# FILED

# December 15, 2023

CLERK, U.S. DISTRICT COURT WESTERN DISTRICT OF TEXAS

DEPUTY

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

UNITED STATES OF AMERICA.

Plaintiff,

VS.

DEFYNED BRANDS a/k/a 5 STAR NUTRITION, LLC.

Defendant.

Case No. --

1:23-cr-00213-DH

# PLEA AGREEMENT [RULE 11(c)(1) BINDING]

The United States Department of Justice Civil Division Consumer Protection Branch, the United States Attorney for the Western District of Texas, and Defendant, DEFYNED BRANDS a/k/a 5 STAR NUTRITION, LLC, through its principals and counsel, enter into the following plea agreement in this cause, pursuant to Federal Rule of Criminal Procedure 11(c)(1):

#### Agreement to Plead Guilty:

Defendant agrees to plead guilty to Counts One through Three of the Information, which charges Defendant with introducing and delivering into interstate commerce articles of food that are misbranded, in violation 21 U.S.C. §§331(a), 333(a)(1) and will not withdraw or attempt to withdraw the plea. The Defendant admits that the Defendant is, in fact, guilty of this offense and will so advise the Court.

Pursuant to Federal Rule of Criminal Procedure 11(c)(1)(A), the Government will not seek additional charges against Defendant for the conduct giving rise to the pending charge in this case based on the facts set forth in this agreement.

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## Penalty:

The statutory penalties for Counts One through Three are as follows:

- a) A term of imprisonment of not more than 1 year, term of supervised release of not more than one year, and a fine of not more than \$100,000;
- b) Restitution;
- c) Forfeiture; and
- d) A mandatory special assessment of \$25 due prior to sentencing.

Any term of imprisonment imposed does not provide for parole. Having discussed the statutory range of punishment with Defendant's attorney, Defendant knows that statutory range and still wants to plead guilty in this case.

Defendant understands that in determining Defendant's sentence, the Court will consider the factors set forth in 18 U.S.C. § 3553(a) and the U.S. Sentencing Guidelines and accompanying policy statements, which are advisory. Because the Sentencing Guidelines are advisory only, Defendant's sentence may lie within, below, or above the Sentencing Guideline range after the Court has considered the § 3553(a) factors. Any estimate of the advisory sentencing range or probable sentence from any source including Defendant's attorney, the attorney for the Government, or the Probation Officer, is merely an estimate and not a prediction or a promise. Defendant stipulates that no person has promised what penalty Defendant will receive. Defendant knows the Court has authority to impose any sentence up to the maximum statutory penalty.

#### Sentencing Agreement pursuant to RULE 11(c)(1)(C):

Pursuant to Rule 11(c)(1)(C), and subject to approval and acceptance by the Court, the Government and Defendant agree that the appropriate disposition of this case is forfeiture in the amount of \$4.5 million dollars, to be paid as described herein, a \$25 special assessment as to each count of conviction, and no fine, term of probation, restitution, or other judicially imposed

punishment. Additionally, as described herein, Defendant agrees to establish and maintain a corporate compliance program and to submit required compliance reports to the Government as

set forth in Attachments A and B to this Plea Agreement. The parties agree not to seek or advocate

any sentence other than the sentence agreed to in this agreement. It is understood by the parties

that the final determination to accept a plea pursuant to Rule 11(c)(1)(C) ultimately remains in the

Court's discretion. Should the Court reject the plea agreement and decline to be bound by it, the

Court will afford Defendant an opportunity to withdraw the plea of guilty. Should Defendant

withdraw the plea of guilty, this plea agreement will be void and neither party will be bound by it.

Should Defendant decline to withdraw the guilty plea, Defendant understands that the Court may

dispose of the case less favorably toward Defendant than this plea agreement contemplates and

that the Court will determine and assess punishment to be imposed on Defendant. Moreover, the

Government reserves the right to advocate in support of the Court's judgment should this case be

presented to an appellate court.

Factual Basis for Plea:

Defendant acknowledges that Defendant's attorney has explained to Defendant all of the

elements of each offense to which Defendant is pleading guilty. Defendant understands that if

Defendant pleads not guilty, the United States would be required to prove each of these elements

to the unanimous satisfaction of a jury beyond a reasonable doubt. By signing this Plea Agreement,

Defendant admits that the facts set out in the factual basis below are true and correct:

From in or around September 2018 to July 2020, in the Western District of Texas and

elsewhere, Defendant introduced and delivered into interstate commerce foods that were

misbranded in violation of 21 U.S.C. §§ 331(a) and 333(a)(1).

