UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF TEXAS HOUSTON DIVISION

UNITED STATES OF AMERICA	§	
v.	§ Criminal No. 4:2 §	23-cr-195-3
VITAMIN SHACK AND SHAKES,	§	
LLC, d/b/a THE SHACK,	§	
Defendant.	§	

PLEA AGREEMENT

The United States of America, by and through Alamdar S. Hamdani, United States Attorney for the Southern District of Texas; and Tyler White, Assistant United States Attorney; and the Defendant, VITAMIN SHACK AND SHAKES, d/b/a THE SHACK ("Defendant"), and Defendant's counsel, David Adler and Rick Collins, pursuant to Rule 11(c)(1)(A) and 11(c)(1)(B) of the Federal Rules of Criminal Procedure, state that they have entered into an agreement, the terms and conditions of which are as follows:

Defendant's Agreements

1. Defendant agrees to plead guilty to Count One of the Information. Count One charges the Defendant with Causing a Drug to be Misbranded after Shipment into Interstate Commerce, in violation of Title 21, United States Code, Sections 331(k) and 333(a)(1). Defendant, by entering this plea, agrees that he is waiving any right to have the facts that the law makes essential to the punishment proven to a jury or a judge beyond a reasonable doubt.

Punishment Range

2. The statutory maximum penalty for each violation of Title 21, United States Code, Sections 331(k) and 333(a)(1), is a term of imprisonment of not more than one year or fined not more than \$1,000, or both. See 21 U.S.C. § 333(a). Additionally, a violation carries a potential maximum term of supervised release after imprisonment of up to one year. See 18 U.S.C. §§ 3559(a), 3583(b)(3). However, Because the defendant is a business organization/entity, the maximum penalty for a violation is a term of probation and/or a fine of up to \$1,000 pursuant to 18 U.S.C. §§ 3561(a), 3571(c)(5) and 3571(e) and Title 21 U.S.C. § 333(a).

Mandatory Special Assessment

3. Pursuant to Title 18, United States Code, Section 3013(B)(iii), immediately after sentencing, Defendant will pay to the Clerk of the United States District Court a special assessment in the amount of one hundred twenty-five dollars (\$125.00) per count of conviction. The payment will be by cashier's check or money order payable to the Clerk of the United States District Court, c/o District Clerk's Office, P.O. Box 61010, Houston, Texas 77208, Attention: Finance.

Waiver of Appeal

4. Defendant is aware that Title 28, United States Code, Section 1291, and Title 18, United States Code, Section 3742, afford Defendant the right to appeal the conviction and sentence imposed. Defendant is also aware that Title 28, United States Code, Section 2255, affords the right to contest or "collateral[ly] attack" a judgment of conviction and sentence after they have become final. Defendant knowingly and voluntarily waives the right to appeal or "collateral[ly] attack" the conviction and sentence, except that Defendant does not waive the right

to raise a claim of ineffective assistance of counsel on direct appeal, if otherwise permitted, or on collateral review in a motion under Title 28, United States Code, Section 2255. Defendant's knowing and voluntary waiver of the right to appeal or collaterally attack the conviction and sentence includes waiving the right to raise on appeal or on collateral review any argument that (1) the statute to which the Defendant is pleading guilty is unconstitutional and (2) the admitted conduct does not fall within the scope of the statute. In the event Defendant files a notice of appeal following the imposition of the sentence or later collaterally attacks his conviction or sentence, the United States will assert its rights under this Plea Agreement and seek specific performance of these waivers.

5. In agreeing to these waivers, Defendant is aware that a sentence has not yet been determined by the Court. Defendant is also aware that any estimate of the possible sentencing range under the sentencing guidelines that he may have received from his counsel, the United States, or the Probation Office, is a prediction and not a promise; did not induce his guilty plea; and is not binding on the United States, the Probation Office, or the Court. The United States does not make any promise or representation concerning what sentence the Defendant will receive. Defendant further understands and agrees that the United States Sentencing Guidelines are "effectively advisory" to the Court. See United States v. Booker, 543 U.S. 220, 245 (2005). Accordingly, Defendant understands that, although the Court must consult the Sentencing Guidelines and must take them into account when sentencing Defendant, the Court is not bound to follow the Sentencing Guidelines nor sentence Defendant within the calculated Guidelines range.

