UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

APPLIED FOOD SCIENCES, INC.,
a corporation,

Defendant.

Civ. No. 1:14-cv:00851

~~[Proposed]~~
STIPULATED ORDER FOR
PERMANENT INJUNCTION
AND MONETARY JUDGMENT

Plaintiff, the Federal Trade Commission, ("Commission" or "FTC"), filed its Complaint for Permanent Injunction or Other Equitable Relief, pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). The Commission and Defendant stipulate to the entry of this Stipulated Order for Permanent Injunction and Monetary Judgment to resolve all matters in dispute 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) and 52, in connection with the sale and marketing of GCA®, also known as Green Coffee Antioxidant, a green coffee bean extract used in dietary supplements and foods, including beverages.

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 it may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date of entry of this Order, and agrees to bear its own costs and attorney fees.

5. Defendant waives 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:

1. "Defendant" means Applied Food Sciences, Inc., ("AFS") and its successors and assigns.

2. "And" and "or" shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

3. "Covered product" shall mean:

   A. Any Dietary Supplement, Food, Drug, or Device;

   B. Any vitamin, mineral, herb or other botanical, or amino acid; or

   C. Any concentrate, metabolite, constitute, extract, or combination of any ingredient described in Paragraph 3(B).

4. "Device" means an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory, that is:

   A. Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them;

   B. Intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals; or

C. Intended to affect the structure or any function of the body of humans or other animals; and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and that is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

5. "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.

6. "Drug" means:

A. 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;

B. Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;

C. Articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and

D. Articles intended for use as a component of any article specified in clause A, B, or C above; but does not include Devices or their components, parts, or accessories.

7. "Endorsement" means, as defined in 16 C.F.R. § 255.0(b), any advertising message (including verbal statements, demonstrations, or depictions of the name, signature, likeness or other identifying personal characteristics of an individual or the name or seal of an organization) that consumers are likely to believe reflects the opinions, beliefs, findings, or experiences of a party other than the sponsoring advertiser, even if the views expressed by that party are identical to those of the sponsoring advertiser.

8. "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 are unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

9. "Food" means:

A. Articles used for food or drink for humans or other animals;

B. Chewing gum; and

C. Articles used for components of any such article.

10. "GCA" or "Green Coffee Antioxidant" means the green coffee bean extract that AFS markets or has marketed under the names GCA and/or Green Coffee Antioxidant.

11. "Including" means including without limitation.

12. "Person" means a natural person, an organization or other legal entity, including a corporation, partnership, sole proprietorship, limited liability company, association, cooperative, or any other group or combination acting as an entity.

13. "Reliably Reported," for a human clinical test or study ("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.

I.

PROHIBITED REPRESENTATIONS:

WEIGHT-LOSS CLAIMS

IT IS HEREBY ORDERED that Defendant, Defendant's officers, agents, servants, 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, marketing, 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 name, Endorsement, depiction, or illustration, any representation that such Covered Product:

A. Causes or helps cause weight loss, fat loss, or any specific amount of weight loss or fat loss; or

B. Causes or helps cause substantial weight loss or fat loss

unless the representation is non-misleading and, at the time of making such representation, Defendant possesses and relies 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 at

least two adequate and well-controlled human clinical tests of the Covered Product or of an Essentially Equivalent Product, conducted by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true. Defendant shall have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

For purposes of this Section, "adequate and well-controlled human clinical study" means a human clinical study that is: (1) randomized, double-blind, and placebo-controlled; (2) conducted by persons qualified by training and experience to conduct such a study; and (3) as to which, all underlying or supporting data and documents generally accepted by experts in weight-loss research as relevant to an assessment of such testing, as set forth in Section XII (Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies), are available for inspection and production to the Commission.

II.

PROHIBITED REPRESENTATIONS:

OTHER HEALTH-RELATED CLAIMS

IT IS FURTHER ORDERED that Defendant, Defendant's officers, agents, servants, 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, marketing, promotion, offering for sale, sale, or distribution of any Covered Product, are hereby permanently restrained and enjoined from making, or assisting others in making, directly or by implication, including through the use of a product name, Endorsement, depiction, or illustration, any representation, other than representations

covered under Section I of this Order, about the health benefits, performance, or efficacy of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, Defendant possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, 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 qualified persons; (2) that are generally accepted in the profession to yield accurate and reliable results; and (3) as to which, when they 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,a s set forth in Section XII (Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies), are available for inspection and production to the Commission.