Specifically,

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Plea Agreement – Defyned Brands Page 3 of 13 • In or about September 2018, Defendant shipped from Hutchins, Texas, to Hanover, Maryland, and subsequently sold in Hanover, Maryland, a product known as Epivar, a misbranded food, as declared on its label 3b-hydroxy-androstane-17-one, a non-dietary ingredient, to be a dietary ingredient.

In or about November 2018, Defendant shipped from Hutchins, Texas, to Offutt,
Nebraska, and subsequently sold in Offutt, Nebraska, a product known as Alpha
Shredded, a misbranded food, as it declared on its label 1-4 OHP17beta-[{}Keoethyl) androsta-1, 4-diene-3-one, 17a-ol, a non-dietary ingredient, to be a
dietary ingredient.

In or about November 2018, Defendant shipped from Hutchins, Texas, to Aurora,
 Colorado, and subsequently sold in Aurora, Colorado, a product known as
 Luxobolic, a misbranded food, as it contained Diosgenin, an ingredient that was not
 declared on the label, and declared on its label 5-alpha-hydroxy-laxogenin, a non-dietary ingredient, to be a dietary ingredient.

#### Forfeiture:

The Defendant acknowledges that pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461(c), the Government is entitled to the immediate forfeiture of any quantities of food which were misbranded when received in interstate commerce, or while in interstate commerce, or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which were introduced into interstate commerce, in violation of 21 U.S.C. § 331. However, because such items have been transferred, or sold to, third parties, pursuant to 21 U.S.C. § 853(p), the Defendant agrees to the substitution of \$4,500,000 in monetary assets for forfeiture, to be paid on the terms described below.

Defendant's forfeiture obligation shall be satisfied with 90 monthly payments of \$50,000 into an account as directed by the government. If at any time during this period Defendant commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of Defendant's debts, or seeking to adjudicate Defendant as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for Defendant or for all or any substantial part of Defendant's assets, Defendant agrees as follows:

- Defendant's obligations under this forfeiture provision may not be avoided pursuant to 11 U.S.C. § 547, and Defendant shall not argue or otherwise take the position in any such case, proceeding, or action that: (i) Defendant's obligations under this provision may be avoided under 11 U.S.C. § 547; (ii) Defendant was insolvent at the time this provision was entered into, or became insolvent as a result of the agreed forfeiture to the United States; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Defendant.
- If Defendant's obligations under this forfeiture provision are avoided for any
  reason, including, but not limited to, through the exercise of a trustee's avoidance
  powers under the Bankruptcy Code, the United States, at its sole option, may deem
  such avoidance to be a breach of this Plea Agreement.
- Defendant agrees that (i) any claims, actions, or proceedings brought by the United
   States to recover the agreed forfeiture amount are not subject to an "automatic stay"
   pursuant to 11 U.S.C. § 362(a), and Defendant shall not argue or otherwise contend
   that the United States' claims, actions, or proceedings are subject to an automatic

stay; (ii) Defendant shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding that are brought by the United States to recover the agreed forfeiture amount; and (iii) the United States has a valid claim against Defendant for the full amount of the agreed restitution (less any amount paid by Defendant prior to any claim, action, or proceeding brought by the United States for recovery of the agreed forfeiture amount), and the United States may pursue its claims in any appropriate case, action, or proceeding.

- Defendant acknowledges that its agreements in this Agreement are provided in exchange for valuable consideration provided in this Agreement.
- Defendant agrees not to contest the administrative, civil, and/or criminal forfeiture
   and further agrees not to assist others in filing a claim or petition.
- Defendant knowingly and voluntarily agrees to waive any further notice to it, its
  agents and/or its attorney regarding the abandonment, forfeiture, and disposition of
  the forfeiture amount.
- Defendant further agrees that the facts set forth in the Factual Basis of this Plea Agreement are true and correct, and establish a nexus between the forfeiture amount and the violation of Title 21 U.S.C. § 331(a), thereby subjecting the monies to forfeiture pursuant to Title 21 U.S.C. §§ 334(a)(1), 853(p), made applicable to criminal forfeiture by Title 28 U.S.C. § 2461(c).
- Defendant hereby waives the requirements of Fed. R. Crim. P. 32.2 with respect to
  the imposition of any forfeiture action carried out in accordance with this Plea
  Agreement. The Defendant waives all constitutional, legal, and equitable defenses

to the forfeiture in any proceedings, and further waives direct appeal of forfeiture

issues including habeas corpus and those arising under the Excessive Fines Clause.

