UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF FLORIDA WEST PALM BEACH DIVISION

Civil Action No. 9:20-cv-80640-DMM

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

RENAISSANCE HEALTH PUBLISHING, LLC, a limited liability company, also d/b/a Renown Health Products; and

JAMES DIGEORGIA, individually and as an owner, officer, and managing member of RENAISSANCE HEALTH PUBLISHING, LLC,

Defendants.

STIPULATED ORDER FOR PERMANENT INJUNCTION AND MONETARY JUDGMENT

Plaintiff, the Federal Trade Commission ("Commission" or "FTC"), filed its Complaint

for 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

Defendants Renaissance Health Publishing, LLC, and James DiGeorgia stipulate to the entry of

this Stipulated Final Judgment and Order for Permanent Injunction and Other Equitable Relief

("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 Defendants participated in deceptive acts or practices and false advertisements in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, in connection with the labeling, advertising, marketing, distribution, and sale of Isoprex.

3. Defendants neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Order. Only for purposes of this action, Defendants admit the facts necessary to establish jurisdiction.

4. Defendants waive any claim that they 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 agree to bear their own costs and attorney fees.

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

DEFINITIONS

For the purpose of this Order:

1. "Clear(ly) and conspicuous(ly)" means that a required disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:

A. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented.
In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be presented simultaneously in both

the visual and audible portions of the communication even if the representation requiring the disclosure is made in only one means.

- B. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.
- C. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.
- D. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.
- E. On a product label, the disclosure must be presented on the principal display panel.
- F. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the representation that requires the disclosure appears.
- G. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.
- H. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.
- I. When the representation or sales practice targets a specific audience, such as children, the elderly, or the terminally ill, "ordinary consumers" includes reasonable members of that group.

2. "Corporate Defendant" means Renaissance Health Publishing, LLC, and its successors and assigns.

3. "Covered Product" means any Dietary Supplement, Food, or Drug, including Isoprex.

4. "Defendants" means the Individual Defendant and the Corporate Defendant, individually, collectively or in any combination.

5. "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.

6. "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.

7. "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 relevant 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.

8. "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.

9. "Individual Defendant" means James DiGeorgia.

10. "Material Connection" means any relationship that materially affects the weight or credibility of any endorsement and that would not reasonably be expected by consumers.

I.

PROHIBITED REPRESENTATIONS REGARDING HEALTH-RELATED CLAIMS REQUIRING HUMAN CLINICAL TESTING FOR SUBSTANTIATION

IT IS ORDERED that Defendants, Defendants' 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, sale, or distribution of any Covered Product are hereby permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation that such product:

A. Relieves pain, including, but not limited to, muscle pain, joint pain, headache, and arthritis;

- B. Reduces inflammation and swelling, including, but not limited to, joint inflammation and knee swelling;
- C. Rebuilds joints and repairs damaged joint cartilage;
- D. Is 100%, or any other percentage, effective in relieving inflammation and swelling;
- E. Provides pain relief comparable or superior to over-the-counter drugs; or
- F. Cures, mitigates or treats any disease,

unless the representation is non-misleading and, at the time of making such representation, Defendants possess and rely upon competent and reliable scientific evidence to substantiate 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 CLAIMS

IT IS FURTHER ORDERED that Defendants, Defendants' 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, sale, or distribution of any Covered Product, are permanently restrained and enjoined from making, or assisting others in making, directly or by implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation, other than representations covered under the Section of this Order entitled Prohibited Representations Regarding Health-Related Claims Requiring Human Clinical Testing For Substantiation, about the health benefits, performance, efficacy, safety, or side effects of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, 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.

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 Defendants rely to substantiate any claim covered by this Order, Defendants 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 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 Defendants, Defendants 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 Corporate Defendant's size and complexity, the nature and scope of Defendants' activities, and the sensitivity of the personal information collected from or about the participants.

IV.

