### Exhibit A

## TAULER SMITH

Leticia Kimble, Esq.
Tauler Smith LLP
626 Wilshire Blvd, Ste 510
Los Angeles, CA 90017
(310) 492-5129
Leticia.Kimble@taulersmith.com

12/15/2017

#### **VIA CERTIFIED MAIL**

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Sunset Liquor 985 Broadway Ste L CHULA VISTA, CA 91911

Re: Unlawful Sexual Enhancement Products

To Whom It May Concern:

We represent Outlaw Laboratory, LP ("Plaintiff"), a manufacturer, distributor and retailer of male enhancement products "TriSteel" and "TriSteel 8 hour." We have recently discovered that your company, Sunset Liquor, is selling illegal sexual enhancement products, including but not limited to, Blue Diamond (the "Illicit Products").

- Enclosed as **EXHIBIT A** are photographs taken at your place of business capturing your sale of the Illicit Products.
- Enclosed as **EXHIBIT B** are notices from the Food and Drug Administration regarding the illegality of the Illicit Products.

As you can see, the Illicit Products are illegal to sell and subject your company to legal action for racketeering and unfair business practices under RICO (Racketeer Influenced Corrupt Organizations) and the Federal Lanham Act. Accordingly, under these federal laws our client is entitled to:

- Your profits from the sale of the Illicit Products dating back four years. (15 U.S.C. § 1117)
- Attorney's fees. (18 U.S.C. § 1964)
- Punitive damages. (15 U.S.C. § 1117)
- Triple damages. (18 U.S.C. § 1964 & 15 U.S.C. § 1117)

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We estimate that you are liable for over \$100,000 if we prosecute this matter to a jury trial. Although Plaintiff is entitled to the monetary remedies detailed above, it is willing to settle all claims in exchange for a one-time settlement agreement of \$9,765, and your agreement to stop selling the Illicit Products. This offer will double if we are forced to file a formal lawsuit, and the offer will be withdrawn if litigation exceeds one month in duration.

Please have your attorney contact our office no later than 12/29/2017 to resolve this matter before we file a lawsuit against your business, a draft of which we have attached as **EXHIBIT C**.

This letter is sent without prejudice to Plaintiff's rights and claims, all of which are expressly reserved. Please direct any communications regarding this matter to my attention.

Best regards,

Leticia Limble

Leticia Kimble, Esq.

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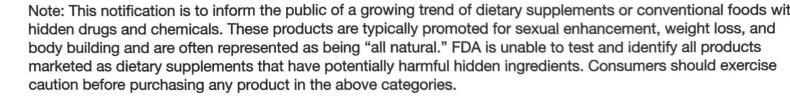
# Public Notification: Blue Diamond Pill contains hidden drug ingredient

[11-20-2017] The Food and Drug Administration (FDA) is advising consumers not to purchase or use Blue Diamond Pill, a product promoted for sexual enhancement. This product was identified by FDA during an examination of international mail shipments.

FDA laboratory analysis confirmed that Blue Diamond Pill contains sildenafil, the active ingredient in the FDA-approved prescription drug Viagra, used to treat erectile dysfunction. This undeclared ingredient may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. People with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates.

Health care professionals and patients should report adverse events or side effects related to the use of this product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online at <u>MedWatch Online</u> <u>Voluntary Reporting Form (https://www.accessdata.fda.-gov/scripts/medwatch/)</u>, or;
- Download and complete the <u>form</u> (<u>http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf)</u>, then submit via fax at 1-800-FDA-0178.



