IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Federal Trade Commission, Plaintiff, v. Quantum Wellness Botanical Institute LLC, et al., Defendants.	No. CV-20-00244-PHX-SMB **STIPULATED ORDER FOR PERMANENT INJUNCTION AND MONETARY JUDGMENT AGAINST MARIA GUTIERREZ VELOSO**

Plaintiff, the Federal Trade Commission ("Commission"), filed its Complaint for Permanent Injunction and Other Equitable Relief ("Complaint"), for a permanent injunction and other equitable relief in this matter, pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). The Commission and Defendant Maria Gutierrez Veloso (for purposes of this Order, "Defendant") stipulate to the entry of this Stipulated Order for Permanent Injunction and Monetary Judgment ("Order") to resolve all matters in dispute in this action between them.

THEREFORE, IT IS ORDERED as follows:

FINDINGS

1. This Court has jurisdiction over this matter.

2. The Complaint charges that Defendant participated in deceptive acts or practices in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52, in the marketing and sale of ReJuvenation.

3. Defendant neither admits nor denies any of the allegations in the Complaint,

except as specifically stated in this Order. Only for purposes of this action, Defendant admits the facts necessary to establish jurisdiction.

4. Defendant waives any claim that she may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date of this Order, and agrees to bear her own costs and attorney fees.

5. Defendant and the Commission waive all rights to appeal or otherwise challenge or contest the validity of this Order.

DEFINITIONS

For the purpose of this Order, the following definitions apply:

A. "Covered Product" means any Dietary Supplement, Food, or Drug, including, but not limited to, ReJuvenation.

B. "Defendant" means Maria Gutierrez Veloso.

C. "Dietary Supplement" means: (a) any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or (b) any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional Food or as a sole item of a meal or the diet.

D. "Drug" means: (1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) articles (other than Food) intended to affect the structure or any function of the body of humans or other animals; and (4) articles intended for use as a component of any article specified in (1), (2), or (3); but does not include devices or their components, parts, or accessories.

E. "Essentially Equivalent Product" means a product that contains the identical ingredients, except for inactive ingredients (e.g., binders, colors, fillers, excipients), in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the Covered Product; provided that the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field indicates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

F. "Food" means: (a) any article used for food or drink for humans or other animals; (b) chewing gum; and (c) any article used for components of any such article.

ORDER

I.

PROHIBITED REPRESENTATIONS:

HEALTH BENEFIT AND DISEASE CLAIMS

IT IS ORDERED that Defendant, Defendant's officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promoting, offering for sale, sale, or distribution of any Covered Product, are permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation that such product:

A. Stimulates or increases the body's production of human growth hormone, including by as much as 682%;

B. Increases stem cells in the body;

C. Reverses the aging process or repairs age-related damage in cells, skin, muscles, tissues, joints, and organs;

D. Reduces wrinkles, lines, and furrows;

E. Improves memory or cognitive function;

F. Repairs heart attack damage and prevents or heals heart disease;

G. Reverses blindness or eye damage;

H. Repairs brain damage from stroke, Alzheimer's disease, or Parkinson's disease;

I. Reverses deafness or hearing loss;

J. Reverses Crohn's disease;

K. Decreases body fat, increases lean muscle mass, or helps users shed excess weight; or

L. Cures, mitigates, or treats any disease;

unless the representation is non misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence substantiating that the representation is true.

For purposes of this Section, competent and reliable scientific evidence shall consist of human clinical testing of the Covered Product, or of an Essentially Equivalent Product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in the Section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

II.

PROHIBITED REPRESENTATIONS:

OTHER HEALTH-RELATED OR SAFETY CLAIMS

IT IS FURTHER ORDERED that Defendant, Defendant's officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promoting, offering for sale, sale, or distribution of any Covered Product, are permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation, other than representations covered under the Section entitled Prohibited Representations: Health Benefit and Disease Claims, about the health benefits, performance, efficacy, safety, or side effects of any Covered Product, unless the representation is non-misleading, and, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Section, competent and reliable scientific evidence means tests, analyses, research, or studies: (1) that have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product, or of an Essentially Equivalent Product, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth in the Section entitled Preservation of Records

Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

III.

