UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. SALUD NATURAL ENTREPRENEUR, INC., a corporation and HECTOR PABLO OLIVA, MICHEL MONFORT, and CAROLINA L. GIRAL, individuals, Defendants.	)	No. 1:22-CV-01123 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;

(2) Through their quality control personnel, reject a component or dietary supplement when a specification established in accordance with 21 C.F.R. § 111.70 is not met, as required by 21 C.F.R. § 113(b)(2);

(3) Prepare and follow a written master manufacturing record for each unique formulation and each batch size of dietary supplement Defendants manufacture, to ensure uniformity in the finished batch and from batch to batch, as required by 21 C.F.R. §§ 111.205 and 111.210. The master manufacturing record must contain all information set forth in 21 C.F.R. § 111.210, including but not limited to:

(a) the name and weight of each dietary ingredient for each batch size, as required by 21 C.F.R. § 111.210(a);

(b) a complete list of components to be used, as required by 21 C.F.R. § 111.210(b);

(c) an accurate statement of the weight and measure of each component to be used, as required by 21 C.F.R. § 111.210(c);

(d) the identity of each ingredient that will be declared on the ingredients list, as required by 21 C.F.R. § 111.210(d);

(e) a statement of any intentional overage amount, as required by 21 C.F.R. § 111.210(e);

(f) a statement of the theoretical yield for each point, step, or stage of the manufacturing process where control is needed to ensure the quality of the dietary supplement, the expected yield when manufacturing of the dietary supplement is finished, and the maximum and minimum percentages of theoretical yield beyond which a deviation investigation of a

batch is necessary and material review is conducted and disposition decision is made, as required by 21 C.F.R. § 111.210(f);

(g) a description of the packaging and a representative label, or a cross reference to the physical location of the actual or representative label, as required by 21 C.F.R. § 111.210(g);

(h) written instructions, as required by 21 C.F.R. § 111.210(h), including:

(i) specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure that the dietary supplement is packaged and labeled as specified in the master manufacturing record, as required by 21 C.F.R. § 111.210(h)(1);

(ii) procedures for sampling and a cross-reference to procedures for tests or examinations, as required by 21 C.F.R. § 111.210(h)(2);

(iii) specific actions necessary to perform and verify points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record, including verifying the weight or measure of any component and verifying the addition of any component, as required by 21 C.F.R. § 111.210(h)(3); and

(iv) corrective action plans for use when a specification is not met, as required by 21 C.F.R. § 111.210(h)(5);

(4) Prepare and follow a batch production record for each batch of dietary supplements Defendants manufacture that includes complete information relating to the production and control of each batch, as required by 21 C.F.R. §§ 111.255 and 111.260. Batch production records must contain all information set forth in 21 C.F.R. § 111.260, including but not limited to:

(a) the identity and weight or measure of each component, as required by 21 C.F.R. § 111.260(e);

(b) documentation, at the time of performance, of the manufacture of the batch including:

(i) the date on which each step of the master manufacturing record was performed, as required by 21 C.F.R. § 111.260(j)(1);

(ii) the initials of the persons performing each step to include the initials of the person responsible for weighing or measuring each component used in the batch, the initials of the person responsible for verifying the weight or measure of each component used in the batch, the initials of the person responsible for adding the component to the batch, and the initials of the person verifying the addition of the components to the batch, as required by 21 C.F.R. § 111.260(j)(2);

(c) documentation, at the time of performance, of packaging and labeling operations, including:

(i) the unique identifier that Defendants assigned to packaging and labels used, the quantity of the packaging and labels

used, and, when label reconciliation is required, reconciliation of any discrepancies between issuance and use of labels, as required by 21 C.F.R. § 111.260(k)(1);

(ii) an actual or representative label, or a cross-reference to the physical location of the actual or representative label specified in the master manufacturing record, as required by 21 C.F.R. § 111.260(k)(2); and

(iii) the results of any tests or examinations conducted on packaged and labeled dietary supplements (including repackaged or relabeled dietary supplements), or a cross-reference to the physical location of such results, as required by 21 C.F.R. § 111.260(k)(3);

(d) documentation, at the time of performance, that quality control personnel:

(i) reviewed each batch production record, as required by 21 C.F.R. § 111.260(l)(1), including review of any monitoring operations, as required by 21 C.F.R. § 111.260(l)(1)(i), and review of the results of any tests and examinations, including tests and examinations conducted on components, in-process materials, finished dietary supplements, and packaged and labeled dietary supplements, as required by 21 C.F.R. § 111.260(l)(1)(ii);