- 6. Defendant understands and agrees that each and all waivers contained in this Plea Agreement are made in exchange for the concessions made by the United States in this Plea Agreement.
 - 7. The United States agrees to each of the following:
 - a. If Defendant pleads guilty to Count One of the superseding criminal information and persists in that plea through sentencing, and if the Court accepts this plea agreement, the United States will dismiss the pending counts in the indictment, 4:23-cr-195-3, against the defendant and will not further criminally prosecute the defendant or its principals in the Southern District of Texas for offenses arising from conduct charged in this information;
- 8. The United States Attorney's Office for the Southern District of Texas agrees that it will not further criminally prosecute Defendant or its principals in the Southern District of Texas for offenses arising from conduct charged in the Information. This plea agreement binds only the United States Attorney's Office for the Southern District of Texas and Defendant. It does not bind any other United States Attorney or any other component of the Department of Justice. The United States Attorney's Office for the Southern District of Texas will bring this Plea Agreement and the full extent of Defendant's cooperation to the attention of other prosecuting offices, if requested.

United States' Non-Waiver of Appeal

- 9. The United States reserves the right to carry out its responsibilities under the Sentencing Guidelines. Specifically, the United States reserves the right to:
 - a. Bring its version of the facts of this case, including its evidence file and any investigative files, to the attention of the Probation Office in connection with that office's preparation of a presentence report;
 - b. Set forth or dispute sentencing factors or facts material to sentencing;
 - c. Seek resolution of such factors or facts in conference with Defendant's counsel and the Probation Office;

- d. File a pleading relating to these issues, in accordance with Section 6A1.2 of the Sentencing Guidelines and Title 18, United States Code, Section 3553(a); and
- e. Appeal the sentence imposed or the manner in which it was determined.

Sentencing Determination

10. Defendant is aware that the sentence will be imposed after consideration of the Sentencing Guidelines and Policy Statements, which are only advisory, as well as the provisions of Title 18, United States Code, Section 3553(a). Defendant nonetheless acknowledges and agrees that the Court has authority to impose any sentence up to and including the statutory maximum set for the offense to which Defendant pleads guilty, and that the sentence to be imposed is within the sole discretion of the sentencing judge after the Court has consulted the applicable Sentencing Guidelines. Defendant understands and agrees that the parties' positions regarding the application of the Sentencing Guidelines do not bind the Court and that the sentence imposed is within the discretion of the sentencing judge. If the Court should impose any sentence up to the maximum established by statute, or should the Court order any or all of the sentences imposed to be run consecutively, Defendant cannot, for that reason alone, withdraw a guilty plea, and will remain bound to fulfill all of the obligations under this Plea Agreement.

Rights at Trial

- 11. Defendant represents to the Court that it is satisfied that his attorney has rendered effective assistance. Defendant understands that by entering into this Plea Agreement, it surrenders certain rights as provided in this Plea Agreement. Defendant understands that those rights include the following:
 - a. If Defendant persisted in a plea of not guilty to the charges, Defendant would have the right to a speedy jury trial with the assistance of counsel. The trial may be conducted by a judge sitting without a jury if Defendant, the United States, and the Court all agree.

- b. At a trial, the United States would be required to present witnesses and other evidence against Defendant. Defendant would have the opportunity to confront those witnesses, and his attorney would be allowed to cross-examine them. In turn, Defendant could, but would not be required to, present witnesses and other evidence on his own behalf. If the witnesses for Defendant would not appear voluntarily, it could require their attendance through the subpoena power of the Court.
- c. At a trial, Defendant could rely on a privilege against self-incrimination and decline to testify, and no inference of guilt could be drawn from such refusal to testify. But if Defendant desired to do so, it could testify on his own behalf.

