of Tianeptine with his Chinese suppliers and continued to strategize regarding mislabeling the packages so that CBP did not seize them into December 2018, six months after the search of the S4W warehouse. *Id*.

About seven months after that in July 2019, SA Hughes discovered that the defendant had created a new website to sell Tianeptine. *Id.*, ¶¶ 41, 43. SA Hughes attempted to place an order for Tianeptine in an undercover capacity to a Massachusetts address. His order was quickly declined, with the message, "Sorry, we are not shipping that product in that state." *Id.* SA Hughes changed his shipping address to a Virginia address and was able to complete a purchase of Tianeptine from the defendant's new website on August 7, 2019. *Id.*, ¶ 42. The return address on the package was a P.O. Box that the defendant had earlier provided as his address when he sought the release of certain materials from the search of the S4W warehouse. *Id.*

In August 2019, SA Hughes seized the discarded trash outside of the defendant's Pasadena, California home. *Id.*, ¶ 45. In the trash, SA Hughes found, among other things: Priority mail labels for the defendant's new website's customers with the defendant's Pasadena address listed as the return address; Tianeptine labels; and packing slips for Tianeptine to the defendant at his Pasadena address from his Chinese supplier. *Id.* FDA-OCI later executed a search warrant on the defendant's Pasadena home and found further evidence of the defendant's continued distribution of Tianeptine to customers through his new website. *Id.*, ¶ 46.

FDA-OCI obtained records showing that the defendant's Chinese supplier had shipped to the defendant approximately 15 kilograms of Tianeptine within the approximately six months before the defendant's indictment on October 24, 2019. *Id.*, ¶ 44. At least one of the defendant's websites on which he sold Tianeptine continued to be live until at least the indictment date. *Id.*

The defendant's continued sale of Tianeptine did not stop after he was federally indicted. The defendant has admitted that several years into his pre-trial supervision, he was still selling Tianeptine on the internet. *Id.*, ¶ 5. In August 2022, SA Hughes discovered another website he suspected the defendant was using to sell Tianeptine online. SA Hughes made an undercover purchase of 20 grams of Tianeptine for shipment to a New Hampshire address and charged it to his undercover credit card. He corresponded with the seller through e-mail, which contained a mailing address associated with the defendant. SA Hughes received the shipment of Tianeptine, and his credit card was charged by Ultra Vulgar Festival Drip, the defendant's company. The Tianeptine package contained the disclaimer, "CAUTION: For laboratory research purpose only." The FDA Laboratory confirmed that the package contained Tianeptine. *See* photographs, e-mails, credit card statements, and lab report related to Aug. 2022 undercover Tianeptine purchase, attached hereto as Exhibit D.

II. The Defendant Merits the Requested Sentence

As the Supreme Court explained in *Gall v. United States*, 128 S.Ct. 586, 596-97 (2007), the district court should begin all sentencing proceedings by correctly calculating the applicable Guidelines range. The Court must then consider all of the factors in 18 U.S.C. § 3553(a) to determine whether they support the requested sentence and impose a sentence that is "sufficient, but not greater than necessary." *United States v. Dixon*, 449 F.3d 194, 203-04 (1st Cir. 2006).

The defendant knew what he was doing was illegal, and he knew what he was selling was highly addictive. He continued to import and sell Tianeptine several times after being warned and even after being indicted. After federal agents searched his S4W warehouse in Los Angeles and SA Hughes told the defendant he had committed a crime, the defendant created a new company and website and continued to sell Tianeptine. Years into his federal pretrial supervision, the

defendant continued to sell Tianeptine through yet another company and website.

The defendant did not sell Tianeptine to his customers because he was trying to help people heal their minds. He did so for a much more common reason – money. The defendant made at least \$2.2 million selling Tianeptine as a conservative estimate. *See* Ex. A. The investigation revealed that the defendant purchased 1 kilogram of Tianeptine from China for approximately \$3,000. He sold 5- to 20- gram quantities for between \$54.95 and \$174.95. PSR, ¶ 24. Thus, without factoring in additional costs, the defendant profited between approximately \$5,750 and \$8,000 for each kilogram of Tianeptine he smuggled from China. And he was smuggling kilogram quantities every few days under false labels like "Collagen." *See* Apr. 2018 Shipment Spreadsheet, attached hereto as Exhibit E.

The government acknowledges that the defendant was struggling with substance use disorder at the time he committed his crimes, and that those struggles continue. However, the defendant's own struggles reveal that he was well aware of the dangers of Tianeptine, as he himself could not function without bringing the drug with him everywhere he went. Investigators found on the defendant's a computer a journal in which he listed reasons to quit taking "[h]igh dose tianeptine," including that his dependence on the drug "prevents [him] from doing anything without bringing tianeptine." *See* Apr. 2, 2018 "IMPORTANT AF TO-DO'S," attached hereto as Exhibit F.

While the defendant points to countries that have legalized Tianeptine as a pharmaceutical drug to treat depression and other illnesses, he ignores the fact that those countries have legalized the drug as a prescription drug, to be taken under the supervision of a physician. Instead of warning his customers about Tianeptine's highly addictive nature, the defendant (not a medical professional) marketed the drug on his website as a mood enhancer. The S4W homepage, which

prominently displayed Tianeptine products as three out of its four best sellers, featured the image of a glowing woman about to ingest a pill. *See* Apr. 25, 2018 Screenshot of S4W Homepage, attached hereto as Exhibit G. The defendant also posted many articles on his website about how to take the various drugs he marketed, with titles like, "What is the best nootropic stack?" *Id*.

The defendant hid from his customers that Tianeptine could have devastating effects. Indeed, the FDA has issued multiple warnings regarding Tianeptine, stating that companies selling Tianeptine have made "dangerous and unproven claims that tianeptine can improve brain function and treat anxiety, depression, pain, opioid use disorder, and other conditions." https://www.fda.gov/consumers/health-fraud-scams/tianeptine (last visited Feb. 9, 2024). The FDA has warned: "In the U.S., reports of severe side effects involving tianeptine are increasing. Poison control center cases involving tianeptine exposure have increased nationwide, from 11 total cases between 2000 and 2013 to 151 cases in 2020 alone." *Id.* Tianeptine, which has come to be known as "gas station heroin," has started to garner public attention regarding its harmful effects. *See* Hoffman, Jan, "Gas Station Heroin' Sold as Dietary Supplement Alarms Health Officials," The New York Times, Jan. 10, 2024, attached hereto as Exhibit H.

To date nine states have banned Tianeptine, classifying it as a Schedule I or II drug: Michigan (2018, Schedule II), Alabama (2021, Schedule II), Tennessee (2022, Schedule II), Ohio (2022, Schedule I), Indiana (2022), Kentucky (2023, Schedule I), Georgia (2023, Schedule I), Florida (2023,Schedule I). See https://www.legislature.mi.gov/documents/2017-2018/billanalysis/House/htm/2017-HLA-0801-CED682C8.htm (last visited Feb. 9, 2024); https://wapp.capitol.tn.gov/apps/Billinfo/default.aspx?BillNumber=HB2043&ga=112 (last visited 9, Feb. 2024); https://www.pharmacy.ohio.gov/documents/pubs/newsreleases/2023/state%20of%20ohio%20bo

ard%20of%20pharmacy%20releases%20retailer%20guidance%20on%20illegal%20drug%20tian eptine%20(aka%20gas%20station%20heroin).pdf (last visited Feb. 9, 2024); https://www.kentucky.gov/Pages/Activity-stream.aspx?n=GovernorBeshear&prId=1712 (last visited Feb. 9, 2024). There is also active a proposed U.S. House of Representatives bill, entitled "Scheduling Tianeptine and Analogues Now to Defend Against Emerging Opioids Act," seeking to add Tianeptine as a DEA Schedule III controlled substance. 2023 Cong. U.S. HR 7068, Jan. 22, 2024.

The defendant cited in his Sentencing Memorandum all the cases of which the government is aware involving Tianeptine smuggling and distribution. Defendant Paul Eftang was sentenced on February 5, 2024 in the District of New Hampshire to three years probation. Linda and Mark Godding were each sentenced in 2022 in the District of Colorado to six months incarceration. Notably, all three of those defendants pled guilty to Informations, and their guidelines ranges were 12 to 18 months (Linda and Mark Godding) and 0 to 6 Months (Paul Eftang). *See* Doc Nos. 210-11, 210-12 at 32, 201-17 at 4. Furthermore, Mr. Eftang, unlike Mr. Stabile, pled only to a misdemeanor because he did not defraud or mislead, "swiftly" took responsibility for his conduct, and "immediately ceased [his] illegal activity" after the investigation became overt. *See* Doc. No. 201-17 at 1, 4. Because there are so few charged cases, and the circumstances surrounding the defendant and his conduct are so different from the available data points, the sentences given to other defendants who have smuggled and sold Tianeptine are difficult to compare to the instant case.

III. <u>Conclusion</u>

For the foregoing reasons, the Government respectfully requests that the Court impose the sentence of incarceration for 48 months; a fine within the Guidelines sentencing range unless the

Court finds the Defendant is not able, and is not likely to become able, to pay a fine; a mandatory special assessment of \$300; and forfeiture of \$1,833,922.13, as set forth in the plea agreement.

