**IN THE UNITED STATES DISTRICT COURT**
**FOR THE**
**NORTHERN DISTRICT OF ILLINOIS**

USA,

Plaintiff(s),

v.

Salud Natural Entrepreneur, Inc., et al.,

Defendant(s).

Case No. 22 C 1123
Judge Edmond E. Chang

# JUDGMENT IN A CIVIL CASE

Judgment is hereby entered (check appropriate box):

☐ in favor of plaintiff(s)
and against defendant(s)
in the amount of $ ,

which ☐ includes pre–judgment interest.
☐ does not include pre–judgment interest.

Post-judgment interest accrues on that amount at the rate provided by law from the date of this judgment.

Plaintiff(s) shall recover costs from defendant(s).

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☐ in favor of defendant(s)
and against plaintiff(s)

Defendant(s) shall recover costs from plaintiff(s).

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☒ other: Consent decree entered.

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This action was *(check one)*:

☐ tried by a jury with Judge presiding, and the jury has rendered a verdict.
☐ tried by Judge without a jury and the above decision was reached.
☒ decided by Judge Edmond E. Chang.

Date: 3/7/2022

Thomas G. Bruton, Clerk of Court

/s/ Michael Wing, Deputy Clerk

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

| | | |
|---|---|---|
| UNITED STATES OF AMERICA,<br><br>Plaintiff,<br><br>v.<br><br>SALUD NATURAL ENTREPRENEUR, INC., a corporation<br><br>and<br><br>HECTOR PABLO OLIVA, MICHEL MONFORT, and CAROLINA L. GIRAL, individuals,<br><br>Defendants. | ) | No. 1:22-CV-01123<br><br>Judge Edmond E. Chang |

**CONSENT DECREE**

Plaintiff, the United States of America, by its undersigned attorneys, having filed a complaint for permanent injunction against Salud Natural Entrepreneur, Inc. ("Salud Natural"), a corporation, and Hector Pablo Oliva, Michel Monfort, and Carolina Giral, individuals (collectively, "Defendants"), and Defendants having appeared by their attorney and consented to entry of this consent decree for permanent Injunction (the "Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree; it is hereby

ORDERED, ADJUDGED, and DECREED that:

1. This court has jurisdiction over the subject matter and all parties to this action.

2. The complaint for permanent injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.* (the "Act").

3. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, and/or causing to be introduced or delivered for introduction, into interstate

commerce articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, or held in violation of the current good manufacturing practice regulations for dietary supplements set forth in 21 C.F.R. Part 111 ("Dietary Supplement CGMP").

4. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1).

5. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, and/or causing to be introduced or delivered for introduction, into interstate commerce articles of food (dietary supplements, as defined at 21 U.S.C. §321(ff)) that are misbranded within the meaning of 21 U.S.C. §§ 343(f), (q)(1)(A), (q)(5)(F), (r)(1)(A), (s)(2)(A)(ii), and/or (s)(2)(C).

6. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of food (dietary supplements, as defined in 21 U.S.C. § 321(ff)) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 343(f), (q)(1)(A), (q)(5)(F), (r)(1)(A), (s)(2)(A)(ii), and/or (s)(2)(C).

7. Defendants violate the Act, 21 U.S.C. § 331(d), by introducing or delivering for introduction, and/or causing to be introduced or delivered for introduction, into interstate commerce new drugs (as defined in 21 U.S.C. § 321(p)), that are neither approved pursuant to 21 U.S.C. § 355 nor exempt from approval.

8. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, and/or causing to be introduced or delivered for introduction, into interstate

commerce articles of drug (as defined by 21 U.S.C. § 321(g)(1)(B)), that are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

9. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drug (as defined by 21 U.S.C. § 321(g)(1)(B)), that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

10. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are hereby permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this court, from directly or indirectly receiving, manufacturing, preparing, packing, repacking, labeling, holding, or distributing any articles of food (including but not limited to dietary supplements and their components) and/or articles of drug, at or from their facility located at 1120 Glen Rock Avenue, Waukegan, Illinois 60085, or at or from any other location(s) at or from which Defendants now or in the future directly or indirectly receive, manufacture, prepare, pack, repack, label, hold, or distribute any articles of food (including but not limited to dietary supplements and their components) and/or articles of drug (hereafter, "Defendants' Facility" or "the Facility"), unless and until:

A. Defendants retain, at Defendants' expense, an independent person (the "CGMP Expert") who has no personal or financial ties (other than a retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, or experience, is qualified to inspect the Facility to determine whether the methods, processes, and controls for receiving, manufacturing, preparing, packing, repacking, labeling, holding, or distributing dietary supplements are operated and administered in

conformity with Dietary Supplement CGMP requirements. Defendants shall notify FDA in writing of the identity and qualifications of the CGMP Expert within ten business days of retaining such expert or, if Defendants already have retained a CGMP Expert, within ten business days after signing this Decree;

B. The CGMP Expert performs a comprehensive inspection of the Facility and the methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements and certifies in writing to FDA that: (1) he or she has inspected the Facility and the methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements; (2) all Dietary Supplement CGMP deviations that have been brought to Defendants' attention by FDA, the CGMP Expert, and any other source have been corrected; and (3) the Facility and the methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements are, in the CGMP Expert's opinion, in compliance with this Decree, the Act, and the Act's implementing regulations. Defendants shall ensure that the CGMP Expert prepares a detailed report of the inspection, to be submitted concurrently to Defendants and FDA as part of the CGMP Expert's certification, no later than fifteen business days after completion of the inspection. Defendants shall ensure that the CGMP Expert's report includes, but is not limited to, a determination that Defendants have methods, processes, and controls to ensure that Defendants:

(1) Establish and follow written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing, as required by 21 C.F.R. § 111.103;

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