(ii) approved or rejected any reprocessing or repackaging, as required by 21 C.F.R. § 111.260(l)(2);

(iii) approved and released, or rejected, the batch for distribution, including any reprocessed batch, as required by 21 C.F.R. § 111.260(l)(3); and

(iv) approved and released, or rejected, the packaged and labeled dietary supplement, including any repackaged or relabeled dietary supplements, as required by 21 C.F.R. § 111.260(l)(4);

(e) documentation, at the time of performance, of any required material review or disposition decision, as required by 21 C.F.R. § 111.260(m).

(5) Maintain equipment to protect components and dietary supplements from being contaminated by any source, as required by 21 C.F.R. § 111.27(a)(3)(v);

(6) Take all necessary precautions during the manufacture of a dietary supplement to prevent contamination of components or dietary supplements, as required by 21 C.F.R. § 111.365;

(7) Hold components and dietary supplements under appropriate conditions, including temperature and humidity, so that the identity, purity, strength, and composition of the components and dietary supplements are not affected, as required by 21 C.F.R. § 111.455;

C. Defendants retain, at Defendants' expense, an independent expert (the "Labeling Expert") who is without any personal or financial ties (other than a retention agreement) to Defendants and/or their families, except that this person may be the same as the CGMP Expert described in paragraph 10.A., and who, by reason of background, training, education, or experience, is qualified to review Defendants' product labeling (including but not limited to labels, catalogs, websites, and social media accounts) and

other promotional/ informational material to determine whether: (1) the labeling complies with 21 U.S.C. § 343 and applicable regulations; and (2) Defendants' claims cause any product that they receive, manufacture, prepare, pack, repack, label, hold, or distribute to be a drug within the meaning of 21 U.S.C. §321(g)(1). Defendants shall notify FDA in writing of the identity and qualifications of the Labeling Expert within ten business days of retaining such expert, or, if Defendants have already retained a Labeling Expert, within ten business days after signing this Decree.

D. The Labeling Expert conducts a comprehensive review of Defendants' product labeling (including but not limited to labels, catalogs, websites, and social media accounts) and other promotional/informational material and certifies in writing to FDA that: (1) he or she has reviewed Defendants' product labeling and other promotional/informational materials; (2) all labeling violations brought to Defendants' attention by FDA, the Labeling Expert, and any other source, have been corrected; and (3) Defendants' products and claims are, in the Labeling Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations. Defendants shall ensure that the Labeling Expert prepares a detailed report of the review, to be submitted concurrently to Defendants and FDA as part of the Labeling Expert's certification, no later than fifteen (15) business days after completion of the review. Defendants shall ensure that the Labeling Expert's report includes, but is not limited to, a determination that:

(1) Defendants have implemented procedures that are adequate to ensure that their product labeling complies with 21 U.S.C § 343 and applicable regulations; and

(2) Defendants have implemented procedures that are adequate to ensure that their claims do not cause any product that they receive, manufacture,

prepare, pack, repack, label, hold, or distribute to be a drug within the meaning of 21 U.S.C. § 321(g)(1), unless and until the product is the subject of an approved new drug application or abbreviated new drug application pursuant to 21 U.S.C. § 355(a), (b), or (j), or an investigational new drug application is in effect for such product pursuant to 21 U.S.C. § 355(i);

E. Defendants report to FDA in writing the actions they have taken to:

(1) Correct the Dietary Supplement CGMP and labeling deviations brought to Defendants' attention by FDA, the CGMP Expert, the Labeling Expert, and any other source;

(2) Ensure that the facilities, methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements are and will be continuously operated in conformity with Dietary Supplement CGMP;

(3) Ensure that Defendants' product labeling complies with 21 U.S.C. § 343 and applicable regulations; and

(4) Ensure that Defendants' claims do not cause any product that they receive, manufacture, prepare, pack, repack, label, hold, or distribute to be a drug within the meaning of 21 U.S.C. § 321(g)(1) unless the product is the subject of an approved new drug application or abbreviated new drug application pursuant to 21 U.S.C. § 355(a), (b), or (j), or an investigational new drug application is in effect for such product pursuant to 21 U.S.C. § 355((i);