PROHIBITED REPRESENTATIONS REGARDING TESTS, STUDIES, OR OTHER RESEARCH

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, servants, employees, and attorneys, and all other persons or entities 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, sale, or distribution of any Covered Product, in or affecting commerce, are hereby permanently restrained and enjoined from misrepresenting, 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 proven to:
 - 1. Relieve pain, including, but not limited to, muscle pain, joint pain, headache, and arthritis pain;
 - 2. Reduce inflammation and swelling, including, but not limited to, joint inflammation and knee swelling;
 - 3. Rebuild joints and repair damaged joint cartilage;
 - 4. Relieve 100%, or any other percentage, of inflammation and swelling; or
 - 5. Provide pain relief comparable or superior to over-the-counter drugs;
- B. That the performance or benefits of any product are scientifically proven; or
- C. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

V.

FDA-APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order prohibits Defendants,

Defendants' 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.

VI.

DISCLOSURE OF MATERIAL CONNECTIONS

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, and employees, 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, sale, or distribution of any goods or services, are permanently restrained and enjoined from making any representation, expressly or by implication, about any consumer or other endorser of such good or service without disclosing, Clearly and Conspicuously, and in close proximity to the representation, any unexpected material connection between such endorser and 1) any Defendant; or 2) any other individual or entity affiliated with the good or service. For the purposes of this provision, "unexpected material connection" means any relationship that might materially affect the weight or credibility of the testimonial or endorsement and that would not reasonably be expected by consumers.

VII.

MONETARY JUDGMENT

IT IS FURTHER ORDERED that:

A. Judgment in the amount of Three Million Nine Hundred Thirty Four Thousand Dollars (\$3,934,000) is entered in favor of the Commission against Individual Defendant and Corporate Defendant, jointly and severally, as equitable monetary relief.

B. Defendants are ordered to pay to the Commission One Hundred Thousand Dollars (\$100,000) as follows:

- 1. Twenty Five Thousand Dollars (\$25,000) within seven (7) days of the entry of this Order;
- 2. Twenty Five Thousand Dollars (\$25,000) within thirty (30) days of the entry this Order;
- 3. Twenty Five Thousand Dollars (\$25,000) within sixty (60) days of the entry of this Order; and
- 4. Twenty Five Thousand Dollars (\$25,000) within ninety (90) days of the entry of this Order.

C. Such payments must be made by electronic funds transfer in accordance with instructions previously provided by a representative of the Commission. Upon payment of the full One Hundred Thousand Dollars (\$100,000) pursuant to Subsection B, the remainder of the

judgment is suspended, subject to the Subsections below.

D. In the event Defendants fail to pay One Hundred Thousand Dollars (\$100,000) within ninety (90) days of entry of this Order, Defendants shall be in default and the full amount of the judgment shall immediately become due, plus interest from the date of entry of this judgment pursuant to 28 U.S.C. § 1961, less any payments already made. *Provided, however*, that in the event of default, the judgment amount set forth in Subsection A above shall not become due if the Defendants cure such default within twenty one (21) calendar days.

E. After the expiration of the time to cure the default, the Commission shall be entitled to immediately exercise any and all rights and remedies against the Defendants and their property to collect the full amount of the judgment amount set forth in Subsection A above and interest thereon, less any payments already made.

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

 Financial Statement of Individual Defendant James DiGeorgia signed on July 16, 2019, including the attachments;

Financial Statement of Corporate Defendant Renaissance Health Publishing,
 LLC, signed by James DiGeorgia on September 19, 2019, including the attachments; and

3. The additional documentation submitted by electronic mail from Defendants' counsel Joel Rothman and /or Aaron Wernick to Commission counsel Sydney Knight and/or Edward Glennon, dated September 11, 2019; September 12, 2019; September 17, 2019; September 18, 2019; September 19, 2019; September 26, 2019; October 1, 2019; October 16, 2019; October 17, 2019; and October 24, 2019; including all attachments thereto.

G. The suspension of the judgment will be lifted as to any 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 attestations identified above.

H. If the suspension of the judgment is lifted, the judgment becomes immediately due as to that 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.

VIII.

ADDITIONAL MONETARY PROVISIONS

IT IS FURTHER ORDERED that:

A. Defendants relinquish 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. Defendants acknowledge that their Taxpayer Identification Numbers (Social Security Numbers or Employer Identification Numbers), which Defendants must submit 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 Defendants' practices alleged in the Complaint. Any money not used for such equitable relief is to be deposited to the U.S. Treasury as disgorgement. Defendants have no right to challenge any actions the Commission or its representatives may take pursuant to this Subsection.

IX.