• Defendant further waives all right to a jury trial on forfeiture issues regarding the

forfeiture amount.

Corporate Compliance Program and Reporting

For a period beginning on the date of sentencing and ending thirty-six (36) months from

that date (the "Compliance Term"), the Defendant agrees to comply with the terms of the Corporate

Compliance Program and Compliance Reporting Requirements as set forth in Attachments A and

B to this Plea Agreement. The Defendant agrees, however, that in the event the Government

determines, in its sole discretion, that the Defendant has failed to completely perform or fulfill

each of the Defendant's obligations relating to the Defendant's compliance program and reporting,

the Government, in its sole discretion, may impose an extension of the Compliance Term for up

to a total additional time period of one year, without prejudice to the Government's right to proceed

as provided under the Breach of Agreement section below. Conversely, in the event the

Government finds, in its sole discretion, that there exists a change of circumstances sufficient to

eliminate the need for the reporting requirements in Attachment B, and that the other provisions

of this Plea Agreement have been satisfied, the Compliance Term may be terminated early.

Defendant's Waiver of Statutory and Constitutional Rights:

Defendant understands and acknowledges that by pleading guilty, Defendant is waiving

the following constitutional and statutory rights:

(1) The right to plead not guilty and persist in that plea.

(2) The right to a speedy and public jury trial.

(3) The right to assistance of counsel at that trial and in any subsequent appeal

of that trial.

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- (4) The right to remain silent at trial.
- (5) The right to testify at trial.
- (6) The right to confront and cross-examine government witnesses.
- (7) The right to present evidence and witnesses on his or her own behalf.
- (8) The right to compulsory process of the court.
- (9) The right to be presumed innocent.
- (10) The right to a unanimous guilty verdict.
- (11) The right to appeal a guilty verdict.

In addition to giving up the rights described above, Defendant agrees to give up and waive the following:

<u>Pretrial Motions:</u> Defendant understands that Defendant could raise issues and challenges by pretrial motion, including motions to suppress evidence and to dismiss the charges. By entering into this agreement and pleading guilty, Defendant agrees to give up all claims Defendant has made or might have made by pretrial motion and to the dismissal of any currently pending motions.

Discovery: Defendant agrees to waive any claims Defendant may have now or may acquire later to any information possessed by the prosecution team that might be subject to disclosure under discovery rules, including but not limited to the Federal Rules of Criminal Procedure; the *Jencks* Act; local court rules and court orders. Defendant waives any continuing discovery request and any additional discovery. Defendant also waives all rights to request from any federal department or agency any records pertaining to the investigation or prosecution of this case, including but not limited to any records that may be sought under the Freedom of Information Act (5 U.S.C. § 552) or the Privacy Act (5 U.S.C. § 552a).

<u>Legal Fees and Expenses:</u> Defendant stipulates that Defendant is not entitled to and shall not seek from the United States any attorney fees or other litigation expenses Defendant has

incurred or will incur in connection with this prosecution.

Defendant's Waiver of Right to Appeal or Challenge Sentence:

In exchange for the concessions made by the United States in this agreement, Defendant

voluntarily and knowingly waives the right to appeal the conviction or sentence on any ground,

including any challenge to the constitutionality of the statute of conviction; any claim that

Defendant's conduct did not fall within the scope of the statute of conviction; any challenges to

the determination of any period of confinement, monetary penalty or obligation, restitution order

or amount, term of supervision and conditions; and any other claim based on rights conferred by

18 U.S.C. § 3742 or 28 U.S.C. § 1291, other than a claim that Defendant's sentence exceeded the

maximum term agreed to by the parties in the Rule 11(c)(1)(C) agreement discussed above if

accepted by the court.

Defendant also voluntarily and knowingly waives any right to contest the conviction or

sentence (or the manner in which the sentence was determined) in any post-conviction proceeding.

including any proceeding under 28 U.S.C. § 2255, 28 U.S.C. § 2241, or any other provision of

law. Consistent with principles of professional responsibility imposed on Defendant's counsel and

counsel for the Government, nothing in this agreement precludes Defendant from raising a claim

of ineffective assistance of counsel or prosecutorial misconduct of constitutional dimension in an

appropriate forum.