F. As and when FDA deems necessary, FDA representatives inspect Defendants' Facility, including the buildings, equipment, products, labeling, and all relevant records contained therein, to determine whether the requirements of this Decree

have been met and whether Defendants are operating in conformity with the Act, its implementing regulations, and this Decree;

G. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in paragraphs 10.A-E. of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

11. Within fifteen business days after entry of this Decree, Defendants, under FDA's supervision, shall destroy all dietary supplements (including components) and/or articles of drug (including raw and in-process materials and finished products) that are in Defendants' possession, custody, or control. Defendants shall bear the costs of destruction and the costs of FDA's supervision. Defendants shall not dispose of any products in a manner contrary to the provisions of the Act, any other federal law, or the laws or any State or Territory, as defined in the Act, in which the products are disposed.

12. Upon resuming operations after complying with paragraphs 10.A.-E. and receiving FDA's written notification pursuant to paragraph 10.G., Defendants shall retain an independent person (the "Auditor") who shall meet the criteria for, and may be the same person as, the CGMP Expert and Labeling Expert described in paragraphs 10.A. and 10.C., to conduct audit inspections of the Facility and the methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements, and of Defendants' dietary supplement labeling (including but not limited to labels, catalogs, websites, and social media accounts) and other promotional/informational material. Such audit inspections must entail the Auditor's physical presence at the Facility; audit inspections may not be conducted entirely by virtual means (*e.g.*, by camera or video link) without FDA's prior approval. The first audit inspection shall occur no later than six (6) months after operations resume. Thereafter:

A. Defendants shall ensure that the Auditor conducts audit inspections no less frequently than once every six months for a period of no less than five years and then at least once every year thereafter. The first audit shall occur not more than six months after Defendants have received FDA's written notification pursuant to paragraph 10.G.

B. Defendants shall ensure that, at the conclusion of each audit inspection, the Auditor prepares a detailed written audit report ("Audit Report") analyzing whether Defendants are in compliance with this Decree, the Act, and its implementing regulations and identifying any deviations from such requirements ("Audit Report Observations"). Defendants shall ensure that each Audit Report contains a written certification that the Auditor personally inspected the Facility, the methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements, and Defendants' dietary supplement labeling (including but not limited to labels, catalogs, websites, and social media accounts) and other promotional/informational material, and whether Defendants are in compliance with this Decree, the Act, and its implementing regulations. Defendants shall ensure that, as a part of every Audit Report (except the first one), the Auditor assesses the adequacy of actions taken by Defendants to correct all previous Audit Report Observations. Defendants shall ensure that the Audit Reports are delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than five business days after the audit inspection is completed. In addition, Defendants shall maintain the Audit Reports in separate files at Defendants' Facility and shall promptly make the Audit Reports available to FDA upon request.

C. If an Audit Report contains any Audit Report Observations, Defendants shall, within ten business days after receipt of the Audit Report, correct those observations,

unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the Audit Report Observations will take longer than ten business days, Defendants shall, within five business days after receipt of the Audit Report, submit to FDA in writing a proposed schedule for completing corrections ("Audit Correction Schedule"). The Audit Correction Schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved Audit Correction Schedule. Within twenty business days after Defendants' receipt of an Audit Report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in an FDA-approved Audit Correction Schedule, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within five business days after beginning that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

13. Upon entry of this Decree, and after receiving FDA's written notification pursuant to paragraph 10.G., 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, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (including but not limited to dietary supplements and their components) that are

adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or misbranded within the meaning of 21 U.S.C. § 343;

B. Violating 21 U.S.C. § 331(k) by causing articles of food (including but not limited to dietary supplements and their components) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or misbranded within the meaning of 21 U.S.C. § 343, while such articles are held for sale after shipment of one or more of their components in interstate commerce;

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

D. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352;

E. Violating 21 U.S.C. § 331(k) by causing articles of drug to become misbranded within the meaning of 21 U.S.C. § 352, which such articles are held for sale after shipment of one or more of their components in interstate commerce; and

F. Failing to implement and continuously maintain the requirements of this Decree.

14. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report, or data prepared or submitted by Defendants, the CGMP Expert, Labeling Expert, Auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, Defendants have violated the Act or its implementing regulations, or additional corrective actions are necessary to achieve compliance with this Decree,

the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease receiving, manufacturing, preparing, packing, repacking, labeling, holding, or distributing any and all products;

B. Recall, at Defendants' expense, any product that in FDA's judgment is adulterated, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports, plans, procedures, or other records prepared pursuant to this Decree;

D. Submit additional reports or information to FDA as requested;

E. Institute or reimplement any of the requirements set forth in this Decree;

F. Issue a safety alert; and/or

G. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, or its implementing regulations. This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law.