PROHIBITED MISREPRESENTATIONS:

TESTS, STUDIES, OR OTHER RESEARCH

IT IS FURTHER ORDERED that Defendant, Defendant's officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promoting, offering for sale, sale, or distribution of any product, are permanently restrained and enjoined from misrepresenting, in any manner, or assisting others in misrepresenting, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration:

A. That any Covered Product is clinically or scientifically proven to:

1. Increase the body's production of human growth hormone by as much as 682% or any other amount;

2. Increase the body's production of stem cells;

3. Reverse the aging process in cells, skin, muscles, tissues, or organs; or

4. Repair age-related damage to the body's organs, tissues, joints, or muscles by stimulating the release of stem cells into the bloodstream;

B. That the performance or benefits of any product are scientifically or clinically proven or otherwise established; or

C. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

IV.

FDA-APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order prohibits Defendant, Defendant's officers, agents, employees, and attorneys, or all other persons in active concert or participation with any of them from:

A. For any Drug, making a representation that is approved in labeling for such Drug under any tentative final or final monograph promulgated by the Food and Drug Administration, or under any new Drug application approved by the Food and Drug Administration; and

B. For any product, making a representation that is specifically authorized for use in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

V.

PRESERVATION OF RECORDS RELATING TO COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Defendant relies to substantiate any claim covered by this Order, Defendant shall secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including:

A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;

B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;

C. Documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including

any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;

D. All documents referring or relating to any statistical analysis of any test data, including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and

E. All documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by: (1) any Defendant; (2) any of Defendant's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Defendant; (4) any person or entity affiliated with or acting on behalf of any Defendant; (5) any supplier of any ingredient contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For purposes of this Section, "reliably reported test" means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

For any test conducted, controlled, or sponsored, in whole or in part, by Defendant, Defendant must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to the nature and scope of Defendant's activities, and the sensitivity of the personal information collected from or about the participants.

VI.

MONETARY JUDGMENT

IT IS FURTHER ORDERED that:

A. Judgment in the amount of TWO MILLION FOUR HUNDRED THOUSAND Dollars ($2,400,000) is entered in favor of the Commission against Defendant as equitable monetary relief.

B. Defendant is ordered to pay to the Commission SIX HUNDRED THOUSAND Dollars ($600,000), which, as such Defendant stipulates, will be placed in escrow no later than August 2, 2020 with her undersigned counsel for no purpose other than payment to the Commission. Such payment must be made within 7 days of entry of this Order by electronic fund transfer in accordance with instructions previously provided by a representative of the Commission. Upon such payment, the remainder of the judgment is suspended, subject to the Subsections below.

C. The Commission's agreement to the suspension of part of the judgment is expressly premised upon the truthfulness, accuracy, and completeness of Defendant's sworn financial statements and related documents (collectively, "financial representations") submitted to the Commission, namely:

1. The Financial Statement of Defendant Maria Gutierrez Veloso signed on April 30, 2019, including the attachments; and

2. The additional documentation submitted by email from Defendant's Counsel to Commission Counsel Tawana E. Davis and Karen Mandel dated June 17, 2019, attaching statements from the TD Ameritrade account of the Maria Veloso Living Trust;

D. The suspension of the judgment will be lifted as to Defendant if, upon motion by the Commission, the Court finds that Defendant failed to disclose any material asset, materially misstated the value of any asset, or made any other material misstatement or omission in the financial representations identified above.

E. If the suspension of the judgment is lifted, the judgment becomes

immediately due as to Defendant in the amount specified in Subsection A above which the parties stipulate only for purposes of this Section represents the consumer injury alleged in the Complaint, less any payment previously made pursuant to this Section plus interest computed from the date of entry of this Order.

VII.

ADDITIONAL MONETARY PROVISIONS

IT IS FURTHER ORDERED that:

A. Defendant relinquishes dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

B. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission, including in a proceeding to enforce its rights to any payment or monetary judgment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

C. The facts alleged in the Complaint establish all elements necessary to sustain an action by the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.

D. Defendant acknowledges that her Taxpayer Identification Numbers (Social Security Numbers or Employer Identification Numbers), which Defendant previously submitted to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

E. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for equitable relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other equitable relief (including consumer information remedies) as it determines to be reasonably related to

Defendant's practices alleged in the Complaint. Any money not used for such equitable relief is to be deposited to the U.S. Treasury as disgorgement. Defendant has no right to challenge any actions the Commission or its representatives may take pursuant to this Subsection.

VIII.