Defendant agrees that the United States preserves all rights set forth in 18 U.S.C. § 3742(b).

If Congress or the U.S. Sentencing Commission amends the Sentencing Guidelines to

lower the guideline range that applies to Defendant's offenses and explicitly makes that

amendment retroactive, the government agrees not to assert this waiver as a bar to Defendant filing

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Plea Agreement – Defyned Brands Page 9 of 13 a motion under 18 U.S.C. § 3582(c)(2) in district court. However, if Defendant files such a motion, the government reserves the right to oppose that motion and to assert this waiver as a bar to

Defendant appealing the district court's decision on that motion.

Advice of Counsel:

Defendant acknowledges reviewing with Defendant's counsel the merits of the charges and

possible defenses that Defendant may have; the advantages and disadvantages of pleading guilty;

the terms and meaning of the plea agreement; and the consequences of pleading guilty. Defendant

has discussed with Defendant's attorney the punishments and consequences of pleading guilty,

understands that not all of the consequences can be predicted or foreseen, and still wants to plead

guilty in this case.

Defendant understands that, if convicted, a defendant who is not a United States citizen or

is a naturalized citizen may be removed from the United States, denied citizenship, and denied

admission to the United States in the future.

Reservation of Rights:

The Government and Defendant each reserve the right to (1) present facts to the

U.S. Probation Office during preparation of a pre-sentence report; (2) dispute sentencing factors

or facts material to sentencing listed in the pre-sentence report; (3) seek resolution of such factors

or facts in conference with opposing counsel and the U.S. Probation Office; and (4) answer any

questions posed by the Court. All parties reserve full rights of allocution as to the appropriate

sentence Defendant should receive unless otherwise provided above.

Breach of Agreement:

If Defendant violates any term of this Plea Agreement, the Government will be released

from its obligations under this Plea Agreement and may, in its sole discretion:

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- (1) move to set aside Defendant's guilty plea and proceed on charges previously filed and any additional charges;
- (2) at sentencing or in any prosecution, use against Defendant any statements or information Defendant provided as part of the guilty plea,
- (3) seek to revoke or modify conditions of release;
- (4) advocate for any sentence up to and including the statutory maximum; and/or
- (5) decline to seek a reduced sentence.

Defendant understands and agrees that Defendant's breach of this Plea Agreement will not entitle Defendant to withdraw a guilty plea already entered. However, if Defendant withdraws from this agreement, Defendant agrees and understands that the factual basis set out in this Plea Agreement (1) may be used against Defendant in the Government's direct case and (2) sets forth facts that are true, accurate, admissible at any trial or hearing, and not subject to challenge under Federal Rule of Evidence 410(a) or Federal Rule of Criminal Procedure 11(f).

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## **Totality of Agreement:**

Defendant understands that this Agreement binds only the U.S. Department Consumer Protection Branch and U.S. Attorney for the Western District of Texas. When this Agreement uses the term Government, it refers only to the U.S. Department of Justice Consumer Protection Branch and the U.S. Attorney's Office for the Western District of Texas. This Plea Agreement sets forth the entirety of the agreement between the U.S. Department of Justice Consumer Protection Branch, the U.S. Attorney's Office for the Western District of Texas, Defendant, and Defendant's counsel. This agreement cannot be modified except in a written document signed by all parties. If an addendum to this agreement has been properly executed, it is incorporated herein by reference.

AMANDA LISKAMM
DIRECTOR
U.S. DEPARTMENT OF JUSTICE
CONSUMER PROTECTION BRANCH

DATE: , 2023

Ву:\_\_\_\_\_

DAVID SULLIVAN
Senior Litigation Counsel

JAMIE ESPARZA UNITED STATES ATTORNEY

DATE: 12/15/, 2023

MATT HARDING

Assistant United States Attorney

Defendant's Initials \_\_\_\_\_\_\_

Plea Agreement – Defyned Brands Page 12 of 13 I am counsel for Defendant, DEFYNED BRANDS a/k/a 5 STAR NUTRITION, LLC, in this case. I have fully explained to Defendant all of Defendant's rights with respect to the pending criminal charge. I have carefully reviewed this plea agreement in its entirety with Defendant and provided Defendant with my best professional advice. In my opinion, Defendant's decision to enter into this plea agreement is made freely, voluntarily, and with full knowledge of its obligations and consequences.