15. Upon receipt of any order issued by FDA pursuant to paragraph 14, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 14 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. Defendants shall pay all

costs of recalls and other corrective actions, including the costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses to implement and monitor the remedies set forth in paragraph 14, at the rates specified in paragraph 18.

16. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' operations and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and all applicable regulations. During such inspections, FDA representatives shall be permitted to: have immediate access to Defendants' places of business including, but not limited to, all buildings, equipment, components, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material therein; take photographs and make video recordings; take samples, without charge to FDA, of Defendants' components, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material; and examine and copy all records relating to the receipt, manufacture, preparing, packing, repacking, labeling, holding, and distribution of any and all of Defendants' products and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

17. Defendants shall promptly provide any information or records to FDA upon request regarding the receipt, manufacture, preparing, packing, repacking, labeling, holding, and distribution of Defendants' products, including components. Within ten business days after FDA's request for any labels, labeling, promotional materials, and/or downloaded copies of any websites and social media accounts owned and/or controlled by or related to Defendants, Defendants shall submit a copy of the requested materials to FDA at the address specified in paragraph 27.

18. Defendants shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree, including the travel incurred by specialized investigatory and expert personnel, at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $105.46 per hour or fraction thereof per representative for inspection and investigative work; $126.24 per hour or fraction thereof per representative for analytical or review work; $0.59 per mile (plus tolls) for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the court. Defendants shall make payment in full to FDA within twenty business days of receiving written notification from FDA of the costs.

19. Within five business days after entry of this Decree, Defendants shall post a copy of this Decree in English and Spanish in a conspicuous location in a common area at Defendants' Facility and shall ensure that the Decree remains posted for as long as the Decree remains in effect. Also within five business days after entry of this Decree, Defendants shall post a copy of this Decree in English and Spanish on all websites under Defendants' control. Within ten business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph.

20. Within ten business days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all employees, at which they shall describe the terms and obligations of this Decree. Within fifteen business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated

therein, stating the fact and manner of compliance with this paragraph and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

21. Within ten business days after entry of this Decree, Defendants shall provide a copy of the Decree, in English and Spanish, by personal service or certified mail (return receipt requested) to 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 ("Associated Persons"). Within twenty business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who have received a copy of this Decree, and attaching a copy of the executed certified mail return receipts.

22. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (return receipt requested) to such Associated Person(s). Within five business days of each time that any of the Defendants becomes associated with any additional Associated Person, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts.

23. Defendants shall notify FDA in writing at least ten business days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation of any Facility, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Salud Natural, or

the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least twenty business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten business days prior to such assignment or change in ownership.

24. If any Defendant fails to comply with any provision of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America: two thousand five hundred dollars ($2,500) in liquidated damages for each day such violation continues; an additional sum of two thousand five hundred dollars ($2,500) in liquidated damages per day per violation, for each violation of this Decree, the Act, or its implementing regulations; and an additional sum in liquidated damages equal to twice the retail value of any product distributed in violation of this Decree, the Act, or its implementing regulations. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, or the court to impose, additional civil or criminal penalties to be paid by Defendants, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

25. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), expert witness fees, travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to such contempt proceedings.

26. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, to the

extent that these decisions are subject to review, shall be reviewed by the court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

27. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be prominently marked "Decree Correspondence" and addressed to the Division Director, Office of Human and Animal Food Operations East 6 (HAFE 6), Chicago District Office, U.S. Food and Drug Administration, 550 West Jackson Blvd., Suite 1500, Chicago, IL 60661, with a copy to orahafeast6firmresponses@fda.hhs.gov, and shall reference this civil action by case name and civil action number.

28. This court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED, this 7th day of March 2022.

Edmond E. Chang

EDMOND E. CHANG
UNITED STATES DISTRICT JUDGE

Entry consented to:

For Defendants

HECTOR PABLO OLIVA
Individually and on behalf of Salud Natural Entrepreneur, Inc.

MICHEL MONFORT
Individually

CAROLINA L. GIRAL
Individually

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