Respectfully submitted,

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Date: February 9, 2024

Certificate of Service

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Deepika Bains Shukla
Deepika Bains Shukla
Assistant United States Attorney

Date: February 9, 2024

Exhibit A

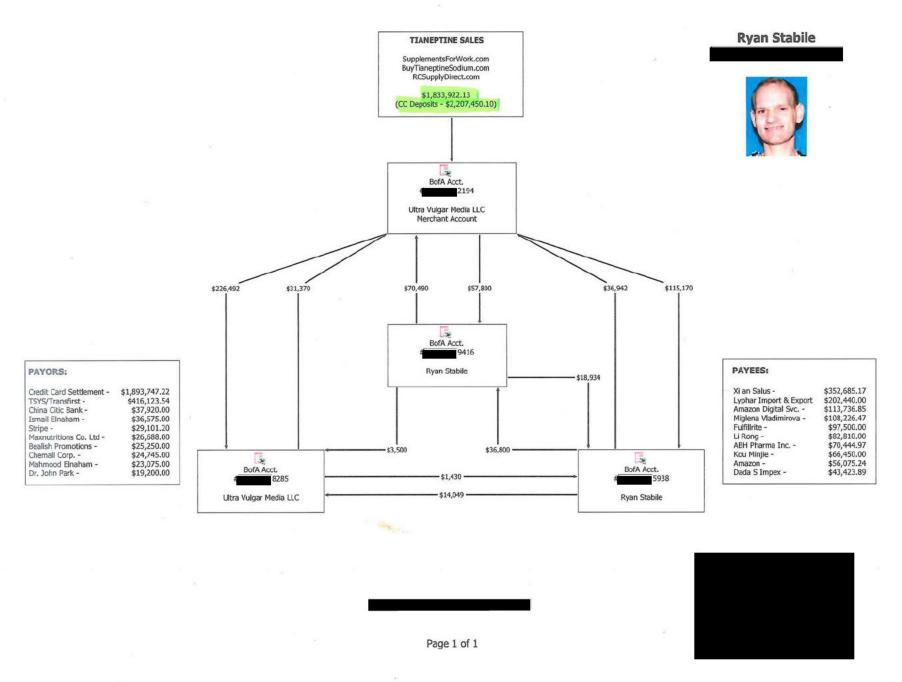


Exhibit B











SKU: TNA424-10a

SKU: TNA424-10a

SHILL THRESH SEE

TIANEPTINE

Supplements For Work TIANEPTINE SODIUM

SODIUM

GRAMS
CAS: 30123-17-2

LOT: NTS-YY20180329

Supplements For Work TIANEPTINE

SKU: TNA424-108

Supplements For Work

TIANEPTINE

SKU: TNA424-10a

LOT: NTS-YY20180329

Supplements For Work

Supplements For Work TIANEPTINE NEW MARKET GRAMS D180329 SKU: TNA424-10a Nork Supplements For Work VE TIANEPTINE ML **VIS** 23-17-2

> Work NE

20180329

123-17-2

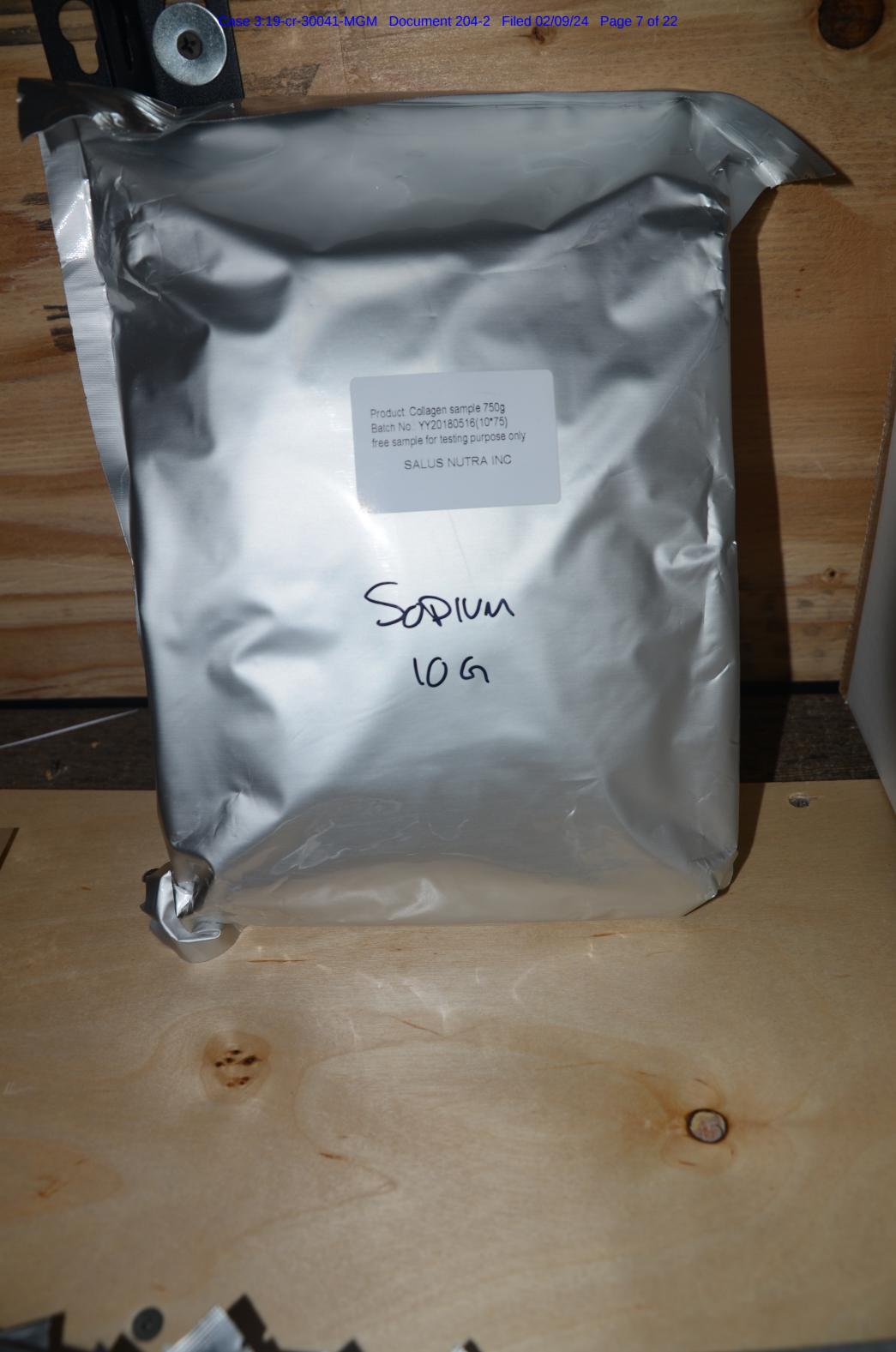
TOTAL SECTION.