DATE: December 14, 2023

NAME]

Attorney for Defendant

I, [NAME], have carefully read and reviewed the entirety of this plea agreement, or it has been read to me (and if necessary, translated for me) and reviewed with me by my attorney. After careful consideration and discussion with my attorney, and fully understanding my rights with respect to the pending criminal charge(s), I freely and voluntarily agree to the specific terms and conditions of the plea agreement.

DATE: December 14, 2023

DAME] Brian Marver

[TITLE] Chief Executive Officer

DEFYNED BRANDS

a/k/a 5 STAR NUTRITION, LLC

Defendant

#### ATTACHMENT A

## **CORPORATE COMPLIANCE PROGRAM**

In order to address any deficiencies in its internal controls, compliance code, policies, and procedures regarding compliance with the Federal Food, Drug, and Cosmetic Act ("FDCA") and its associated regulations ("Relevant Law"), DEFYNED BRANDS a/k/a 5 STAR NUTRITION, LLC (the "Company"), on behalf of itself and its subsidiaries and affiliates, agrees to continue to conduct, in a manner consistent with all of its obligations under this Plea Agreement, appropriate reviews of its existing internal controls, compliance code, policies, and procedures.

Where necessary and appropriate, the Company agrees to adopt a new or to modify its existing compliance program, including internal controls, compliance code, policies, and procedures, to ensure that it maintains an effective compliance program that is designed, implemented, and enforced to effectively deter and detect violations of the Relevant Law. At a minimum, this should include, but not be limited to, the following elements to the extent they are not already part of the Company's existing internal controls, compliance code, policies, and procedures:

## Commitment to Compliance

1. The Company will ensure that its directors and senior management provide strong, explicit, and visible support and commitment to its corporate policy against violations of the Relevant Law and the Company's compliance codes, and demonstrate rigorous adherence by example. The Company will also ensure that middle management, in turn, reinforce those standards and encourage employees to abide by them. The Company will create and foster a culture of ethics and compliance with the law in its day-to-day operations at all levels of the company.

#### Policies and Procedures

- 2. The Company will develop and promulgate a clearly articulated and visible corporate policy against violations of the Relevant Law, which policy shall be memorialized in a written compliance code or codes.
- 3. The Company will develop and promulgate compliance policies and procedures designed to reduce the prospect of violations of the Relevant Law and the Company's compliance code, and the Company will take appropriate measures to encourage and support the observance of ethics and compliance policies and procedures against violation of the Relevant Law by personnel at all levels of the Company. These policies and procedures shall apply to all directors, officers, and employees and, where necessary and appropriate, outside parties acting on behalf of the Company, including, but not limited to, agents and intermediaries, consultants, representatives, distributors, teaming partners, contractors and suppliers, consortia, and joint venture partners (collectively, "agents and business partners"). The Company shall notify all employees that compliance with the policies and procedures is the duty of individuals at all levels of the company.
- 4. The Company will ensure that it has a system of procedures, including a system of internal controls, reasonably designed to ensure the maintenance of good manufacturing practices. This system shall be designed to provide reasonable assurances that:
- a. the Company maintains a dedicated business unit with sufficient resources, including Quality Assurance resources, to manage the qualification of third-party contract manufacturers, processors, packers, distributors, specification designers, and testing laboratories;
- b. the Company has oversight into the ongoing performance of third-party contract manufacturers, processors, packers, distributors, specification designers, and testing laboratories through monitoring and metrics;

- c. individuals who conduct oversight of third-party contract manufacturers, processors, packers, distributors, specification designers have the appropriate training and experience to determine whether the Company and such third parties are in compliance with the Relevant Law; and
- d. the Company documents, adequately investigates, and properly responds to all alleged deficiencies related to the quality of the Company's products.

#### Periodic Risk-Based Review

- 5. The Company will develop these compliance policies and procedures on the basis of a periodic risk assessment addressing the individual circumstances of the Company.
- 6. The Company shall review its compliance policies and procedures designed to reduce the prospect of violations of the Relevant Law or the Company's compliance code no less than annually and update them as appropriate to ensure their continued effectiveness, taking into account relevant developments in the field, evolving industry standards, and the risk profile of the Company, its customers, and its products.

## Proper Oversight and Independence

7. The Company will assign responsibility to one or more senior corporate executives of the Company for the implementation and oversight of the Company's compliance code, policies, and procedures regarding the Relevant Law. Such corporate official(s) shall have the authority to report directly to independent monitoring bodies, including internal audit, the Company's Board of Directors, or any appropriate committee of the Board of Directors, and shall have an adequate level of stature and autonomy from management as well as sufficient resources and authority to maintain such autonomy.

