ZACHARY A. KELLER (Texas 24087838)
zkeller@ftc.gov; (214) 979-9382
REID A. TEPFER (Texas 24079444)
rtepfer@ftc.gov; (214) 979-9395
EDWARD HYNES (New York 4887584)
ehynes@ftc.gov; (214) 979-9381
Federal Trade Commission
1999 Bryan Street, Suite 2150
Dallas, Texas 75201
Fax: (214) 953-3079

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

FEDERAL TRADE COMMISSION, Plaintiff, v. **GOLDEN SUNRISE NUTRACEUTICAL, INC.**, a corporation, **GOLDEN SUNRISE PHARMACEUTICAL, INC.**, a corporation, **HUU TIEU**, individually and as an officer of Golden Sunrise Nutraceutical, Inc. and Golden Sunrise Pharmaceutical, Inc., and **STEPHEN MEIS**, individually and as an officer of Golden Sunrise Nutraceutical, Inc., Defendants.	Case No.: 1:20-cv-01060-DAD-SKO **STIPULATION TO PRELIMINARY INJUNCTION AS TO DEFENDANT STEPHEN MEIS**

The FTC filed its Complaint for Permanent Injunction and Other Equitable Relief ("Complaint"), pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b) (Doc. No. 2), and has moved, pursuant to Fed. R. Civ. P. 65(b), for a preliminary injunction to issue against Golden Sunrise Nutraceutical, Inc., Golden Sunrise Pharmaceutical,

Inc., Huu Tieu, and Stephen Meis.

THEREFORE, IT IS ORDERED as follows:

FINDINGS OF FACT

A. This Court has jurisdiction over the subject matter of this case, and there is good cause to believe that it will have jurisdiction over all parties hereto and that venue in this district is proper.

B. This Court has authority to enter a preliminary injunction pursuant to FED. R. CIV. P. 65.

C. The Complaint charges that Stipulating Defendant and Defendants participated in deceptive and unfair acts or practices in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C., §§ 45 and 52, in connection with the sale of dietary supplements.

D. Stipulating Defendant neither admits nor denies any of the allegations in the Complaint related to Stipulating Defendant, except as specifically stated in this Order. Only for purposes of this action, Stipulating Defendant admits the facts necessary to establish jurisdiction.

E. Stipulating Defendant waives any claim that he 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 his own costs and attorney fees.

F. Stipulating Defendant waives all rights to appeal or otherwise challenge or contest the validity of this Order.

G. This Court has authority to issue this Order pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b); Federal Rule of Civil Procedure 65; and the All Writs Act, 28 U.S.C. § 1651.

H. No security is required of any agency of the United States for issuance of a

preliminary injunction. FED. R. CIV. P. 65(c).

DEFINITIONS

For purposes of this Order, the following definitions apply:

A. "**Asset**" means any legal or equitable interest in, right to, or claim to, any property, wherever located and by whomever held.

B. "**Covered Product**" means any Food, Drug, Dietary Supplement, or any Plan of Care or any ingredient included in a Plan of Care, with "Plan of Care" meaning the products and services Defendants have marketed as the "Primary Plan of Care," the "Emergency D-Virus Plan of Care," the "Metabolic Plan of Care," and the "Cancer Plan of Care."

C. "**Dietary Supplement**" means:

1. any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or
2. 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. "**Document**" is synonymous in meaning and equal in scope to the usage of "document" and "electronically stored information" in Federal Rule of Civil Procedure 34(a), FED. R. CIV. P. 34(a), and includes writings, drawings, graphs, charts, photographs, sound and video recordings, images, Internet sites, web pages, websites, electronic correspondence,

including e-mail and instant messages, contracts, accounting data, advertisements, FTP Logs, Server Access Logs, books, written or printed records, handwritten notes, telephone logs, telephone scripts, receipt books, ledgers, personal and business canceled checks and check registers, bank statements, appointment books, computer records, customer or sales databases and any other electronically stored information, including Documents located on remote servers or cloud computing systems, and other data or data compilations from which information can be obtained directly or, if necessary, after translation into a reasonably usable form. A draft or non-identical copy is a separate document within the meaning of the term.

E. "**Drug**" means: (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic 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.