Please refer to the links below for more information:

- <u>Tainted Sexual Enhancement Products</u>
   (http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/Medication-HealthFraud/ucm234539.htm)
- <u>Subscribe to the RSS feed</u>
   (http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/TDS/rss.xml)
- <u>Beware of Fraudulent 'Dietary Supplements'</u> (http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm246744.htm)



#### Case 3:18-cv-00840-GPC-BGS Document 32-1 Filed 11/30/18 PageID.298 Page 5 of 18 Contact FDA

Toll Free (855) 543-3784, or (301) 796-3400

#### druginfo@fda.hhs.gov (mailto:druginfo@fda.hhs.gov)

**Human Drug Information** 

**Division of Drug Information** 

(http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm082585) (CDER Office of Communications

Feedback Form (http://www.accessdata.fda.gov/scripts/email/cder/comment.cfm)

10001 New Hampshire Avenue Hillandale Building, 4th Floor Silver Spring, MD 20993

#### Resources for You

- Sign Up for Email Alerts on Tainted Products Sold as Dietary Supplements (https://service.govdelivery.com/service/subscribe.html?code=USFDA 198)
- <u>Tainted Products That are Marketed as Dietary Supplements RSS Feed</u>

  (http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/TDS/rss.xml)

More in Medication Health Fraud

(/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/default.htm)

Leticia Kimble (SBN 262012)
Tauler Smith LLP
626 Wilshire Blvd., Suite 510
Los Angeles, California 90017
Tel: (310) 492-5129
Leticia.Kimble@taulersmith.com

Attorneys for Plaintiff OUTLAW LABORATORY, LP

# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF CALIFORNIA

OUTLAW LABORATORY, LP,a Texas limited partnership,

Plaintiff

VS.

Sunset Liquor;
[DISTRIBUTOR REDACTED];
[SUPPLIER REDACTED];
[ADDITIONAL DEFENDANTS
REDACTED] and DOES 1 through
10, inclusive,

Defendants.

**CASE NO.12801642** 

#### **COMPLAINT FOR:**

- (1) FALSE ADVERTISING IN VIOLATION OF THE LANHAM ACT § 43 (a)(1)(B)); AND
- (2) VIOLATION OF THE CIVIL RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT (RICO)

[DEMAND FOR A JURY TRIAL]

Case 3:18-cy-20840-GPC-BGS. Document 32-1 Filed 11/30/18 Pagel D. 300. Page 7 of 18 "Plaintiff Outlaw Laboratory, LP, a Texas limited partnership ("Outlaw" or "Plaintiff"), by and through its undersigned attorneys, submits this Complaint against defendants Sunset Liquor, [DISTRIBUTOR REDACTED] ("Distributor") and [SUPPLIER REDACTED] ("the Supplier Defendants"), [ADDITIONAL DEFENDANTS REDACTED] and Does 1-10 (collectively, the "Defendants"), and in support thereof avers as follows:

#### **INTRODUCTION**

- 1. Defendants are engaged in a scheme to distribute tainted "male enhancement" pills containing undisclosed pharmaceuticals to the general public. Specifically, Defendants offer for sale various sexual enhancement products, including but not limited to, Blue Diamond (collectively, the "Enhancement Products"). All of the Enhancement Products have been the subject of testing by the FDA and been found to contain sildenafil, among other hidden drug ingredients.
- 2. The Enhancement products are distributed through a network of coconspirators, named herein as co-defendants (the "Conspiracy Defendants"), who own
  and operate independent businesses selling the Enhancement Products, and who profit
  from the sale of the illegal and dangerous products by making false statements including
  that the Enhancement Products are "all natural" and have limited side effects. Aside from
  these patently false statements, Defendants have failed to disclose the true nature of the
  Enhancement Products to its customers, even though they are aware of their dangerous
  secret ingredients.
- 3. Plaintiff is the manufacturer of competing products called "TriSteel" and "TriSteel 8hour," which are all natural male enhancement products made in the USA and distributed for sale in all 50 US States.
- 4. The illegal male enhancement supplement industry that has flourished in the shadows of weak regulatory and criminal enforcement of nutritional supplement laws.

  Distributor and the Conspiracy Defendants have made significant profits sellingdangerous

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productis and openly engaging in illegal activity. In this regard, the FDA has issued several public notices regarding the use of sildenafil in over the counter "male enhancement" supplements, but has only pursued criminal action intermittently.