#### Training and Guidance

- 8. The Company will implement mechanisms designed to ensure that its compliance code, policies, and procedures regarding the Relevant Law are effectively communicated to all directors, officers, employees, and, where necessary and appropriate, agents and business partners. These mechanisms shall include: (a) periodic training for all directors and officers, all employees in positions of leadership or trust or in positions that require such training (e.g., regulatory, quality, manufacturing, research and development, sales, marketing, internal audit, legal, compliance), and, where necessary and appropriate, agents and business partners; and (b) corresponding certifications by all such directors, officers, employees, agents, and business partners, certifying compliance with the training requirements. The Company will conduct training in a manner tailored to the audience's size, sophistication, or subject matter expertise and, where appropriate, will discuss prior compliance incidents.
- 9. The Company will maintain, or where necessary establish, an effective system for providing guidance and advice to directors, officers, employees, and, where necessary and appropriate, agents and business partners, on complying with the Company's compliance code, policies, and procedures regarding the Relevant Law, including when they need advice on an urgent basis.

#### Internal Reporting and Investigation

10. The Company will maintain, or where necessary establish, an effective system for internal and, where possible, confidential reporting by, and protection of, directors, officers, employees, and, where appropriate, agents and business partners concerning violations of the Relevant Law or the Company's compliance code, policies, and procedures regarding the Relevant Law.

11. The Company will maintain, or where necessary establish, an effective and reliable process with sufficient resources for responding to, investigating, and documenting allegations of violations of the Relevant Law or the Company's compliance code, policies, and procedures regarding the Relevant Law. The Company will handle the investigations of such complaints in an effective manner, including routing the complaints to proper personnel, conducting timely and thorough investigations, and following up with appropriate discipline where necessary.

## Enforcement and Discipline

- 12. The Company will implement mechanisms designed to effectively enforce its compliance code, policies, and procedures, including appropriately incentivizing compliance and disciplining violations.
- 13. The Company will institute appropriate disciplinary procedures to address, among other things, violations of the Relevant Law and the Company's compliance code, policies, and procedures regarding the Relevant Law by the Company's directors, officers, and employees. Such procedures should be applied consistently, fairly, and in a manner commensurate with the violation, regardless of the position held by, or perceived importance of, the director, officer, or employee. The Company shall implement procedures to ensure that where misconduct is discovered, reasonable steps are taken to remedy the harm resulting from such misconduct, and to ensure that appropriate steps are taken to prevent further similar misconduct, including assessing the internal controls, compliance code, policies, and procedures and making modifications necessary to ensure the overall compliance program regarding the Relevant Law is effective.

#### Third-Party Relationships

- 14. The Company will institute appropriate risk-based due diligence and compliance requirements regarding the Relevant Law that pertain to the retention and oversight of agents and business partners, including:
- a. properly documented due diligence pertaining to the hiring and appropriate and regular oversight of agents and business partners;
- b. informing agents and business partners of the Company's commitment to abiding by the Relevant Law and of the Company's compliance code, policies, and procedures regarding the Relevant Law; and
- c. seeking a reciprocal commitment from agents and business partners.

  The Company will understand and record the business rationale for using a third party, and will conduct adequate due diligence with respect to the risks posed by a third-party partner such as a third-party partner's reputations and relationships, if any, with regulatory authorities and agencies. The Company will ensure that contract terms with third parties specifically describe the services to be performed, that the third party is actually performing the described work, and that its compensation is commensurate with the work being provided in that industry and geographical region. The Company will engage in ongoing monitoring of third-party relationships through updated due diligence, training, audits, and/or annual compliance certifications by the third party.
- 15. Where necessary and appropriate, the Company will include standard provisions in agreements, contracts, and renewals thereof with agents and business partners that are reasonably calculated to prevent violations of the Relevant Law, which may, depending upon the circumstances, include: (a) undertakings relating to compliance with the Relevant Law; (b) rights to conduct audits of the facilities, documents, and records of the agent or business partner to ensure

compliance with the foregoing; and (c) rights to terminate an agent or business partner as a result of any breach of the Relevant Law, the Company's compliance code, policies, or procedures, or the representations and undertakings related to such matters.