Supplements For Work TIANEPTINE

CAS: 30123-17-2

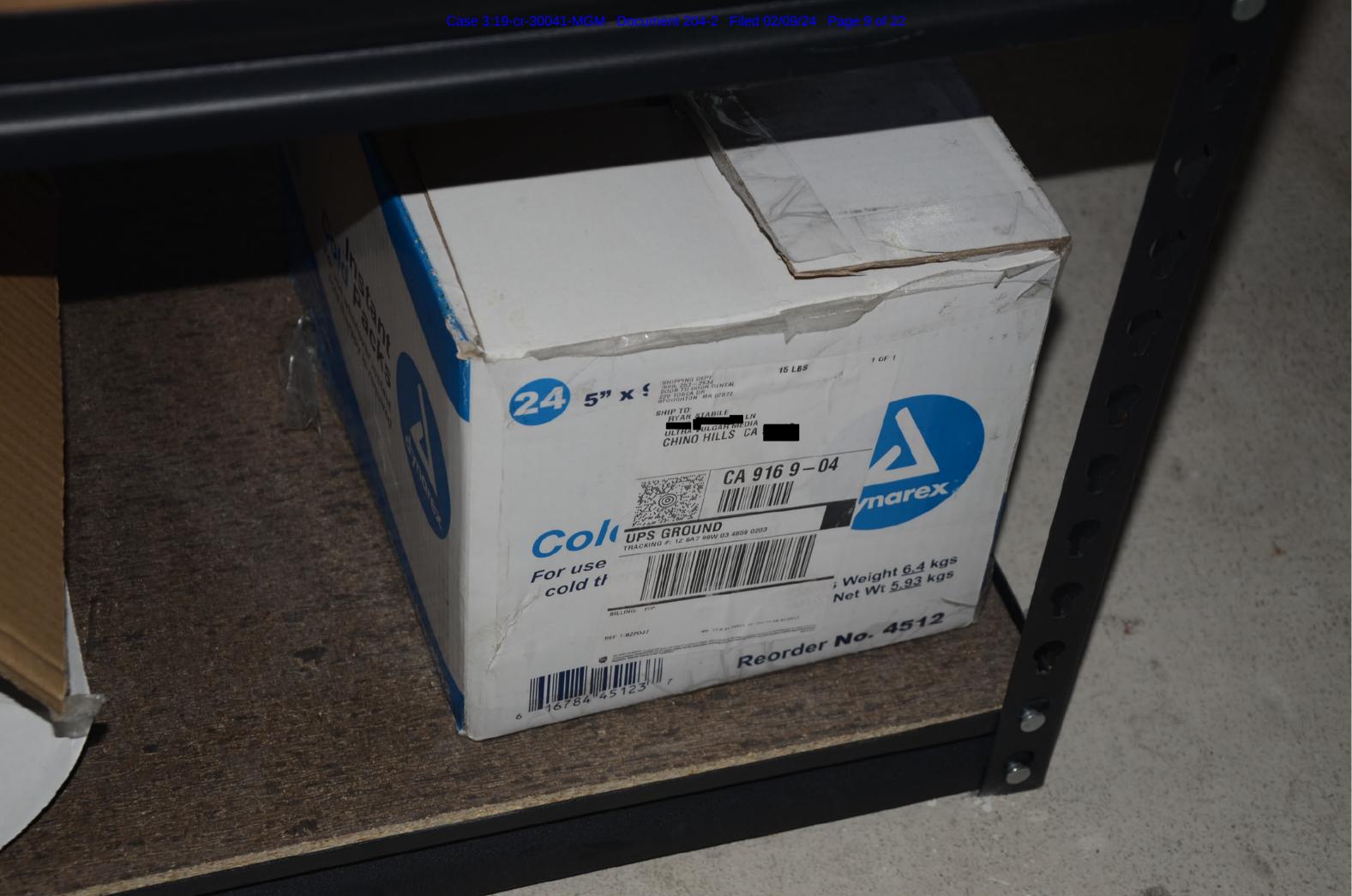
SALE SEES OF STREET MAKE SEE

BROLL TRANSPARISH

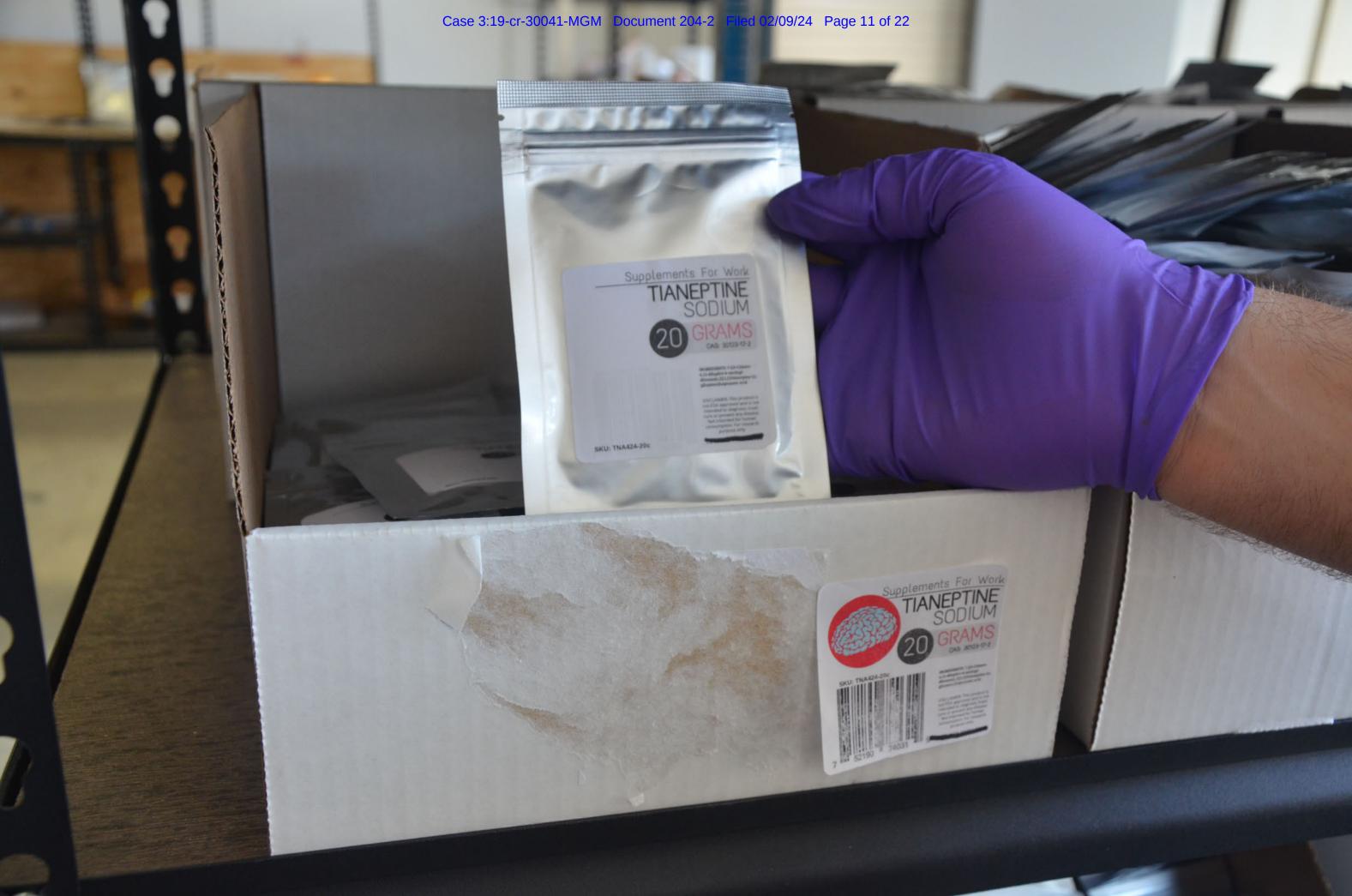


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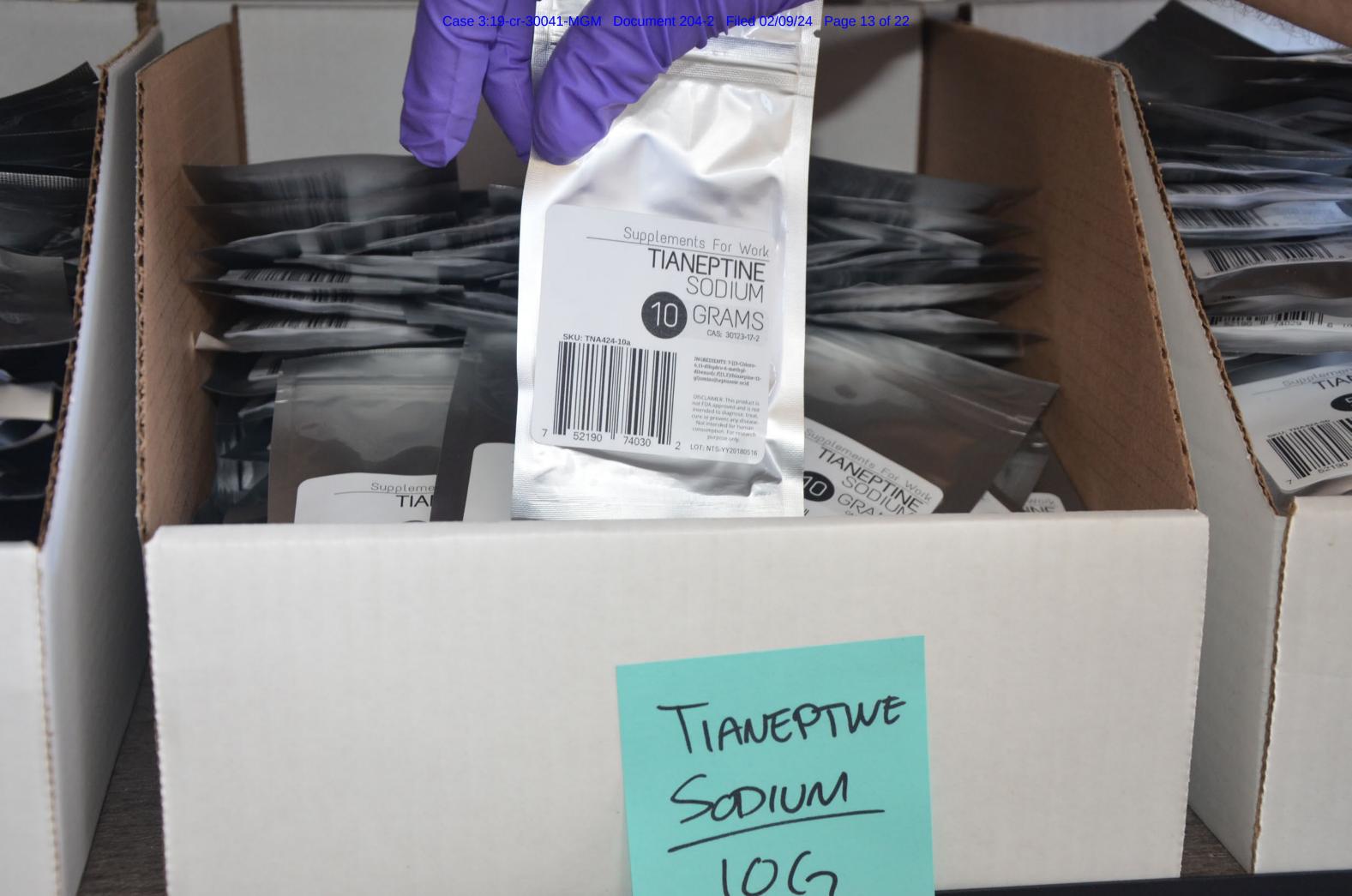