CUSTOMER INFORMATION

IT IS FURTHER ORDERED that Defendant, Defendant's officers, agents, and employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, are permanently restrained and enjoined from directly or indirectly:

A. Disclosing, using, or benefitting from customer information, including the name, address, telephone number, email address, social security number, other identifying information, or any data that enables access to a customer's account (including a credit card, bank account, or other financial account), that any Defendant obtained prior to entry of this Order in connection with the manufacturing, labeling, advertising, promoting, offering for sale, sale, or distribution of any Covered Product; and

B. Failing to destroy such customer information in all forms in her possession, custody, or control within 30 days after receipt of written direction to do so from a representative of the Commission.

Provided, however, that customer information need not be disposed of, and may be disclosed, to the extent requested by a government agency or required by law, regulation, or court order.

IX.

ORDER ACKNOWLEDGMENTS

IT IS FURTHER ORDERED that Defendant obtain acknowledgments of receipt of this Order:

A. Defendant, within 7 days of entry of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 10 years after entry of this Order, Defendant for any business that such Defendant, individually or collectively with any other Defendants, is the majority owner or controls directly or indirectly, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for the manufacturing, labeling, advertising, promoting, offering for sale, sale, or distribution of any Covered Product and all agents and representatives who participate in the manufacturing, labeling, advertising, promoting, offering for sale, sale, or distribution of any Covered Product; and (3) any business entity resulting from any change in structure as set forth in the Section titled Compliance Reporting. Delivery must occur within 7 days of entry of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which Defendant delivered a copy of this Order, that Defendant must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

X.

COMPLIANCE REPORTING

IT IS FURTHER ORDERED that Defendant make timely submissions to the Commission:

A. One year after entry of this Order, Defendant must submit a compliance report, sworn under penalty of perjury:

1. Defendant must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission may use to communicate with Defendant; (b) identify all of that Defendant's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Defendant (which Defendant must describe if she knows or should know due to her own involvement); (d)

describe in detail whether and how that Defendant is in compliance with each Section of this Order; and (e) provide a copy of each Order Acknowledgment obtained pursuant to this Order, unless previously submitted to the Commission.

2. Additionally, Defendant must: (a) identify all telephone numbers and all physical, postal, email and Internet addresses, including all residences; (b) identify all business activities, including any business for which such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has any ownership interest; and (c) describe in detail such Defendant's involvement in each such business, including title, role, responsibilities, participation, authority, control, and any ownership.

B. For 10 years after entry of this Order, Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Defendant must report any change in: (a) any designated point of contact; or (b) the structure of any entity that Defendant has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

2. Additionally, Defendant must report any change in: (a) name, including aliases or fictitious name, or residence address; or (b) title or role in any business activity, including any business for which such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has any ownership interest, and identify the name, physical address, and any Internet address of the business or entity.

C. Defendant must submit to the Commission notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Defendant within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under

penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: FTC v. Quantum Wellness Botanical Institute, LLC, et al. File No._____.

XI.

RECORDKEEPING

IT IS FURTHER ORDERED that Defendant must create certain records for 10 years after entry of the Order, and retain each such record for 5 years. Specifically, Defendant for any business that such Defendant, individually or collectively with any other Defendants, is a majority owner or controls directly or indirectly, must create and retain the following records:

A. A copy of each unique advertisement or other marketing material;

B. Accounting records showing the revenues from all goods or services sold;

C. Personnel records showing, for each person providing services, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

D. Records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response; and

E. All records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission.

XII.

COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Defendant's compliance with this Order:

A. Within 14 days of receipt of a written request from a representative of the Commission, Defendant must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury; appear for depositions; and produce documents for inspection and copying. The Commission is also authorized to obtain discovery, without further leave of court, using any of the procedures prescribed by Federal Rules of Civil Procedure 29, 30 (including telephonic depositions), 31, 33, 34, 36, 45, and 69.

B. For matters concerning this Order, the Commission is authorized to communicate directly with Defendant. Defendant must permit representatives of the Commission to interview any employee or other person affiliated with any such Defendant who has agreed to such an interview. The person interviewed may have counsel present.

C. The Commission may use all other lawful means, including posing, through its representatives, as consumers, suppliers, or other individuals or entities, to Defendant or any individual or entity affiliated with Defendant, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

D. Upon written request from a representative of the Commission, any consumer reporting agency must furnish consumer reports concerning Defendant, pursuant to Section 604(1) of the Fair Credit Reporting Act, 15 U.S.C. § 1681b(a)(1).

XIII.

RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court retains jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

Dated this 10th day of February, 2020.

Honorable Susan M. Brnovich
United States District Judge