## Mergers and Acquisitions

- 16. The Company will develop and implement policies and procedures for mergers and acquisitions requiring that the Company conduct appropriate risk-based due diligence on potential new business entities, including appropriate due diligence regarding the Relevant Law by legal and compliance personnel.
- 17. The Company will ensure that the Company's compliance code, policies, and procedures regarding the Relevant Law apply as quickly as is practicable to newly acquired businesses or entities merged with the Company and will promptly:
- a. train the directors, officers, employees, agents, and business partners consistent with Paragraph 8 above on the Relevant Law and the Company's compliance code, policies, and procedures regarding the Relevant Law; and
- b. where warranted, conduct an audit of all newly acquired or merged businesses as quickly as practicable concerning compliance with the Relevant Law.

## Monitoring, Testing, and Remediation

18. In order to ensure that its compliance program does not become stale, the Company will conduct periodic reviews and testing of its compliance codes, policies, and procedures regarding the Relevant Law that are designed to evaluate and improve their effectiveness in preventing and detecting violations of the Relevant Law and the Company's compliance codes, policies, and procedures regarding the Relevant Law, taking into account relevant developments in the field, evolving industry standards, and the risk profile of the Company, its customers, and

its products. The Company will ensure that compliance and control personnel have sufficient direct or indirect access to relevant sources of data to allow for timely and effective monitoring and/or testing. Based on such review and testing and its analysis of any prior misconduct, the Company will conduct a thoughtful root cause analysis and timely and appropriately remediate to address the root causes.

#### ATTACHMENT B

## **COMPLIANCE REPORTING REQUIREMENTS**

DEFYNED BRANDS a/k/a 5 STAR NUTRITION, LLC, (the "Company") agrees that, as part of this Plea Agreement ("Agreement"), it will report to the United States Department of Justice Consumer Protection Branch, and the United States Attorney's Office for the Western District of Texas (collectively, the "Offices") periodically. Unless otherwise directed by the Offices in writing, the Company shall transmit copies of all work plans, reports, certifications, and other notices to the Offices as required herein by electronic mail to Consumer.Compliance@usdoj.gov and to any additional email addresses provided by the Offices. The subject line of the email must begin with the Company's name. In the event that electronic mail is unavailable, the notice may be sent by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail to an address provided by the Offices. Notice shall be effective upon actual receipt by the Offices.

During the Compliance Term as defined in the Agreement, the Company shall review, test, and update its compliance program and internal controls, policies, and procedures described in Attachment A. The Company shall be required to: (a) conduct an initial ("first") review and submit a first report and (b) conduct and prepare at least two follow-up reviews and reports, as described below. Prior to conducting each review, the Company shall be required to prepare and submit a work plan for the review. The Company shall also be required to submit additional types of reports on a periodic basis, as described below. The Company shall also, if requested by the Offices during the Compliance Term, provide additional information, including documents, or meet with the Offices regarding remediation, implementation, and testing of its compliance program and the internal controls, policies, and procedures described in Attachment A.

In conducting the reviews, the Company shall undertake the following activities, among others: (a) inspection of relevant documents, including the Company's current policies, procedures, and training materials concerning compliance with the FDCA and its associated regulations ("Relevant Law"); (b) inspection and testing of the Company's systems procedures, and internal controls, including record keeping and internal audit procedures; (c) meetings with, and interviews of, relevant current and, where appropriate, former directors, officers, employees, business partners, agents, and other persons; and (d) analyses, studies, and, comprehensive testing of the Company's compliance program.

## Written Work Plans, Reviews, Reports, and Certifications

- 1. The Company shall conduct a first review and prepare a first report, followed by at least two follow-up reviews and reports.
- 2. Within sixty (60) calendar days after the date of sentencing, the Company shall, after consultation with the Offices, prepare and submit a written work plan to address the Company's first review. The Offices shall have thirty (30) calendar days after receipt of the written work plan to provide comments, which the Company shall incorporate into its written work plan.
- 3. With respect to each follow-up review and report, after consultation with the Offices, the Company shall prepare a written work plan within forty-five (45) calendar days after the submission of the prior report, and the Offices shall provide comments within thirty (30) calendar days after receipt of the written work plan, which the Company shall incorporate into its written work plan.
- 4. All written work plans shall identify with reasonable specificity the activities the Company plans to undertake to review and test each element of its compliance program, as described in Attachment A.