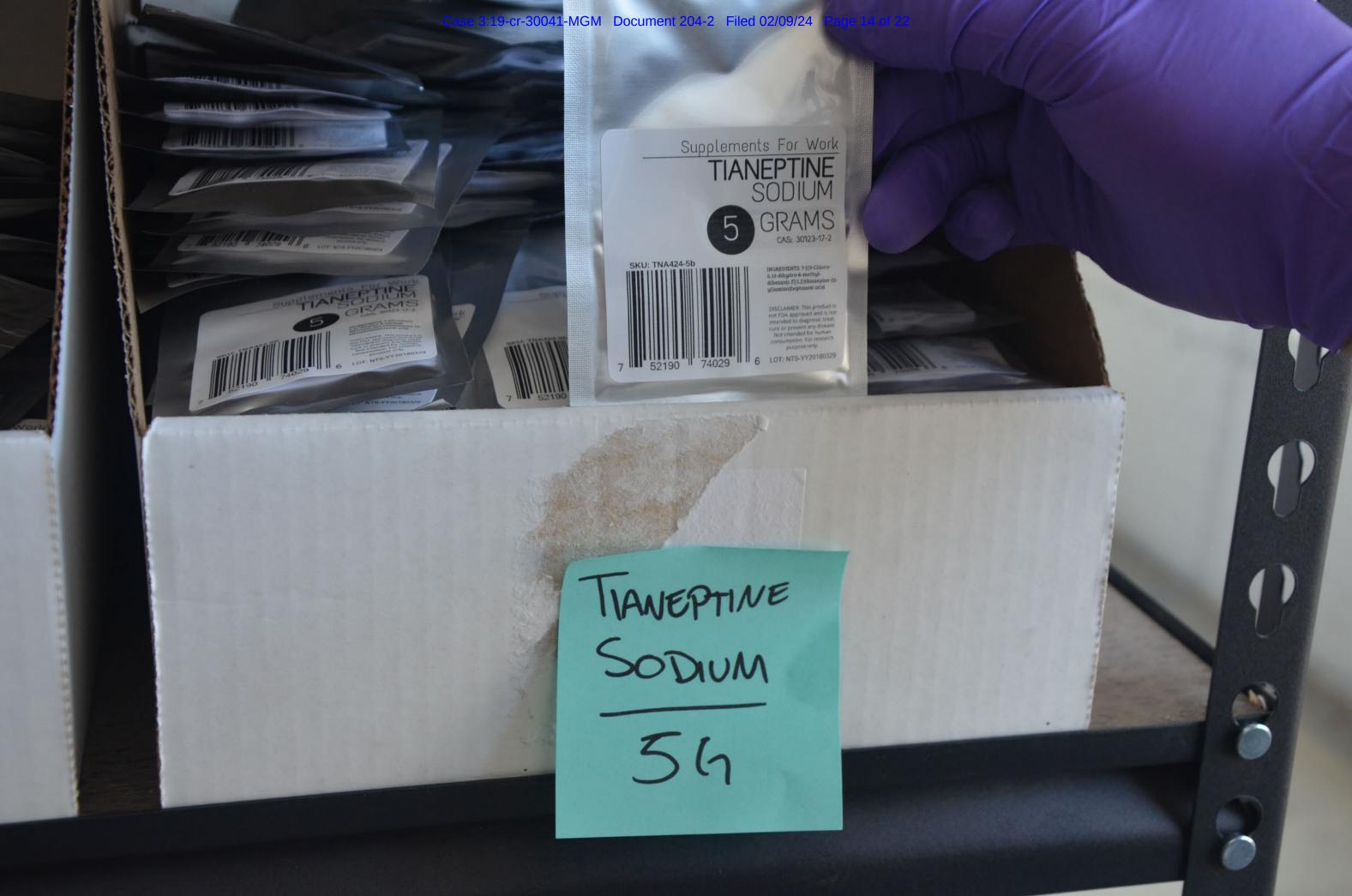




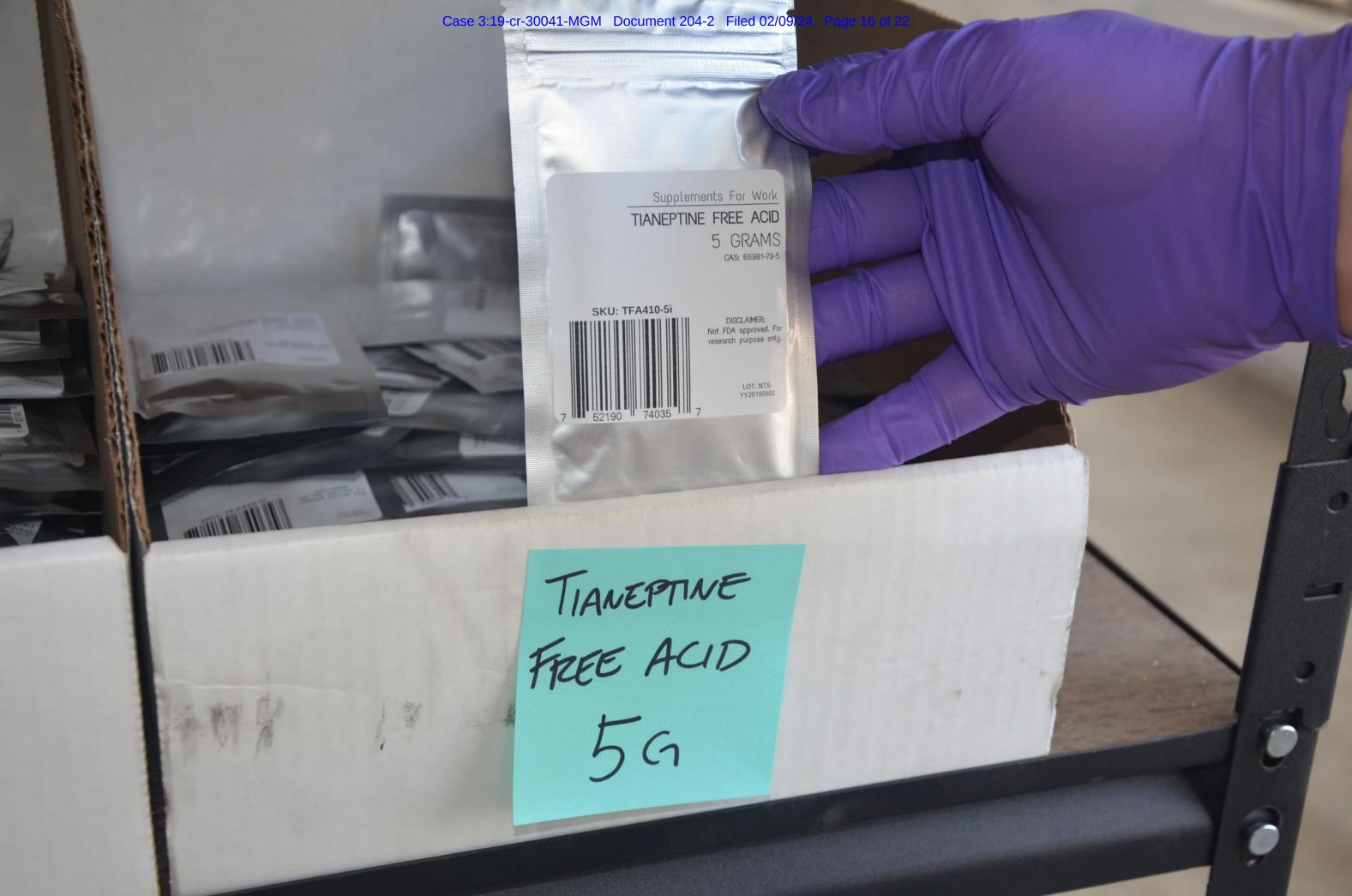


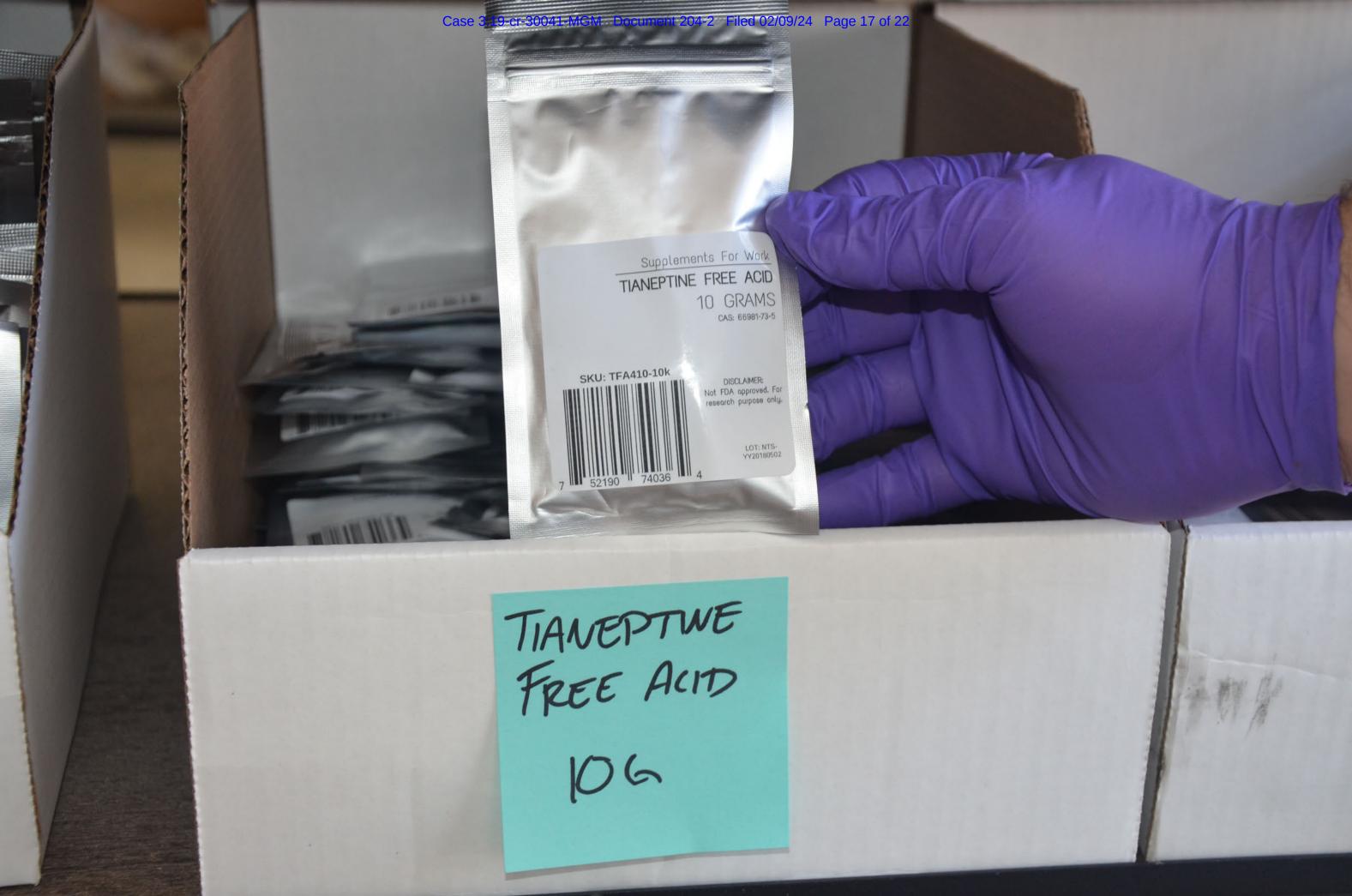












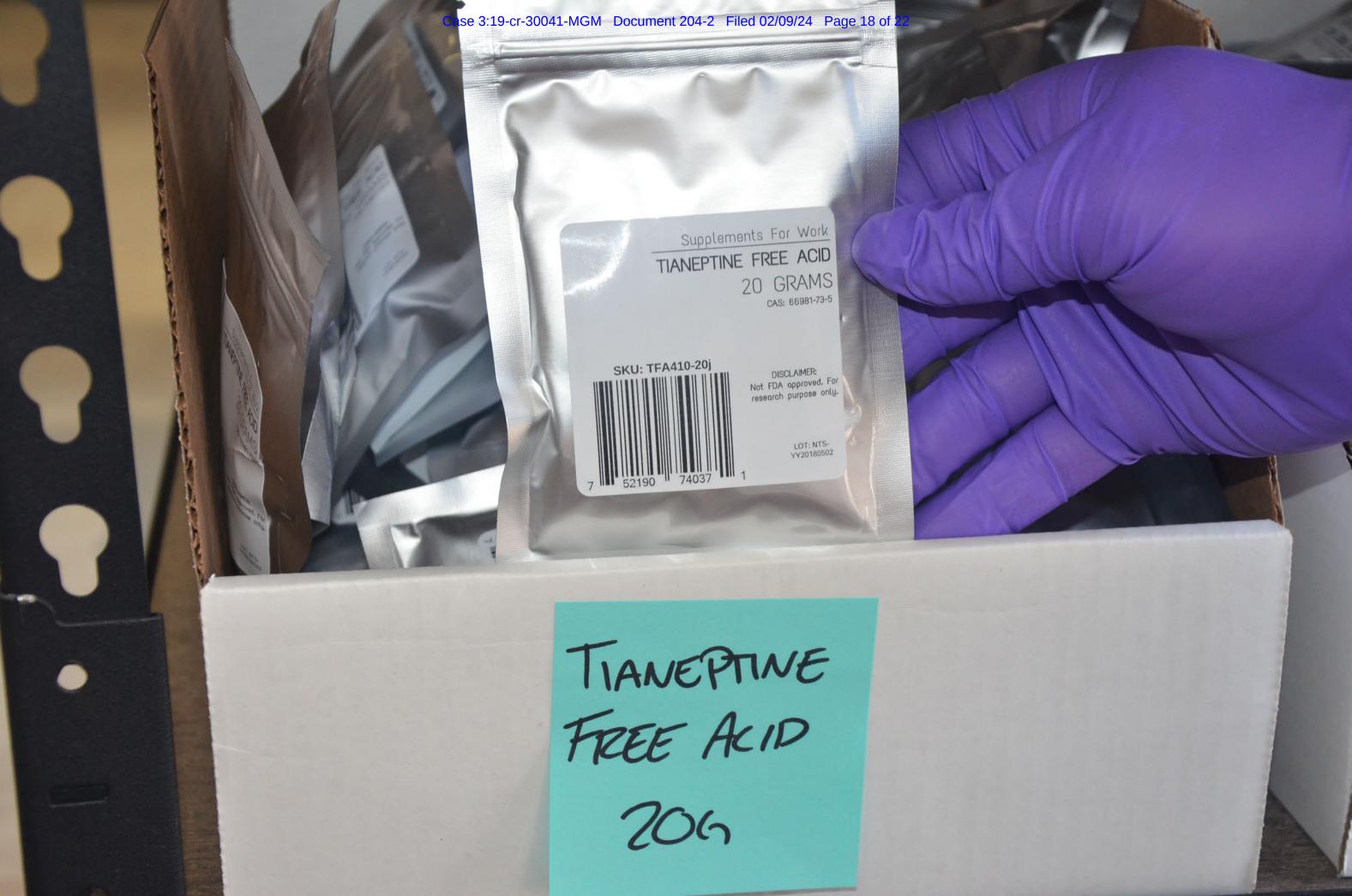






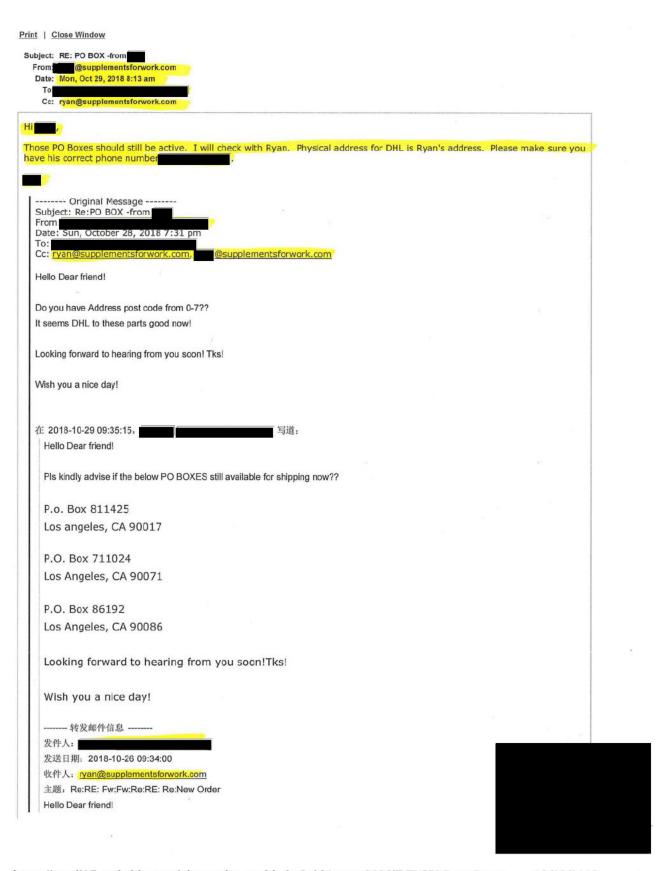




Exhibit C

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Page 1 of 5

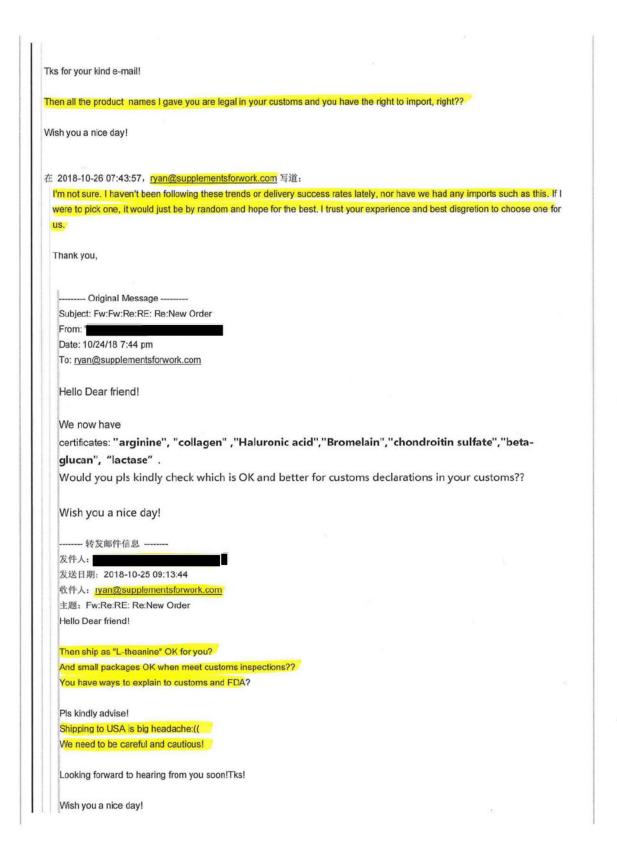


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12/19/2018

Workspace Webmail :: Print

Page 2 of 5

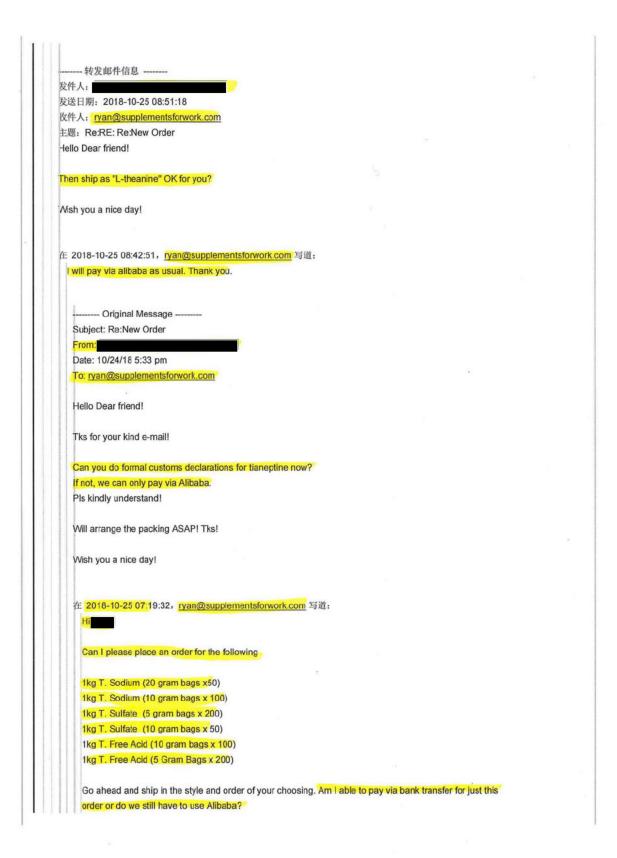


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12/19/2018

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Page 3 of 5

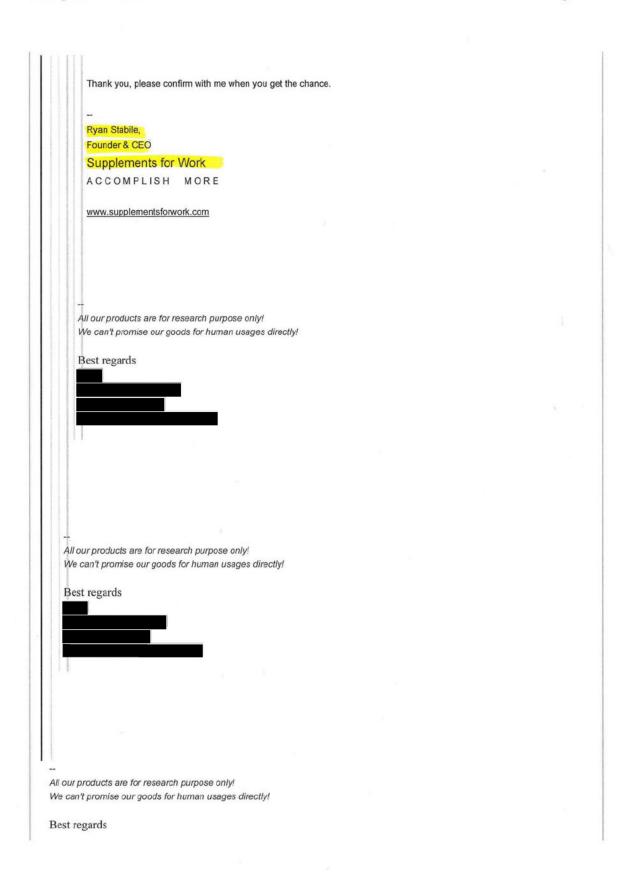


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12/19/2018

Workspace Webmail:: Print

Page 4 of 5



https://email17.godaddy.com/view_print_multi.php?uidArray=2029|INBOX.Sent_Items...

12/19/2018

Workspace Webmail :: Print

Page 5 of 5



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Exhibit D



You've received an invoice 2014 from Research T USA (ATRA)

3 messages

Research T USA (ATRA) <invoice@authorize.net>
Reply-To: "Research T USA (ATRA)" <fastestshipping001@gmail.com>
To: @gmail.com

Mon, Aug 22, 2022 at 12:05 PM

Hello Jason

You have a new invoice from Research T USA (ATRA) for 156.92 USD due on August 22, 2022.

Thank you for your order. Please pay this invoice before 12 p.m. PST for same-day shipping. If you have any questions please contact us at our 24/7 customer service line 415-636-6680. Do not reply to this email.

VIEW AND PAY INVOICE

Research T USA (ATRA)

2105 Vista Oeste NW

Albuquerque CA, 87120

-4689

Research T USA (ATRA) <invoice@authorize.net>
Reply-To: "Research T USA (ATRA)" <fastestshipping001@gmail.com>
To: @gmail.com

Bill @gmail.com>
To: "Research T USA (ATRA)" <fastestshipping001@gmail.com>

Mon, Aug 22, 2022 at 3:28 PM

this came in while I was out, I still want it, can you send it again? [Quoted text hidden]





Invoice 2014 from Research T USA (ATRA) is now canceled

1 message

Research T USA (ATRA) <invoice@authorize.net>
Reply-To: "Research T USA (ATRA)" <fastestshipping001@gmail.com>
To: @gmail.com

Mon, Aug 22, 2022 at 2:56 PM

Hello Jason

Research T USA (ATRA) has canceled this invoice.

Thank you.

Research T USA (ATRA)

2105 Vista Oeste NW

Albuquerque CA, 87120

(347) 921-4689





You've received an invoice 2019 from Research T USA (ATRA)

1 message

Research T USA (ATRA) <invoice@authorize.net>
Reply-To: "Research T USA (ATRA)" <fastestshipping001@gmail.com>
To: Dgmail.com