F. "**Essentially Equivalent Product**" means a product that contains the identical ingredients, except for inactive ingredients (e.g., inactive 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 are unlikely to impede or inhibit the effectiveness of the ingredients in the essentially equivalent product.

G. "**FDA**" means the United States Food and Drug Administration.

H. "**Food**" means: (1) any article used for food or drink for humans or other animals; (2) chewing gum; and (3) any article used for components of any such article.

I. "**Defendants**" means individually, collectively, or in any combination: (1) Golden Sunrise Nutraceutical, Inc., and its successors and assigns; (2) Golden Sunrise Pharmaceutical, Inc., and its successors and assigns; (3) Huu Tieu and Stephen Meis.

J. "**Stipulating Defendant**" means Stephen Meis.

I. PROHIBITED DISEASE CLAIMS

IT IS ORDERED that Stipulating Defendant and Stipulating 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, promotion, offering for sale, or sale of any Covered Product must not make any representation, expressly or by implication, that such product (1) treats, mitigates the symptoms of, or cures COVID-19; (2) treats, mitigates the symptoms of, or cures cancer; (3) treats, mitigates the symptoms of, or cures Parkinson's disease; or (4) prevents, treats, mitigates the symptoms of, or cures any disease, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of this Section, "competent and reliable scientific evidence" means 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 (1) be randomized, double-blind, and placebo-controlled; and (2) be 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 relevant field as relevant to an assessment of such testing as described in the Section titled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Stipulating Defendant will have the burden of proving that a product satisfies the definition of an Essentially Equivalent Product.

II. OTHER PROHIBITED HEALTH BENEFIT CLAIMS

IT IS FURTHER ORDERED that Stipulating Defendant and Stipulating 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, promotion, offering for sale, or sale of any Covered Product must not make any representation, other than representations covered under the Section titled Prohibited Disease Claims, expressly or by implication, about the health benefits, performance, or efficacy of such product, unless the representation is non-misleading, including that, 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 described in the Section of this Order titled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Stipulating Defendant will have the burden of proving that a product satisfies the definition of an Essentially Equivalent Product.

III. PROHIBITED MISREPRESENTATIONS REGARDING TESTS, STUDIES, OTHER RESEARCH, OR FDA APPROVAL

IT IS FURTHER ORDERED that Stipulating Defendant and Stipulating 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, promotion, offering for sale, or sale of any product must not make any misrepresentation, expressly or by implication:

A. About the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research, including that studies, research, or trials prove that any Covered Product (1) prevents, treats, mitigates the symptoms of, or cures COVID-19; (2) prevents, treats, mitigates the symptoms of, or cures cancer; (3) prevents, treats, mitigates the symptoms of, or cures Parkinson's disease; or (4) prevents, treats, mitigates the symptoms of, or cures any other disease.

B. That any benefit of such product is scientifically or clinically proven or otherwise

established; or

C. That the FDA has designated such product as a Regenerative Medicine Advance Therapy or otherwise approved, endorsed, authorized, or recommended the product for any use.

IV. 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 Stipulating Defendant relies to substantiate any claim covered by this Order, Stipulating Defendant must 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 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 Stipulating Defendant, Stipulating 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 size and complexity of Stipulating Defendant's enterprise, the nature and scope of Stipulating Defendant's activities, and the sensitivity of the personal information collected from or about the participants.

V. FDA APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order prohibits Stipulating Defendant, or Stipulating 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 FDA, or under any new Drug application approved by the FDA; and

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

VI. FINANCIAL DISCLOSURES

IT IS FURTHER ORDERED that Stipulating Defendant, within five (5) days of service of this Order upon them, shall prepare and deliver to Plaintiff's counsel:

A. Completed financial statements on the forms attached to this Order as **Attachment A** (Financial Statement of Individual Defendant); and

B. Completed **Attachment C** (IRS Form 4506, Request for Copy of a Tax Return).

VII. PROHIBITION ON RELEASE OF CUSTOMER INFORMATION

IT IS FURTHER ORDERED that Stipulating Defendant, Stipulating 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, are hereby restrained and enjoined from:

A. Selling, renting, leasing, transferring, or otherwise disclosing, the name, address, birth date, telephone number, email address, credit card number, bank account number, Social Security number, or other financial or identifying information of any person that any Defendant obtained in connection with any activity that pertains to the subject matter of this Order; and

B. Benefitting from or using the name, address, birth date, telephone number, email

address, credit card number, bank account number, Social Security number, or other financial or identifying information of any person that any Defendant obtained in connection with any activity that pertains to the subject matter of this Order.