- 5. Thus, Plaintiff's only recourse is a civil action to protect the commercial interests recognized by the Lanham Act and to expose the civil conspiracy detailed herein. As such, Defendants have knowingly and materially participated in a false and misleading advertising campaign to promote and sell its Enhancement Products, giving consumers the false impression that these products are safe when in reality, Defendants are well aware that the Enhancement Products contain hidden drug ingredients that require a prescription from a medical doctor.
- 6. Defendants' false and misleading statements and advertising pose extreme health risks to consumers in at least two ways. First, Defendants mislead consumers into believing that the advice and authorization of a licensed medical professional is not required to mitigate or avoid the potentially life-threatening side effects, drug interactions and contraindications of the sildenafil and other drug ingredients hidden in the Enhancement Products. Second, by failing to inform consumers that the Enhancement Products contain sildenafil, consumers who know that their medical history and drug prescriptions make sildenafil consumption dangerous may nevertheless consume the Enhancement Products because they are unaware that they contain sildenafil.
- 7. Defendants have knowingly and materially participated in false and misleading marketing, advertising and labeling to promote and sell the Enhancement Products, giving consumers the false impression that these products are safe and natural dietary supplements when in reality Defendants know that the Enhancement Products contain artificially manufactured prescription drug ingredients that pose extreme health dangers when taken without the supervision of a licensed medical professional.
- 8. Such false and misleading marketing and advertising is extremely dangerous to individual consumers and harmful to the dietary supplement industry as a whole.

Defendants have created an illegitimate marketplace of consumers seeking to enhance their sexual performance but who are not informed, or who are misinformed, of the serious dangers of using Defendants' Enhancement Products. Consumers of the Enhancement Products have little or no incentive to use natural, legitimate and safe sexual performance enhancement products, such as Plaintiff's TriSteel or TriSteel 8hour, until they are harmed or Defendants' Enhancement Products are taken off of the shelves. Defendants' continuing false, misleading, illegal and deceptive practices have violated the Lanham Act and have unjustly enriched Defendants at the expense of Plaintiff, and have caused Plaintiff extensive and irreparable harm, including but not limited to, loss of revenue, disparagement and loss of goodwill.

9. Among other things, this action seeks to enjoin Defendants from the marketing and sale of any and all of the Enhancement Products, punitive damages and attorneys' fees as Defendants are illegally and falsely marketing such products in violation of the Lanham Act and the Civil Racketeer Influenced and Corrupt Organizations Act of 1970.

#### **JURISDICTION AND VENUE**

- 10. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. § 1121 and 28 U.S.C. § 1331 (federal question jurisdiction).
- 11. This Court has personal jurisdiction over Defendants because they have, directly or through their intermediaries (including distributors, retailers, and others), developed, licensed, manufactured, shipped, distributed, offered for sale, sold, and advertised their products, including but not limited to the Enhancement Products, in the United States, the State of California and this district. Defendant has purposefully and voluntarily placed these products into the stream of commerce with the expectation that they will be purchased in this district.
- 12. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions which gave rise to the claim

#### **PARTIES**

- 13. Plaintiff Outlaw Laboratory, LP is a Texas limited partnership organized under the laws of the State of Texas.
  - 14. Upon information and belief, defendant [DISTRIBUTOR REDACTED]
  - 15. Upon information and belief, defendant [SUPPLIER REDACTED]
- 16. Upon information and belief, defendant Sunset Liquor is an entity of unknown type with its principal place of business located at 985 Broadway Ste L, CHULA VISTA CA 91911.
- 17. Plaintiff is ignorant of the true names and capacities of defendants sued herein as Does 1- 10, inclusive, and therefore sued these defendants by such fictitious names. Plaintiff will amend this Complaint to allege their true names and capacities when ascertained. Plaintiff is informed and believes and thereon alleges that each of these fictitiously named defendants is responsible in some manner for the occurrences herein alleged, and that Plaintiff's injuries as herein alleged were proximately caused by the aforementioned defendants.