Mon, Aug 22, 2022 at 9:53 PM

Hello Jason

You have a new invoice from Research T USA (ATRA) for 156.92 USD due on August 22, 2022.

Thank you for your order. Please pay this invoice before 12 p.m. PST for same-day shipping. If you have any questions please contact us at our 24/7 customer service line 415-636-6680. Do not reply to this email.

VIEW AND PAY INVOICE

Research T USA (ATRA)

2105 Vista Oeste NW

Albuquerque CA, 87120

(347) 921-4689



Invoice 2019 from Research T USA (ATRA) is now canceled

1 message

Research T USA (ATRA) <invoice@authorize.net>
Reply-To: "Research T USA (ATRA)" <fastestshipping001@gmail.com>
To: @gmail.com

Tue, Aug 23, 2022 at 12:57 PM

Hello Jason

Research T USA (ATRA) has canceled this invoice.

Thank you.

Research T USA (ATRA)

2105 Vista Oeste NW

Albuquerque CA, 87120

(347) 921-4689



Bill		Damail com
DIII	-	@gmail.com>

Your Research T. Order

3 messages

Mon, Aug 22, 2022 at 11:07 PM

Hi there.

Sorry, Bill / Jason but we stopped shipping today at 3 p.m. EST. But I'll re-send the invoice one more time. As long as you pay it before 9 a.m. your order will go out first thing tomorrow morning. Thanks.

°°° Thanks for shopping with the

The American Tianeptine Research Association

- Overnight shipping as low as \$20 in select states
- Over a dozen ways to pay for your order 6
- For 24 hour customer service, text: 415-636-6680

Sent from Proton Mail mobile

Bill @gmail.com>

Wed, Aug 24, 2022 at 11:29 AM

To: "T. Research USA" <Orders@tianeptineresearchersusa.com>

I'm confused, this is getting weird, what is the time limit on opening the invoice to pay? I don't have access to my phone or computer every minute of the day because of work. If i can, i still want the tia. Can you tell me a time of day the invoice window will be open?

Jason

[Quoted text hidden]

T. Research USA <Orders@tianeptineresearchersusa.com>
Reply-To: "T. Research USA" <Orders@tianeptineresearchersusa.com>
To: @gmail.com

Fri, Aug 26, 2022 at 1:45 PM

Hi again, for future reference, we need to cancel invoices that don't get paid in less than 24 hours or else Route charges us the shipping protection price for orders that don't get shipped.

"" Thanks for shopping with the

The American Tianeptine Research Association

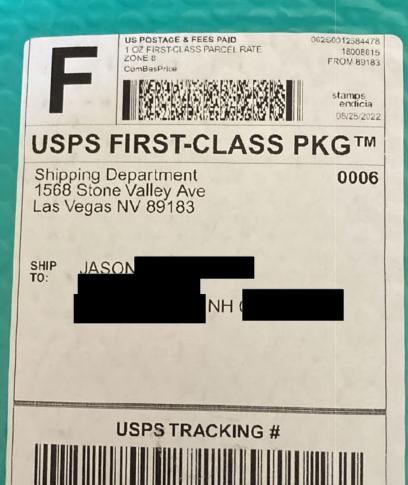
- Overnight shipping as low as \$20 in select states
- Over a dozen ways to pay for your order
- For 24 hour customer service, text: 415-636-6680

Case 3:19-cr-30041-MGM Document 204-4 Filed 02/09/24 Page 8 of 14

Sent from Proton Mail mobile

