UNITED STATES DISTRICT COURT WESTERN DISTRICT OF TEXAS AUSTIN DIVISION

FILED

December 15, 2023 CLERK, U.S. DISTRICT COURT WESTERN DISTRICT OF TEXAS

 $_{\mathrm{BY:}}$ LRT

DEPUTY

UNITED STATES OF AMERICA Plaintiff

V

DEFYNED BRANDS a/k/a 5 STAR NUTRITION, LLC Defendant CAUSE NO. ---

1:23-cr-213-DH

INFORMATION

[Cts. 1-3: 21 U.S.C. § 331(a) – Introduction of Misbranded Foods into Interstate Commerce]

THE UNITED STATES ATTORNEY CHARGES:

- 1. The Food and Drug Administration ("FDA") was the agency of the United States responsible for enforcing the provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"). One of the purposes of the FDCA is to ensure that foods entering interstate commerce are safe to eat and bear labeling containing true and accurate information.
- 2. The FDCA defined "food" as "articles used for food or drink for man or other animals" and "articles used for components of any such article." 21 U.S.C. § 321(f)(1) and (3).
- 3. The FDCA defined a dietary supplement, in part, as "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients... (A) a vitamin; (B) a mineral; (C) an herb or other botanical..." 21 U.S.C. § 321(ff)(1). A dietary supplement was deemed to be a food within the meaning of the FCA. 21 U.S.C. § 321(ff). As a component of dietary supplements, dietary ingredients were also deemed to be "food" under the FDCA. 21 U.S.C. § 321(f)(3).
- 4. Food was misbranded under the FDCA if "its labeling is false or misleading in any particular." 21 U.S.C.§ 343(a)(1).

COUNT 1

(Introduction of Misbranded Food into Interstate Commerce)

- 5. Paragraphs 1 through 4 of the Information are incorporated here.
- 6. In or about September 2018, in the Western District of Texas and elsewhere, the defendant, **DEFYNED BRANDS** a/k/a 5 STAR NUTRITION, LLC, introduced and delivered into interstate commerce a food that was misbranded, to wit, the defendant, **DEFYNED BRANDS** a/k/a 5 STAR NUTRITION, LLC, shipped from Hutchins, Texas, to Hanover, Maryland, Epivar, which was labeled as a dietary supplement, that was misbranded within the meaning of Title 21, United States Code, Section 343(a)(1) in that its labeling was false and misleading because Epivar declared on its label 3b-hydroxy-androstane-17-one, a non-dietary ingredient, to be a dietary ingredient.

All in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 18 U.S.C. § 2.

COUNT 2

(Introduction of Misbranded Food into Interstate Commerce)

- 7. Paragraphs 1 through 4 of the Information are incorporated here.
- 8. In or about November 2018, in the Western District of Texas and elsewhere, the defendant, **DEFYNED BRANDS a/k/a 5 STAR NUTRITION, LLC,** introduced and delivered into interstate commerce a food that was misbranded, to wit, the defendant, **DEFYNED BRANDS a/k/a 5 STAR NUTRITION, LLC**, shipped from Hutchins, Texas, to Offutt, Nebraska, Alpha Shredded, which was labeled as a dietary supplement, that was misbranded within the meaning of Title 21, United States Code, Section 343(a)(1) in that its labeling was false and misleading because Alpha Shredded 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.

All in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 18 U.S.C. § 2.

COUNT 3

(Introduction of Misbranded Food into Interstate Commerce)

- 9. Paragraphs 1 through 4 of the Information are incorporated here.
- 10. In or about November 2018, in the Western District of Texas and elsewhere, the defendant, DEFYNED BRANDS a/k/a 5 STAR NUTRITION, LLC, introduced and delivered into interstate commerce a food that was misbranded, to wit, the defendant, DEFYNED BRANDS a/k/a 5 STAR NUTRITION, LLC, shipped from Hutchins, Texas, to Aurora, Colorado, Laxobolic, which was labeled as a dietary supplement, that was misbranded within the meaning of Title 21, United States Code, Section 343(a)(1) in that its labeling was false and misleading because Laxobolic contained Diosgenin, an ingredient that was not declared on the label, and the label of Laxobolic declared 5-alpha-hydroxy-laxogenin, a non-dietary ingredient, to be a dietary ingredient.

All in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 18 U.S.C. § 2.

FORFEITURE ALLEGATION

- 11. Upon conviction of the offenses set forth in Counts 1 through 3 of this Information, the defendant, **DEFYNED BRANDS a/k/a 5 STAR NUTRITION LLC**, shall forfeit to the United States, \$4,500,000 in monetary assets.
- 12. Pursuant to 21 U.S.C. § 334 and 28 U.S.C. § 2461(c), the Defendant shall forfeit 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, pursuant to 21 U.S.C. § 853(p), the United States seeks monetary forfeiture equal to \$4,500,000 because such misbranded foods have been transferred, or sold to, third parties.

U.S. DEPARTMENT OF JUSTICE

U.S. ATTORNEY'S OFFICE CONSUMER PROTECTION BRANCH FOR THE WESTERN DISTRICT OF TEXAS

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