#### **FACTUAL ALLEGATIONS**

#### <u>Sildenafil</u>

- 18. The FDA has approved sildenafil for treatment of erectile dysfunction. However, because of known side effects, drug interactions and contraindications, the FDA has deemed these drugs to be prescription drugs.
- 19. The serious side effects of sildenafil include, for example, priapism (i.e., prolonged penile erections leading to tissue death and potential permanent erectile dysfunction), severe hypotension (i.e., low blood pressure), myocardial infarction (i.e., heart attack), ventricular arrhythmias, stroke, increased intraocular pressure (i.e., increased eye fluid pressure), anterior optic neuropathy (i.e., permanent optic nerve

Case 3:18-cv-00840-GPC-BGS Document 32-1 Filed 11/30/18 PageID.304 Page 11 of 18 damage), blurred vision, sudden hearing loss, and dizziness.

- 20. The serious negative drug interactions of sildenafil include, for example, (i) interacting with alkyl nitrites and alpha-1 blockers to cause angina and life-threatening hypotension, (ii) interacting with protease inhibitors to increase the incidence and severity of side effects of sildenafil alone, and (iii) interacting with erythromycin and cimetidine to cause prolonged plasma half-life levels.
- 21. In addition to these risks, contraindications of sildenafil include underlying cardiovascular risk factors (such as recent heart surgery, stroke or heart attack) since consumption of sildenafil by individuals with these conditions can greatly increase the risk of heart attack.
- 22. Because of these dangerous side effects, drug interactions and contraindications, the advice and authorization of appropriate licensed medical professionals is absolutely crucial for the safe consumption of sildenafil. Without such safeguards, the consequences can be dire. Indeed, the sale of mislabeled sildenafil has led to multiple deaths reported in the media.

#### **Defendants' Conspiracy**

- 23. The Supplier Defendants are wholesale suppliers and distributors of various sexual enhancement supplements, which are often imported from China, rarely contain any manufacturer information on their packaging and contain hidden drug ingredients. The Supplier Defendants distribute the Enhancement Products through a network of coconspirators, named herein as co-defendants (the "Conspiracy Defendants"), who own and operate independent businesses selling the Enhancement Products, and profit from the sale of the illegal and dangerous products.
- 24. The Supplier Defendants contact retailers such as Sunset Liquor and offer the Enhancement Products for sale. The Enhancement Products are high-margin products and as such are situated at or near the check out counter. The Enhancement Products are all subject to FDA public announcements regarding their illicit contents; however, the

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Conspiracy Defendants still participate in their sale, due to their profitability.

#### **Defendants' False Statements Regarding The Enhancement Products**

- 25. Sunset Liquor is an owner and operator of the Retail Location, which advertises and offer for sale various sexual enhancement supplements, including without limitation, Blue Diamond.
- 26. The Enhancement Products claim that they are "all natural" and have limited side effects. However, such claims are materially false and misleading. Contrary to Defendants' statements, recent FDA laboratory analyses have confirmed that the Enhancement Products contain sildenafil, a synthetic pharmaceutical with profound side effects.
- 27. Defendants' false statements and advertising pose extreme health risks to consumers in at least two ways. First, by stating that no prescription is necessary to consume the Enhancement Products, Defendants mislead consumers into believing that the advice and authorization of a licensed medical professional is not required to mitigate or avoid the potentially life-threatening side effects, drug interactions and contraindications of sildenafil hidden in the Enhancement Products. Second, by failing to inform consumers that the Enhancement Products contain sildenafil, consumers who know that their medical history and drug prescriptions make sildenafil consumption dangerous may nevertheless consume the Enhancement Products because they are unaware that they contain sildenafil.
- 28. Accordingly, Defendants' false and misleading advertising is extremely dangerous to individual consumers and harmful to the dietary supplement industry as a whole. Defendants have created an illegitimate marketplace of consumers seeking to enhance their sexual performance but who are not informed, or who are misinformed, of the serious dangers of using Defendants' Enhancement Products. Consumers of the Enhancement Products have little or no incentive to use safe and legitimate sexual

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performance enhancement products, such as TriSteel or TriSteel 8hour, until they are injured or Defendants' Enhancement Products are taken off of the shelves.