CUSTOMER INFORMATION

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, servants, 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. Failing to provide sufficient customer information to enable the Commission to efficiently administer consumer redress. Defendants represent that they have provided this redress information to the Commission. If a representative of the Commission requests in writing any information related to redress, Defendants must provide it, in the form prescribed by the Commission, within 14 days.

B. 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 sale of the Covered Products; and

C. Failing to destroy such customer information in all forms in their 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.

X.

NOTICE TO CONSUMERS

IT IS FURTHER ORDERED that, within 30 days of the entry of this Order,

Defendants shall send by first-class mail an exact copy of the notice attached as Attachment A, showing the date of the mailing, to any consumer who, as of the date of entry of this Order, is or has been a customer of that Defendant and has received or will receive at least one bottle of Isoprex. The notice required by this Section shall not include any other document or enclosure.

XI.

ORDER ACKNOWLEDGMENTS

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

A. Each 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, the Individual Defendant for any

business that such Defendant, individually or collectively with the Corporate Defendant, is the majority owner or controls directly or indirectly, and the Corporate Defendant must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees, agents, and representatives who participate in conduct related to the subject matter of the Order; 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 a Defendant delivered a copy of this Order, that Defendant must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

XII.

COMPLIANCE REPORTING

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

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

1. Each 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 products and services offered, the means of advertising, marketing, and sales, and the involvement, if any, of the other Defendant (which the Individual Defendant must describe if he knows or should know due to his 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, the Individual 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 20 years after entry of this Order, each Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Each Defendant must report any change in: (a) any designated point of contact; or (b) the structure of the Corporate Defendant or any entity that Defendant has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: the 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, the Individual 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. Each Defendant must submit to the Commission notice of the filing of any bankruptcy petition, insolvency proceeding, or any 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 <u>DEbrief@ftc.gov</u> 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, D.C. 20580. The subject line must begin: *FTC v. Renaissance Health Publishing, et al.*, [insert X number].

XIII.

RECORDKEEPING

IT IS FURTHER ORDERED that Defendants must create certain records for 20 years after entry of the Order, and retain each such record for 5 years. Specifically, the Corporate Defendant and the Individual Defendant, for any business that the Individual Defendant, individually or collectively with the Corporate Defendant, is a majority owner or controls directly or indirectly, must create and retain the following records:

A. Accounting records showing the revenues from all products or services sold, all costs incurred in generating those revenues, and the resulting net profit or loss;

B. 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;

C. Complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;

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

E. A copy of each unique advertisement or other marketing material disseminated since the date of entry of this Order.

XIV.

COMPLIANCE MONITORING

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

A. Within 14 days of receipt of a written request from a representative of the Commission, each 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 also is 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 each Defendant. Defendants must permit representatives of the

Commission to interview any employee or other person affiliated with any Defendant who has agreed to such an interview. The person interviewed may have counselpresent.

C. The Commission may use all other lawful means, including posing, through its representatives, as consumers, suppliers, or other individuals or entities, to Defendants or any individual or entity affiliated with Defendants, 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.

XV.

RETENTION OF JURISDICTION

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

SO ORDERED:

DATED:

DONALD M. MIDDLEBROOKS UNITED STATES DISTRICT JUDGE

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ATTACHMENT A

[On Renaissance Health Publishing letterhead]

[on envelope]

IMPORTANT NOTICE ABOUT ISOPREX COURT SETTLEMENT

[content of letter, 16-point font]

Dear [Recipient]:

We're writing to you because you bought Isoprex, a pill advertised to have many health benefits. The Federal Trade Commission (FTC), the nation's consumer protection agency, sued our company for deceptive advertising. As part of a settlement, our company will no longer claim that Isoprex or any other product can help with pain, inflammation, swelling, or has any other health benefit — unless we have the evidence to back it up.

Here are some of the health claims that we can't make unless we have scientific proof:

- Effectively relieves all types of pain, including muscle pain, joint pain, headache and arthritis;
- Effectively reduces inflammation and swelling, including joint inflammation and knee swelling;
- Effectively rebuilds and repairs damaged joint cartilage;
- Is 100% effective in relieving inflammation and swelling; and
- Provides pain relief comparable or superior to over-the-counter drugs.

You can find out more about the FTC's lawsuit at [URL].

Sincerely,

[Renaissance Health Publishing]