Factual Basis for Guilty Plea

- 12. Defendant is pleading guilty because it <u>is</u> guilty of the charges contained in Count One of the Information as described in this agreement. If this case were to proceed to trial, the United States could prove each element of the offense beyond a reasonable doubt. The following facts, among others, would be offered to establish Defendant's guilt:
- 13. Luis "Louie" Palacios ("Palacios") owns and operates The Shack, a supplement and shakes retail outlet with several locations in McAllen, Edinburg, Pharr, and the surrounding area in the Southern District of Texas. The Shack is a Texas corporation in good standing with the Secretary of State.
- 14. On or about May 18, 2020, The Shack sold numerous products in violation of the Food, Drug and Cosmetics Act ("FDCA"). Specifically, The Shack sold a Selective Androgen Receptor Modulators ("SARMs") Ostarine under the private label name Jintro Pharmaceuticals. SARMs are substances that do not meet the definition of a dietary ingredient under 21 U.S.C. § 321(ff). Products containing the non-dietary ingredients SARMs that are intended to be used for

weight loss or to increase muscle mass (structure function claims) are considered to be drugs under the FDCA.

- 15. While the drug was held for sale and after its component had been shipped in the Defendent course. In the Defendent course the product's labeling to be false and misleading in any particular, in that the labeling falsely stated it was a "research product" when in fact it was intended to be used to increase muscle mass, which act resulted in the drug being misbranded within the meaning of Title 21, United States Code, Section 352(a), in violation of 21 U.S.C. §§ 331(k) and 333(a)(1).
- 16. Food and Drug Administration (FDA) agents (as well as other assisting agencies) executed a search warrant of two retail locations of The Shack on September 16, 2020. FDA-CI agents seized numerous private labeled supplements containing unsafe and non-dietary ingredients. Vitamin Shack and Shakes' private labeled products were tested and SARMs were detected.

Breach of the Plea Agreement

- 17. This Plea Agreement is being entered into by the United States on the basis of Defendant's express representation that it will make a full and complete disclosure of all assets over which it exercises direct or indirect control, or in which it has any financial interest. Defendant agrees not to dispose of any assets or take any action that would affect a transfer of property in which he has an interest, unless Defendant obtains the prior written permission of the United States.
- 18. Defendant agrees to make complete financial disclosure by truthfully executing a sworn financial statement (Form OBD-500) no later than 14 days after the re-arraignment. Defendant agrees to authorize the release of all financial information requested by the United States, including, but not limited to, executing authorization forms permitting the United States

to obtain tax information, bank account records, credit histories, and social security information. Defendant agrees to discuss and answer any questions by the United States relating to Defendant's complete financial disclosure.

- 19. Defendant agrees to take all steps necessary to pass clear title to forfeitable assets to the United States and to assist fully in the collection of restitution and fines, including, but not limited to, surrendering title, executing a warranty deed, signing a consent decree, stipulating to facts regarding the transfer of title and the basis for the forfeiture, and signing any other documents necessary to effectuate such transfer.
- 20. Defendant also agrees to direct any banks that have custody of his assets to deliver all funds and records of such assets to the United States. Defendant understands that forfeiture, restitution, and fines are separate components of sentencing and are separate obligations.

Financial Statement

- 21. Defendant agrees to truthfully complete under penalty of perjury within 14 days of the execution of this Plea Agreement, a financial statement on a form provided by the United States Attorney's Office and to update the statement within seven days of material change. Defendant also agrees to make full disclosure to the United States Probation Office of all current and anticipated assets in which Defendant has an interest both before sentencing and again before termination of supervised release or probation, such disclosure to be shared with the United States Attorney's Office.
- 22. Defendant further agrees not to dispose or transfer any assets without the prior written permission of the United States and to authorize the release of all financial information requested by the United States and to authorize the release of all financial information requested by the United States, including, but not limited to, credit histories and tax returns. Defendant

agrees to discuss and answer any questions by the United States relating to Defendant's financial disclosure, including in a deposition or informal debtor exam, whether before or after sentencing.