Plaintiff's Dietary Supplements: TriSteel and TriSteel 8hour

29. Plaintiff Outlaw is a manufacturer of all-natural dietary supplements. Plaintiff manufactures and offers for sale TriSteel and TriSteel 8hour, male sexual performance enhancement supplements that promote increased sexual desire and stamina. The ingredients in TriSteel are Epimedium Extract (leaves), Yohimbe Extract (8mg Yohimbine Alkaloids), Xanthoparmelia Scarbrosa Extract (Lichen), Gamma Amino Butyric Acid (GABA), L-Arginine, Gelatin, Cellulose, Magnesium Stearate and Silica. Plaintiff sells TriSteel and TriSteel 8hour through its website www.outlawlaboratory.com, as well as through many other online and storefront retail locations across the United States.

### CLAIMS FOR RELIEF FIRST CLAIM FOR RELIEF

(False Advertising in Violation of Section 43(a)(1)(B) of the Lanham Act)

- 30. Plaintiff incorporates the allegations contained in the foregoing paragraphs as though fully set forth herein in their entirety.
- descriptions of fact concerning the nature, characteristics and qualities of the Enhancement Products by, without limitation, commercially marketing and claiming that the Enhancement Products that they sell are safe and natural "dietary supplements" that will enhance a consumer's sexual performance without requiring a doctor's prescription, all while purposefully omitting that (a) the Enhancement Products contain sildenafil and therefore cannot be "dietary supplements," (b) sildenafil is not naturally occurring, (c) sildenafil is a prescription drug requiring the prior authorization of a licensed medical professional, and (d) consumption of sildenafil without consultation and advice from a licensed medical professional poses extreme health risks, including without limitation,

hypotension, heart attack and death.

- 32. The use of such false, misleading and disingenuous marketing has the tendency to deceive a substantial segment of the public and consumers, including those in this district, into believing that they are purchasing a product with different characteristics.
- 33. This deception is material because: (i) it is likely to influence a consumer's purchasing decision, especially if the consumer (a) is looking for an all-natural sexual enhancement dietary supplement, (b) is purchasing the Enhancement Products out of an attempt to avoid Sildenafil because the consumer knows that Sildenafil poses special health risks given such consumer's medical history or current drug prescriptions, and/ or (c) wants to avoid taking any prescription drugs, generally, but especially without the supervision of a licensed medical professional; and (ii) such decision could lead to dangerous and unanticipated health consequences for such consumers.
- 34. Defendants have introduced their false and misleading statements into interstate commerce via marketing and advertising on product packages and labels, and on display cases placed in Retail Locations in the state of California.
- 35. Plaintiff has been injured as a result of Defendants' false and misleading statements. Specifically, Defendants' false and misleading advertising concerning the Enhancement Products has negatively impacted Plaintiff's sales of TriSteel and TriSteel 8hour because both products are intended for sexual performance enhancement and target the same consumers. Thus, Plaintiff has suffered both an ascertainable economic loss of money and reputational injury by the diversion of business from Plaintiff to Defendants and the loss of goodwill in Plaintiff's products. Moreover, Defendants conduct has created reputational damage in that Defendants' misconduct damages the industry as a whole and has the tendency to disparage Plaintiff's products and goodwill.
- 36. Defendants' actions, as described above, constitute false and misleading descriptions and misrepresentations of fact in commerce that, in commercial advertising

and promotion, misrepresent the nature, characteristics, and qualities of its products in violation of Section 43(a)(1)(B) of the Lanham Act.