----- Original Message ------

[Quoted text hidden]



9400 1112 0255 7908 2556 53



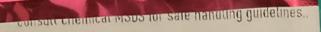
Tianeptine Sodium Powder

20 Gram Lab Sample

CAS 30123-17-2 |

sodium 7-((3-chtoro-6-methyt-5,5-dioxido-6,11dihydrodibenzo[c,f][1,2]thiazepin-11-yt)aminothattans

CAUTION: For laboratory research purpose only.



Tianeptine Sodium Powder 20 Gram Lab Sample

Sodium 7-1(3-chtoro-6-methyl-5,5-dioxido-6,11-dihydrolithenzo[c.t][1,2]thiazepin-11-yl]eminothaltana

CAUTION: For laboratory research purpose only.



P.O. BOX 15284 WILMINGTON, DE 19850

JASON

Customer Service Information:

www.bankofamerica.com 1.800.421.2110

Mail billing inquiries to:

Bank of America P.O. Box 672050 Dallas TX 75267-2050

Mail payment to:

Bank of America P.O. Box 15019

Wilmington DE 19886-5019

Account#

August 7 - September 6, 2022

Account Summary

Previous Balance Payments and Other Credits Purchases and Adjustments Fees Charged Interest Charged	\$0.00 \$0.00 \$143.77 \$0.00 \$0.00
New Balance Total	\$143.77
Total Credit Line	\$5,000.00
Total Credit Available	\$4,856.23
Cash Credit Line	\$5,000.00
Portion of Credit Available	
for Cash	\$4,856.23
Statement Closing Date	09/06/2022
Days in Billing Cycle	31

Payment Information

New Balance Total	\$143.77
Current Payment Due	\$35.00
Total Minimum Payment Due	\$35.00
Payment Due Date	10/03/2022

Late Payment Warning: If we do not receive your Total Minimum
Payment by the date listed above, you may have to pay a late fee of up to
\$40.00 and your APRs may be increased up to the Penalty APR of 29.99%.
Total Minimum Payment Warning: If you make only the Total Minimum
Payment each period, you will pay more in interest and it will take you
longer to pay off your balance. For example:

If you make no additional charges using this card and each month you pay	You will payoff the balance shown on this statement in about	And you will end up paying an estimated total of		
Only the Total Minimum Payment	5 months	\$149.00		

If you would like information about credit counseling services, call 866.300.5238.

JASON

| August 7 - September 6, 2022

Transactions

Date Date Description		Number	Number	Amount	Total
	and Adjustments	6275	0.443	1.42.77	
	GAR FESTIVAL DRI347-9214689 CA PURCHASES AND ADJUSTMENTS FOR THIS PERIO	6375 D	9441	143.77	\$143. 77



U.S. Food and Drug Administration, Forensic Chemistry Center 6751 Steger Drive, Cincinnati, Ohio 45237-3097 Telephone: (513) 679-2700 FAX: (513) 679-2761

Case/Sample Summary Report

Date: October 18, 2022

From: Juaneka Hayes, Ph.D.