III.

PROHIBITED REPRESENTATIONS:

TESTS OR STUDIES

IT IS FURTHER ORDERED that Defendant, Defendant's officers, agents, servants, 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, marketing, promotion, offering for sale, sale, or distribution of any Covered Product, are permanently restrained and enjoined from misrepresenting, or assisting others in misrepresenting, in any manner, expressly or by implication:

A. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or research; or

B. That the benefits of such Covered Product are scientifically proven.

IV.

MEANS AND INSTRUMENTALITIES

IT IS FURTHER ORDERED that Defendant, Defendant's officers, agents, servants, 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, marketing, promotion, offering for sale, sale, or distribution of any Covered Product,a re hereby permanently restrained and enjoined from providing the means and instrumentalities with which to make, expressly or by implication, any false or misleading statement of material fact, including, but not limited to, the representations prohibited in Sections I - III above. For purposes of this Section, "means and instrumentalities" shall mean any information, including, but not limited to, any advertising, labeling, promotional, or purported substantiation materials, for use by trade customers in manufacturing, labeling, advertising, marketing, promotion, offering for sale, sale, or distribution of any Covered Product.

V.

FDA APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order shall prohibit Defendant from:

A. Making any representation for any Drug that is permitted in labeling for such Drug under any tentative or final standard promulgated by the Food and Drug Administration, or under any new Drug application approved by the Food and Drug Administration; and

B. Making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

VI.

MONETARY JUDGMENT

IT IS FURTHER ORDERED that:

A. Judgment in the amount of three million, five-hundred thousand dollars ($3,500,000) is entered in favor of the Commission against Defendant as equitable monetary relief.

B. Defendant is ordered to pay to the Commission three million, five-hundred thousand dollars ($3,500,000). Such payment must be made within seven (7) days of entry of this Order by electronic fund transfer in accordance with instructions previously provided by a representative of the Commission.

C. 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.

D. 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.

E. 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.

F. Defendant acknowledges that its Taxpayer Identification Number, 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.

G. 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.

VII.

CUSTOMER INFORMATION

IT IS FURTHER ORDERED that Defendant, shall, no later than twenty (20) days after the date of entry of this Order, deliver to undersigned Commission counsel a list, in the form of a declaration sworn under penalty of perjury, of all customers or potential customers to whom, from the period since January 1, 2012, through the date of entry of this Order, (1) Defendant sold GCA or (2) Defendant attempted to sell GCA and provided advertising, marketing, labeling,

promotional, or purported substantiation materials regarding the purported weight-loss or fat-loss benefits of GCA, to the extent that such customers or potential customers are known to Defendant through a diligent search of its records, including, but not limited to, computer files, sales records, and inventory lists. Such list shall include each customer or potential customer's name, address, telephone number, and email address and, if applicable, the quantity sold and the amount paid.

VIII.

ORDER ACKNOWLEDGMENT

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

A. Defendant, within seven (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 ten (10) years after entry of this Order, 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 manufacturing, labeling, advertising, marketing, promotion, 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 seven (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, Defendant must obtain, within thirty (30) days, a signed and dated acknowledgment of receipt of this Order.

IX.

NOTICE TO TRADE CUSTOMERS

IT IS FURTHER ORDERED that within thirty (30) days of the entry of this Order, Defendant shall send an exact copy of the notice attached hereto as Appendix A, showing the date of mailing, to each customer or potential customer to whom, since January 1, 2012, (1) Defendant sold GCA or (2) to which Defendant attempted to sell GCA and provided advertising, marketing, labeling, promotional, or purported substantiation materials regarding the purported weight-loss or fat-loss benefits of GCA. The mailing shall not include any other document, information, or enclosures. The notice shall be sent by first-class mail, postage prepaid, and return receipt requested.

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, in which Defendant must:

1. 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;
2. Identify all of Defendant's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses;
3. Describe the activities of each business, including the goods and services offered, and the means of advertising, marketing, and sales;

4. Describe in detail whether and how Defendant is in compliance with each Section of this Order; and

5. Provide a copy of each Order acknowledgment obtained pursuant to this Order, unless previously submitted to the Commission.