- 5. Any disputes between the Company and the Offices with respect to any written work plan shall be decided by the Offices in their sole discretion.
- 6. No later than twelve (12) months after the date of sentencing, the Company shall submit to the Offices a first written report setting forth: (1) a complete description of its remediation efforts to date; (2) a complete description of the testing conducted to evaluate the effectiveness of the compliance program and the results of that testing; and (3) its proposals to ensure that its compliance program is reasonably designed, implemented, and enforced so that the program is effective in deterring and detecting violations of the Relevant Law. A certification from the Chief Executive Officer of the Company, in the form of executing the document attached as Attachment C to the Agreement, shall accompany the report. The certification will be deemed a material statement and representation by the Company to the executive branch of the United States for purposes of 18 U.S.C. §§ 1001 and 1519, and it will be deemed to have been made in the judicial district in which the Agreement is filed. With prior written approval of the Offices, the Company may extend the time period for issuance of the first report and certification.

## Follow-up Reviews, Reports, and Certifications

- 7. The Company shall undertake at least two follow-up reviews, reports, and certifications, incorporating the views of the Offices on the Company's prior reviews, reports, and certifications, to further monitor and assess whether the Company's compliance program is reasonably designed, implemented, and enforced so that it is effective at deterring and detecting violations of the Relevant Law.
- 8. The first follow-up ("second") review, report, and certification shall be completed and delivered to the Offices by no later than twelve (12) months after the first report and certification is submitted to the Offices.

- 9. The second follow-up ("third") review, report, and certification shall be completed and delivered to the Offices no later than thirty (30) calendar days before the end of the Compliance Term.
- 10. With prior written approval of the Offices, the Company may extend the time period for submission of any of the follow-up reports and certifications.

## Additional Reporting Requirements

11. The Company shall submit written reports to the Offices concerning Reportable Events on a quarterly basis. A Reportable Event is any matter that, after a reasonable opportunity to conduct an appropriate review or investigation of the allegations, a reasonable person would consider a material violation of the Relevant Law. A Reportable Event may be the result of an isolated event or a series of occurrences. The written report shall include: (a) whether any Reportable Events have been determined to have occurred during the preceding calendar quarter, and providing updated information about Reportable Events that the Company determined to have occurred during any prior calendar quarter, as may be necessary in the reasonable determination of the Company or at the Offices' request; (b) a description of the Reportable Event, including the relevant facts, the positions of the persons involved, and the legal authorities implicated; (c) a description of the Company's actions taken to investigate and correct the Reportable Event; and (d) a description of any further steps the Company plans to take to address the Reportable Event and prevent it from recurring. The written reports shall be submitted to the Offices no later than fifteen (15) calendar days after the end of each calendar quarter (that is, by January 15 for the calendar quarter ending December 31, April 15 for the calendar quarter ending March 31, July 15 for the calendar quarter ending June 30, and October 15 for the calendar quarter ending

September 30), excepting any calendar quarter that ends within thirty (30) calendar days of the end of the Compliance Term.

12. Within sixty (60) calendar days of retaining a new third-party contract manufacturer, processor, packer, distributor, specification designer, or testing laboratory, the Company shall submit a report to the Offices setting forth a complete description of its efforts to comply with the requirements for Third-Party Relationships as set forth in Attachment A as it relates to that new third party.

## Additional Information and Meetings During the Compliance Term

- 13. Upon request of the Offices in their sole discretion, the Company shall provide to the Offices additional information or documents regarding their compliance-related improvements, processes, and controls. The Company's cooperation pursuant to this Paragraph is subject to applicable law and regulations, as well as valid claims of attorney-client privilege or attorney work product doctrine; however, the Company must provide to the Offices a log of any information or cooperation that is not provided based on an assertion of law, regulation, or privilege, and the Company bears the burden of establishing the validity of any such an assertion.
- 14. When the Offices deem it appropriate in their sole discretion, representatives from the Company and the Offices will meet to discuss the status of the review and reporting obligations, and any suggestions, comments, or improvements the Company may wish to discuss with or propose to the Offices.

#### Confidentiality of Submissions

15. Submissions by the Company, including the work plans and reports, will likely include proprietary, financial, confidential, and competitive business information. Moreover, public disclosure of the submissions could discourage cooperation, impede pending or potential

government investigations and thus undermine the objectives of the reporting requirement. For these reasons, among others, the submissions and the contents thereof are intended to remain and shall remain non-public, except as otherwise agreed to by the parties in writing, or except to the extent the Offices determine in their sole discretion that disclosure would be in furtherance of the Offices' discharge of their duties and responsibilities or is otherwise required by law.