Chemist, Organic Branch

Subject: Results of Analysis, OCI Case # 18-BOM-713-0178

OCI IE #18-0178-30396, FDA FACTS # 1202440

To: William Hughes, Special Agent

Boston Resident Office, FDA/OCI

Through: Jonathan J. Litzau - Digitally signed by Jonathan J. Litzau - Date: 2022.11.01 15:00:39 -04'00'

Jonathan J. Litzau Director, Organic Branch

I. Description of Samples Received for Analysis

Sample 1202440 was received via UPS on 09/26/2022 and contained one item.

Item 1 consisted of a self-seal turquoise bubble mailer/envelope with an affixed white label, labeled "***USPS FIRST-CLASS PKG***Shipping Department***1568 Stone Valley Ave Las Vegas NV 89183***SHIP TO: JASON THOMPSON PO BOX 4767 MANCHESTER NH 03108-4767***." The self-seal turquoise bubble mailer/envelop contained a resealable foil bag, red in color, with an affixed white label, labeled in part "***Tianeptine Sodium Powder 20 Gram Lab Sample CAS 30123-17-2***CAUTION: For laboratory research purpose only." The red foil bag contained a clear resealable bag, with no markings, containing a white powder.

II. Analytical Tests Performed on Samples

Per the Request for Laboratory Services, portions of the Item 1 powder were prepared and analyzed using liquid chromatography with mass spectrometric detection (LC-MS). Analytical testing was performed on the sample from October 3, 2022 to October 18, 2022.

III. Results

Using LC-MS, tianeptine was identified in the analyzed portions of the Item 1 powder based on retention time and mass spectral match to a tianeptine standard.

IV. Opinions and Interpretations

Not applicable.

V. Sample Retention/Disposition/Feedback Information

This evidence will be retained by the Forensic Chemistry Center pending instructions from your office for disposition. If you have any questions, concerns or a need for additional information, please do not hesitate to contact me at (513) 679-2700, Ext 2205, or Kevin Kubachka at (513) 679-2700, Ext 2223.

Juaneka M. Hayes - S Hayes - S Date: 2022.10.21 11.06:00 -04'00'

Juaneka Hayes, Ph.D.

Section Authors Concurrences

Section 1 and 767:

Juaneka M. Hayes - 5 | Digitally signed by Juaneka M. Hayes - 5 | https://disease.2022.10.2111.07.26-0400' |

Juaneka M. Hayes, Ph.D.

ate: 2022.10.21 11:07:26 -04'00' Reviewer/Acting Supervisor:

Kevin M. Digitally signed by Kevin M. Kubachka -S Date: 2022.10.21 12:06:35 -04'00'

Kevin M. Kubachka, Ph.D.

1202440 10/18/2022 Page 1 of 1

Exhibit E

Date	Product	Amount	Pack Out	Marked as	Lot Number	Price	EMS Tracking	Recipient	Delivered	Notes	
18/4/13	Tianeptine sulphate	1kg	20g/bag* 50 bag	Collagen	20180309	3450	EA264267112CN		4/23		
18/4/19	Tianeptine sodium	1kg	1kg/bag	Collagen	20180329	3100	EA268506285CN	Ryan po box		Attempted delive	ery 4/25
18/4/19	Tianeptine sodium	1kg	1kg/bag	Collagen	20180329	3100	EA268508030CN			In SF 4/24	
18/4/20	Tianeptine sodium	500g	5g/bag	Collagen	20180329	1550	EA268506303CN	Ryan po box		In China 4/24	
18/4/20	Tianeptine sodium	500g	5g/bag	Collagen	20180329	1550	EA268506294CN			In China 4/24	
18/4/21	Tianeptine sodium	500g	10g/bag	Collagen	20180329	1550	EA268506317CN	Ryan po box		In China 4/24	
18/4/23	Tianeptine sodium	500g	10g/bag	Collagen	20180329	1550	EA268506382CN	Ryan po box		In China 4/24	
18/4/14	Tianeptine Free Acid	1kg	1kg/bag	Collagen	20171208	3100	EA264267143CN	Ryan po box	4/19		
18/4/16	Tianeptine sulphate	1kg	1kg/bag	Collagen	20180309	3450	EA264267165CN		4/23		
18/4/17	Tianeptine Free Acid	1kg	1kg/bag	Collagen	20171208	3100	EA264267174CN	Ryan po box	4/25		
18/4/18	Tianeptine Free Acid	1kg	1kg/bag	Collagen	20171208	3100	EA268506277CN	Ryan po box	4/25		
18/4/17	L-Theanine	2kg	2kg		20171230		EA270801587CN		4/24/18		
18/4/24	Tianeptine sodium	1kg	20g/bag	Collagen	20180329	3100	EA268506325CN	Ryan po box		In China 4/24	
18/4/23	Aniracetam	1kg	50g/bag * 20 bag	Collagen	20171029		6576384625			Customs Hold DHL shipment	
18/4/24	Phenibut hcl	1250g	50g/bag * 25 bag	Collagen	20180409		EA268506351CN			In China 4/24	
18/4/25	Tianeptine sodium	1kg	20g/bag	Collagen	20180329	3100	EA264267863CN			In China 4/25	

Exhibit F

Critical Habit Formation & Absololution

Friday, June 9, 2017 | 12:01 PM

In order to lead a happier, healthier, and more successful life in the long term, these are the current habit I must change. Each of these have manifested their selves into daily addictions that I have become physically and mentally dependent upon.

> Meth

WHY?

- 1. It's a risk to my mental health and heart health.
- 2. It is damaging my complexion, which prevents me from going on dates and gives bad impressions, therefore decreasing my overall happiness.
- 3. It's socially unacceptable and would raise an enormous scandal if any of my colleagues found out.
- 4. To benefit my sleep and therefore my overall body and physical well-being.
- 5. The value of stopping meth greatly outweighs any benefits it provides.

HOW?

- 1. Have someone keep me accountable
- 2. Close off any and all access routes to procure more meth, including Petey L.
- 3. More away from Chino hills to avoid triggers.
- 4. Develop a skill to help cope with stress and negative emotions.
- 5. For energy, meth can be supplemented with adrafinil, sulbutiamine, coffee, or phenylpiracetam, and other high energy nootropics.

WHEN?

- 1. It will take 3-4 days.
- 2. Commit to a timeline to guit forever.
- 3. Create a support system to prevent any chance of relapse.

High dose tianeptine

WHY?

- 1. It is devastating my complexion.
- 2. Save \$\$\$ (about \$360 monthly)
- 3. Dependence to the 3 hour half life prevents me from doing anything without bringing tianeptine.

HOW?

- 1. Tapper down without the expectation of euphoria.
- 2. Substitute with kratom, then quit kratom with phenibut.

WHEN?

- 1. It will take 7-14 days
- 2. Commit to a timeline to guit forever.
- 3. Create a support system to prevent any chance of relapse
- Vaping

WHY?

- 1. I can't go more than 1 hour without vaping
- 2. Improve heart health
- 3. Save \$\$\$



HOW?

- 1. Supplement with nicotine gum
- 2. Change triggers and habit related to vaping.

WHEN?

- 1. It will take 7-14 days.
- 2. Commit to a timeline to quit forever.
- 3. Create a support system to prevent any chance of relapse

✓ ADDICTION TRIGGERS ✓

- 1. Sadness
- 2. Stress
- 3. Rejection

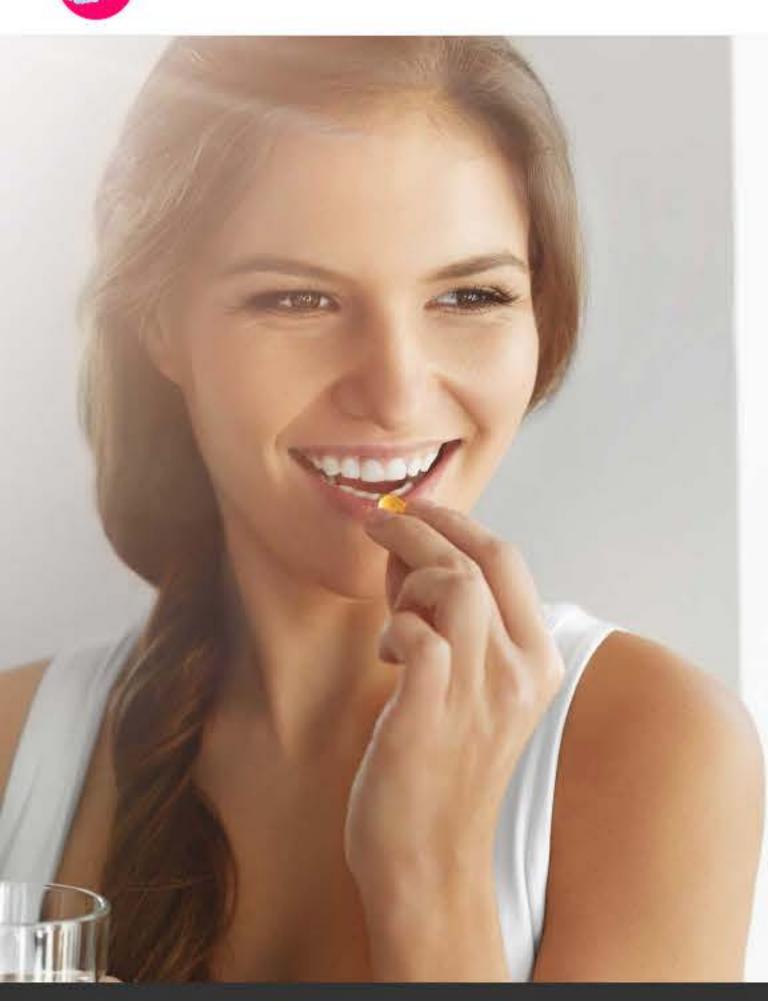
Remember...