Provided, however, that Stipulating Defendant may disclose such identifying information to a law enforcement agency, to their attorneys as required for their defense, as required by any law, regulation, or court order, or in any filings, pleadings or discovery in this action in the manner required by the Federal Rules of Civil Procedure and by any protective order in the case.

VIII. PRESERVATION OF RECORDS

IT IS FURTHER ORDERED that Stipulating Defendant, Stipulating 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, are hereby restrained and enjoined from:

A. Destroying, erasing, falsifying, writing over, mutilating, concealing, altering, transferring, or otherwise disposing of, in any manner, directly or indirectly, Documents that relate to: (1) the business, business practices, Assets, or business or personal finances of any Defendant; (2) the business practices or finances of entities directly or indirectly under the control of any Defendant; or (3) the business practices or finances of entities directly or indirectly under common control with any other Defendant; and

B. Failing to create and maintain Documents that, in reasonable detail, accurately, fairly, and completely reflect Defendants' income, disbursements, transactions, and use of Defendants' Assets.

IX. REPORT OF NEW BUSINESS ACTIVITY

IT IS FURTHER ORDERED that Stipulating Defendant, Stipulating 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, are hereby restrained and enjoined from creating, operating, or exercising any control over any business entity, whether newly formed or previously inactive, including any partnership, limited partnership, joint venture, sole proprietorship, or corporation, without first providing Plaintiff's counsel with a written statement disclosing: (1) the name of the business entity; (2) the address and telephone number of the business entity; (3) the names of the business entity's officers, directors, principals, managers, and employees; and (4) a detailed description of the business entity's intended activities.

X. DISTRIBUTION OF ORDER BY DEFENDANTS

IT IS FURTHER ORDERED that Stipulating Defendant shall immediately provide a copy of this Order to each affiliate, telemarketer, marketer, sales entity, successor, assign, member, officer, director, employee, agent, independent contractor, client, attorney, spouse, subsidiary, division, and representative of Stipulating Defendant, and shall, within ten (10) days from the date of entry of this Order, and provide Plaintiff with a sworn statement that this provision of the Order has been satisfied, which statement shall include the names, physical addresses, phone number, and email addresses of each such person or entity who received a copy of the Order. Furthermore, Stipulating Defendant shall not take any action that would encourage officers, agents, members, directors, employees, salespersons, independent contractors, attorneys, subsidiaries, affiliates, successors, assigns or other persons or entities in active concert or participation with them to disregard this Order or believe that they are not bound by its provisions.

XI. SUSPENSION OF COLLECTION OF ACCOUNTS

IT IS FURTHER ORDERED that Stipulating Defendant and Stipulating 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, are hereby restrained and enjoined from assigning any right to collect, attempting to collect, or collecting any payment for the Covered Products.

XII. SERVICE OF THIS ORDER

IT IS FURTHER ORDERED that copies of this Order as well as the Motion for Preliminary Injunction and Other Equitable Relief and all other pleadings, Documents, and exhibits filed contemporaneously with that Motion (other than the complaint and summons), may be served by any means, including facsimile transmission, electronic mail or other electronic messaging, personal or overnight delivery, U.S. Mail or FedEx, by agents and employees of Plaintiff, by any law enforcement agency, or by private process server, upon Stipulating Defendant or any person (including any financial institution) that may have possession, custody or control of any Asset or Document of Stipulating Defendant, or that may be subject to any provision of this Order pursuant to Rule 65(d)(2) of the Federal Rules of Civil Procedure. For purposes of this Section, service upon any branch, subsidiary, affiliate or office of any entity shall effect service upon the entire entity.

XIII. RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court shall retain jurisdiction of this matter for all purposes.

IT IS SO ORDERED.

Dated: **August 27, 2020**

UNITED STATES DISTRICT JUDGE