Forfeiture

- 23. Defendant agrees to a money judgment against him and in favor of the United States in the amount of \$175,000. Defendant understands that he is liable for the full amount of the money judgment imposed by the Court.
- 24. Defendant agrees to forfeit any of Defendant's property, or Defendant's interest in property, up to the value of the unpaid portion of the money judgment, until the money judgment is fully satisfied. Defendant stipulates and agrees that one or more of the conditions set forth in 21 U.S.C. § 853(p) exists. The United States shall credit against the money judgment the moneys paid under paragraph 18 of this agreement, and the final proceeds recovered from the final forfeiture of any property of Defendant or of any property that appears to be proceeds of the scheme of which Defendant has been convicted.
- 25. Defendant agrees to waive any and all interest in any asset which is the subject of a related administrative or judicial forfeiture proceeding, whether criminal or civil, federal or state.
- 26. Defendant waives the right to challenge the forfeiture of property in any manner, including by direct appeal or in a collateral proceeding.

Additional Agreements

27. Defendant must show proof of registration for The Shack's warehouse with the FDA as an own-label distributor, if required by law. Proof must be given to the United States Probation Office or the United States Attorney's Office.

- 28. Defendant further agrees to develop policy regarding batch record keeping, recalls, adverse events reporting, and periodic product testing for any own-labeled products pursuant as an own-label distributor.
- 29. The United States agrees to not request that the Court to issue any *additional* fine(s) or monetary penalties, other than those mandated by law, as a condition of any probationary sentence that the defendant receives, as both parties agree that the \$175,000 forfeiture amount justly satisfies both the punishment and restitution amounts that the case calls for.

Complete Agreement

30. This written plea agreement, consisting of 13 pages, including the attached addendum of Defendant and its attorney, constitutes the complete plea agreement between the United States, Defendant, and Defendant's counsel. Other than any written proffer agreement(s) that may have been entered into between the United States and Defendant, this Agreement supersedes any prior understandings, promises, agreement, or conditions between the United States and Defendant. No additional understandings, promises, agreements, or conditions have been entered into other than those set forth in this agreement, and none will be entered into unless in writing and signed by all parties. Defendant acknowledges that no threats have been made against it and that it is pleading guilty freely and voluntarily because it is guilty.

Filed at Houston, Texas, on December 6, 2024.

Duly Authorized Corporate Officer

Vitamin Shack and Shakes, d/b/a The Shack,

LLC

Defendant

Subscribed and sworn to before me on December 6, 2024.

NATHAN OCHSNER, Clerk UNITED STATES DISTRICT CLERK

By:

Deputy United States District Clerk

APPROVED:

ALAMDAR S. HAMDANI UNITED STATES ATTORNEY

By:

Tyler S. White

Assistant United States Attorney Southern District of Texas

713-567-9333

David Adler Rick Collins

Attorney for Defendant

Attorney for Defendant

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF TEXAS HOUSTON DIVISION

UNITED STATES OF AMERICA 999999 v. Criminal No. 4:23-cr-195-3 VITAMIN SHACK AND SHAKES, LLC, d/b/a THE SHACK, § Defendant.

PLEA AGREEMENT -- ADDENDUM

I have fully explained to Defendant its rights with respect to the pending Superseding Information. I have reviewed the provisions of the United States Sentencing Commission's Guidelines Manual and Policy Statements and I have fully and carefully explained to Defendant the provisions of those Guidelines which may apply in this case. I have also explained to Defendant that the Sentencing Guidelines are only advisory and the court may sentence Defendant up to the maximum allowed by statute per count of conviction. Further, I have carefully reviewed every part of this plea agreement with Defendant. To my knowledge, Defendant's decision to enter into this agreement is an informed and voluntary one.

I have consulted with my attorney and fully understand all my rights with respect to the indictment pending against me. My attorney has fully explained, and I understand, all my rights with respect to the provisions of the United States Sentencing Commission's Guidelines Manual which may apply in my case. I have read and carefully reviewed every part of this plea agreement with my attorney. I understand this agreement and I voluntarily agree to its terms.

Defendant Date