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

1. Any designated point of contact;

2. The structure of Defendant and 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.

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 fourteen (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. Applied Food Sciences, Inc.*, Matter No. 142 3054.

XI.

RECORDKEEPING

IT IS FURTHER ORDERED that Defendant must create certain records for ten (10) years after entry of the Order, and retain each such record for five (5) years. Specifically, Defendant in connection with the manufacturing, labeling, advertising, marketing, promotion, offering for sale, or distribution of any Covered Product, must create and retain the following records:

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

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

D. A copy of each unique advertising, marketing, labeling, promotional, or purported substantiation material or other marketing material.

XII.

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, but not necessarily limited to:

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, but not limited to, 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 shall not apply to a Reliably Reported test, unless the test was conducted, controlled, or sponsored, in whole or in part (1) by Defendant, or any person or entity affiliated with or acting on behalf of Defendant, including officers, agents, representatives, and employees, or by any other person or entity in active concert or participation with Defendant ("Defendant's affiliates"), (2) by the supplier or

manufacturer of the product at issue, or (3) by a supplier to Defendant, to Defendant's affiliates, or to the product's manufacturer of any ingredient contained in such product.

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 shall be documented in writing and shall contain administrative, technical, and physical safeguards appropriate to Defendant's size and complexity, the nature and scope of Defendant's activities, and the sensitivity of the personal information collected from or about the participants.

XIII.

COMPLIANCE MONITORING BY THE COMMISSION

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

A. Within fourteen (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 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.

XIV.

COMPLIANCE MONITORING BY DEFENDANT

IT IS FURTHER ORDERED that Defendant, in connection with the manufacturing, labeling, advertising, marketing, promotion, offering for sale, or distribution of any Covered Product, shall:

A. Take reasonable steps sufficient to monitor and ensure that all employees and agents engaged in marketing, sales, order verification, or other customer service functions comply with the provisions of this Order. Such steps shall include adequate monitoring of all advertisements, promotions, sales presentations, and other oral and written communications with customers regarding such products. Defendant, at a minimum, shall:

1. Conduct periodic monitoring of representations concerning any Covered Product made by Persons engaged in sales or other customer service functions, including representations made orally or through electronic communications, on behalf of Defendant; and
2. Conduct periodic monitoring of representations made about any Covered Product on all Internet websites operated or maintained by Defendant or its agents.

B. Dismiss any employee or agent who knowingly engages in any conduct prohibited by this Order once Defendant knows or should know that such Person is or has been engaging in such conduct.

XV.

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.

SO ORDERED this 10th day of September, 2014.

Sam Sparks
UNITED STATES DISTRICT JUDGE

SO STIPULATED AND AGREED:

FOR PLAINTIFF:

Date: 9-5-2014

ELIZABETH OLIVIA TUCCI
KATHERINE A. CAMPBELL
Federal Trade Commission
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FOR DEFENDANT:

Jc R Prochnow Date: 7-23-14

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COUNSEL for Applied Food Sciences, Inc.

DEFENDANT Applied Food Sciences, Inc.

Date: 7/21/14

Loretta Zapp
Chief Executive Officer and President

Appendix A
GOVERNMENT-ORDERED DISCLOSURE

[Insert Date]

Dear AFS Customer:

We're writing because you may have bought our product, GCA®, also known as Green Coffee Antioxidant. The Federal Trade Commission ("FTC"), the nation's consumer protection agency, has sued us for making deceptive weight-loss claims about GCA.

The FTC claims that we did not have reasonable support for our claims that GCA causes weight loss or fat loss, including (1) 17.7 pounds (8.04 kilograms), 10.5% of body weight, and 16% of body fat, without diet or exercise, in twenty-two weeks; and (2) 17.7 pounds (8.04 kilograms), 10.5% of body weight, and 16% of body fat, in combination with diet or exercise, in twenty-two weeks.

As part of our settlement with the FTC, we have agreed to stop claiming that GCA causes weight loss until we have adequate scientific proof. We also agreed to tell our customers – and potential customers who received promotional materials from us about the purported weight-loss or fat-loss benefits of GCA – about the FTC's lawsuit. In addition, we gave the FTC a list of customers who bought GCA from us.

If you have any questions, please call [insert name and telephone number of the responsible AFS Attorney or Officer].

Sincerely,

Loretta Zapp
Chief Executive Officer, President
Applied Food Sciences, Inc.