#### SECOND CLAIM FOR RELIEF

(Violation of the Civil Racketeer Influenced and Corrupt Organizations Act)

- 37. Plaintiff incorporates the allegations contained in the foregoing paragraphs as though fully set forth herein in their entirety.
- 38. Defendants are engaged in a conspiracy and scheme to defraud and mislead consumers by way of their false and misleading labeling and advertisements concerning the Enhancement Products, which they unlawfully distribute, market, and offer for sale knowing that the products contain illicit ingredients. Thus, Defendants have a plan or scheme to defraud and intent to defraud.
- 39. Due to the nature of the scheme, it is reasonably foreseeable that the mail or wires will be used, and, in fact, defendants have used the mail or wires to further the scheme on multiple occasions in purchase orders sent and received and in the unlawful importation and distribution of sildenafil. Thus, Defendants have engaged in mail fraud as defined in § 1961(1).
- 40. As detailed above, Defendants mislabel, advertise, and offer for sale the Enhancement Products as "dietary supplements." Defendants falsely claim that these products are natural and do not require a prescription, among other misrepresentations. Defendants make these misrepresentations despite the fact that they know that such products unlawfully contain hidden prescription drug ingredients.
- 41. Indeed, Defendants fail to disclose that the Enhancement Products contain drug ingredients. The sale of products containing undisclosed drug ingredients (without requiring a prescription and without informing consumers of the health and safety risks of these drugs) is unlawful and seriously endangers consumers. In this regard, Defendants also fail to disclose any of the adverse health consequences of taking sildenafil.

According to the FDA, these undisclosed ingredients may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels, among other negative side effects.

- 42. Thus, Defendants market and sell the Enhancement Products using false and fraudulent labeling claims and representations, using the wires, in violation of federal law.
- 43. Defendants have knowingly imported, purchased, and sold the Enhancement Products to be delivered by commercial interstate carrier, including but not limited to, use of the mails in furtherance of their scheme to defraud and mislead consumers of their products.
- 44. Defendants have violated the substantive RICO statute, 18 U.S.C.A. § 1962, as detailed above by receiving income from a pattern of racketeering activity involving interstate commerce, wires, and electronic communications.
- 45. Plaintiff has been injured in its business or property by reason of Defendants' violation of section 1962 by, inter alia, the massive diversion of sales to Defendants, which sell products directly in competition with Plaintiff's products, including the Enhancement Products at issue here.

#### **PRAYER**

Wherefore, plaintiff Outlaw prays for judgment against Defendants as follows:

- 46. For preliminary and permanent injunctive relief enjoining Defendant from producing, licensing, marketing, and selling any of the Enhancement Products, including but not limited to, [FDA BANNED PRODUCTS];
- 47. For an award of compensatory damages to be proven at trial in accordance with 15 U.S.C. § 1117;
- 48. For an award of any and all of Defendant's profits arising from the foregoing acts in accordance with 15 U.S.C. § 1117 and other applicable laws;
  - 49. For restitution of Defendant's ill-gotten gains;

- 50. For treble damages in accordance with 15 U.S.C. § 1117;
- 51. For treble damages in accordance with 18 U.S.C. § 1964;
- 52. For punitive damages;
- 53. For costs and attorneys' fees; and
- 54. Any other relief the Court may deem appropriate.

DATED: 12/15/2017

TAULER SMITH LLP

By: <u>/s/ Leticia Kimble</u>

Leticia Kimble, Esq.
PLAINTIFF
OUTLAW LABORATORY, LP

#### **DEMAND FOR JURY TRIAL**

Plaintiff hereby demands a trial by jury.

DATED: 12/15/2017

TAULER SMITH LLP

By: /s/ Leticia Kimble

Leticia Kimble, Esq.
PLAINTIFF
OUTLAW LABORATORY, LP