ALL THINGS SHALL PASS...

Including withdrawal symptoms.

What is remain after overcoming my addictions will be more happiness from day to day, better health, more quality relationships, and better decision making in business and in life. ©

Exhibit G



I want to research:



Same Day Shipping! Order before 12 PM PST M-F to ensure same-day shipping.

Best Sellers



Tianeptine Sodium



Tianeptine Free Acid



Tianeptine Sulfate



Phenibut HCL

ALL PRODUCTS

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Receive exclusive discounts and product updates.

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OK

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Hydrafinil (also known as Fluorenol) is a compound discovered by the biopharmaceutical company Cephalon, in 2012, in their search for a nextgeneration improvement upon 2-benzhydrylsulfinylacetamide. They were looking for eugeroic compounds (wakefulness-promoting agents), of which 2-benzhydrylsulfinylacetamide...

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Exhibit H

'Gas-Station Heroin' Sold as Dietary Supplement Alarms Health Officials

Tianeptine, found at convenience stores, at smoke shops and online, can mimic an opioid. It is among a growing class of substances that are difficult to control.



By Jan Hoffman

Jan. 10, 2024

The young father headed across the parking lot to join the other parents meeting their children's new preschool teachers. After a few steps, he began sweating and twitching. As the sky reeled, he staggered back to the car, desperate to lie down in the back seat and breathe, hidden by tinted windows.

"Did you take something?" his wife, Anne, shouted at him while dialing 911. Eric, 26, had completed rehab earlier in the summer.

"The shot! The shot!" he groaned, just before he hit the ground and blacked out.

In the emergency room of a nearby hospital in southern New Jersey, doctors tried to revive him with a defibrillator.

"What's he on?" they yelled at Anne.

She showed them a shot-size bottle of the cherry-flavored elixir she had fished out of the car. It was labeled Neptune's Fix. Eric had bought it at a local smoke shop.

"What the hell is that?" a doctor asked.

Neptune's Fix features an ingredient called tianeptine — popularly known as gas-station heroin.

Often sold as a dietary supplement and promoted by retailers as a mood booster and focus aid, tianeptine is among a growing, unregulated class of potentially addictive products available in gas stations, convenience stores and smoke shops and across the internet. They typically include synthetic pharmaceuticals and plant-derived substances.

Some, like kratom and phenibut, can be addictive and, in rare cases, fatal. They often originate in other countries, including Indonesia and Russia, where they are commonly used, even prescribed, for mood management. But the Food and Drug Administration has not approved them as medicines in the United States.

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"Tianeptine is an emerging threat," said Kaitlyn Brown, clinical managing director of America's Poison Centers, which represents and collects data from 55 centers nationwide. "We have people who are able to get a substance that's not well regulated, that has abuse potential and that, in high doses, can cause similar effects to opioids, leading to really harmful outcomes."

At least nine states have banned or severely restricted tianeptine, including Florida, Michigan and Ohio. In late November, the F.D.A. issued a nationwide alert about Neptune's Fix specifically and tianeptine in general, telling people not to take it and warning that it had been associated with overdoses and deaths.

Tianeptine, which also appears as a concentrated powder or an ingredient in products such as Tianaa, Zaza and Pegasus, "is illegally sold with claims to improve brain function and treat anxiety, depression, pain, opioid use disorder and other conditions," the agency's warning said.

The F.D.A. loosely oversees dietary supplements, an expanding universe of some 50,000 products that includes minerals, vitamins and compounds like melatonin. But the agency does not evaluate supplements for safety or effectiveness; it can only forbid manufacturers to market them as medical treatments. It requires product labels making health claims to list ingredients and include boilerplate disclaimers, such as noting that the product has not been reviewed by the F.D.A. The agency does not review those labels before a product is released.

Because the F.D.A.'s enforcement powers are limited by law, many products with tianeptine have long skirted labeling requirements. Although the F.D.A. has explicitly said, for example, that tianeptine does not qualify as a dietary supplement, the labels of some brands, like Tianaa, still make that claim.

"There are now at least a dozen different products that are foreign drugs being openly marketed as dietary supplements right under the F.D.A.'s eyes, without them being able to stop the sales," said Dr. Pieter Cohen, an associate professor at Harvard Medical School who studies the regulation of supplements.

Tianeptine is a drug developed by French researchers in the 1960s as an antidepressant. It is approved in low doses for that use in many European, Asian and Latin American countries.

But at higher doses, it also works much as an opioid does, delivering short-lived euphoria. In the United States, many people take tianeptine under the widespread, mistaken belief that it is a safe alternative to street opioids like fentanyl or heroin, or even a way to taper off using them. On social media sites like Reddit, its merits are hotly debated, with more than 5,000 people subscribing to a "Quitting Tianeptine" forum.

"People develop a tolerance very quickly, and so they rapidly start advancing the dosing," said Dawn Sollee, a clinical toxicologist and director of the Poison Control Center in Jacksonville, Fla. "They will set alarms to wake themselves every two hours to take tianeptine pills so they do not go into withdrawal. And then they have to keep taking more and more just to stay functional."

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Kratom leaves for sale in a market in Bangkok in 2021. Narong Sangnak/EPA, via Shutterstock

Expenses can mount swiftly, along with dangers. At a convenience store in Montclair, N.J., recently, 15 capsules of Tianaa Red cost \$34. A bottle of Neptune's Fix, which comes in lemon, tropical, cherry or chocolate-vanilla flavor, runs about \$16. A salesman at a roadside smoke shop farther west said customers typically purchased 12-bottle boxes. A salesman at another roadside shop said that one customer bought 10 boxes each week — whether for resale or personal use, he did not know.

Determining the number of cases of tianeptine abuse is challenging, because hospitals do not test for it. Reports to poison-control centers are voluntary, typically made by a worried relative, so officials say the numbers represent a drastic undercount.

But case reports are increasing. In 2013, only four cases of tianeptine exposure were reported nationwide. In 2023, 391 cases were reported, according to America's Poison Centers. New Jersey, which typically has one report a year, received 27 in 2023, with patients ranging in age from 20 to 69.

"Some people apparently think it can help with chronic pain instead of having to use an opioid, which might explain the older demographic," said Dr. Diane Calello, medical director of the New Jersey Poison Control Center.

Similarly to many illicit drugs, tianeptine is often sloppily mixed with unlabeled ingredients, such as potent synthetic cannabinoids. That is one reason overdose symptoms appear to range widely, poison-control medical directors said, including clamminess, nausea, low blood pressure and unconsciousness as well as seizures and severe stomach cramps.

Sometimes naloxone, a drug that reverses opioid overdoses, can be effective in reviving patients, they said — and sometimes not. At least four deaths have been associated with tianeptine.

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About a year ago, Dr. Raymond Pomm, an addiction psychiatrist at Gateway Community Services in Jacksonville, saw his first tianeptine patient. To treat the patient's withdrawal symptoms, he tried buprenorphine, a medication that dulls opioid cravings. He said he found that it helped patients to manage withdrawal from tianeptine and to maintain abstinence.



"Since it was being sold in stores, I thought it can't be that bad," said Eric, a man who suffered severe tianeptine symptoms, about Neptune's Fix. Hannah Beier for The New York Times

Last summer, after Eric completed rehab for kratom, a potentially addictive herb from Southeast Asia that is readily available in convenience stores and smoke shops, doctors recommended medication for anxiety and depression. But Eric, a corporate salesman from a suburb in South Jersey, was determined to stay away from mood-altering prescriptions, to which he had been addicted in the past.

At a tobacco shop, he spotted Neptune's Fix. A salesman said it could help with his mood and would not hook him.

"Since it was being sold in stores, I thought it can't be that bad," said Eric, who, like Anne, asked to be identified by his middle name to protect his family's privacy. "You know, an energy drink type of thing."

After tossing back a shot, he felt better almost immediately: more talkative, happy, confident.

But soon, Eric said, "I couldn't stop taking it."

Within a few weeks, he was up to five bottles a day, spending over \$400 a week. His energy was flagging. Though he was a former college athlete still accustomed to working out daily, he now could not even get himself to the gym.

When he tried quitting cold turkey, withdrawal hit him with cold sweats, muscle aches, restlessness and irritability.

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Weeks after he collapsed in the preschool parking lot, doctors from the New Jersey Poison Control Center tested the contents of his Neptune's Fix bottles. Results included synthetic cannabinoids and other unlisted ingredients as well as tianeptine.

The F.D.A. sent warnings in 2021 and 2022 to two companies that it said were "illegally marketing tianeptine products as dietary supplements and unapproved drugs."

But enforcement requires huge resources, in part because manufacturers and purveyors can be difficult to track down. An inquiry from The New York Times to the makers of Neptune's Fix submitted through its website received no response. The Sheridan, Wyo., location listed on the company's bottles is an address for a registration agent for numerous companies.

Regulatory experts disagree about how the F.D.A. should grapple effectively with tianeptine and other supplements. Some say the agency should establish a strict registry of approved supplements.

In interviews, some poison-center directors did not endorse a full ban of tianeptine, saying that could lead to dangerous underground trafficking. Educating emergency responders and consumers about inherent risks in such products would be a more effective course, they said.

Getting tianeptine off store shelves, they added, would be not only a staggering task but also of limited utility because customers could simply buy it from the most convenient store of all — the internet.

While Eric was recovering from tianeptine poisoning, Anne stormed over to the local smoke shop where he had bought it.

"My husband's in the hospital because of this product and you're still going to keep it on the shelves?" she yelled.

"Yes," she said the owner replied, "because people want it and we need to make money."

Audio produced by Tally Abecassis.

Jan Hoffman writes about behavioral health and health law. Her wide-ranging subjects include opioids, tribes, reproductive rights, adolescent mental health and vaccine hesitancy. More about Jan Hoffman

A version of this article appears in print on , Section A, Page 1 of the New York edition with the headline: Elixirs Peddled At Gas Stations Provoke Alarm