## UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

| FEDERAL TRADE COMMISSION,<br>Plaintiff,  | Case No. <u>19-cv-982 (LDH)</u> (ST)                                  |
|--|---|
| v.<br>CURE ENCAPSULATIONS, INC., a New York<br>corporation; and  | STIPULATED ORDER FOR<br>PERMANENT INJUNCTION AND<br>MONETARY JUDGMENT |
| NAFTULA JACOBOWITZ, a/k/a Nat Jacobs and<br>Nate Jacobs, individually and as an officer of CURE<br>ENCAPSULATIONS, INC., |   |

Defendants.

Plaintiff, the Federal Trade Commission ("Commission" or "FTC"), 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 Defendants 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 Defendants participated in deceptive acts or practices 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 Quality Encapsulations Garcinia Cambogia Extract with HCA, a product that purportedly causes weight loss.

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.

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

1. "Corporate Defendant" means Cure Encapsulations, Inc. and its successors and assigns.

"Individual Defendant" means Naftula Jacobowitz, also known as Nat Jacobs and Nate Jacobs.

B. "**Covered Product**" means any Dietary Supplement, Food, or Drug, including Quality Encapsulations Garcinia Cambogia Extract with HCA.

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. "**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.

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: (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.

## ORDER

# I. PROHIBITED WEIGHT-LOSS AND DISEASE CLAIMS

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 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, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation that such product:

A. causes or helps cause weight loss or any specific amount of weight loss;

B. causes or helps cause rapid weight loss;

C. causes or helps cause substantial weight loss;

D. suppresses or reduces appetite;

E. blocks the formation of fat cells; or

F. 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. OTHER PROHIBITED 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 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, 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 of this Order entitled Prohibited Weight-Loss 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 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 Defendants' size and complexity, the nature and scope of Defendants' activities, and the sensitivity of the personal information collected from or about the participants.

# IV. 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.

# V. PROHIBITION AGAINST MISREPRESENTATIONS REGARDING ENDORSEMENTS

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 labeling, advertising, promotion, offering for sale, sale, or distribution of any product are permanently restrained and enjoined from making, or assisting others in making, any misrepresentation, expressly or by implication:

A. that any endorsement is a truthful endorsement or by an actual user of such product; or

B. through the use of any endorsement of such product.

# VI. MONETARY JUDGMENT AND PARTIAL SUSPENSION

# IT IS FURTHER ORDERED that:

A. Judgment in the amount of \$12,845,724 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 \$50,000, which, as Defendants stipulate, their undersigned counsel holds in escrow 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 and the payment by Defendants of their outstanding 2017 federal and state tax obligations in the amounts set forth in Item 20 of the Financial Statement of Individual Defendant Naftula Jacobowitz signed on October 18, 2018, 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 Defendants' sworn financial statements and related documents (collectively, "financial representations") submitted to the Commission, namely:

the Financial Statement of Individual Defendant Naftula Jacobowitz signed on October
18, 2018;

 the Financial Statement of Corporate Defendant Cure Encapsulations, Inc. signed by Naftula Jacobowitz as its President on August 9, 2018 (with the Item 19 Current-Year-to-Date Financial Summary corrected by an unsigned amended financial statement attached to an October 12, 2018 email from Defendants' counsel August Horvath to Commission Counsel Richard Cleland and Michael Ostheimer);

3. the representations and additional documentation submitted by Defendants' counsel August Horvath to Commission Counsel Richard Cleland and Michael Ostheimer dated August 13, 2018, August 16, 2018 (attaching loan applications), August 21, 2018 (four emails including ones attaching bank statements, property appraisals, tax returns, and check images), August 24, 2018 (two emails), August 27, 2018, August 29, 2018 (attaching an accountant's letter, a loan denial, and a letter from counsel), October 12, 2018 (attaching amended Financial Statement of Corporate Defendant Cure Encapsulations, Inc.), and October 18, 2018 (attaching tax returns);

D. 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 representations identified above.

E. 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.

## VII. 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 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 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.

F. The Commission may request any tax-related information, including amended tax returns and any other filings, that Defendants have the authority to release. Within 14 days of receipt of a written request from a representative of the Commission, Defendants must take all necessary steps (such as filing a completed IRS Form 4506 or 8821) to cause the Internal Revenue Service or other tax authority to provide the information directly to the Commission.

## VIII. CUSTOMER INFORMATION

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 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. 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 labeling, advertising, marketing, distribution, or sale of Quality Encapsulations Garcinia Cambogia Extract with HCA; 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.

## IX. NOTICE TO PAST CUSTOMERS

IT IS FURTHER ORDERED that Defendants must notify customers as follows: Defendants must identify all consumers who purchased Quality Encapsulations Garcinia Cambogia Extract with HCA from them on or after March 6, 2017 and through the date of entry of this Order ("identified past customers"). Within 30 days after the date of entry of this Order, Defendants must email all identified past customers a notice in the form of Attachment A, with an attachment in the form of Attachment B. The email to identified past customers must not include any additional content or attachments.

# X. NOTIFICATION REGARDING PREVIOUSLY POSTED PRODUCT REVIEWS

IT IS FURTHER ORDERED that within 30 days of the date of entry of this Order, Defendants must notify Amazon, Inc. that Defendants or their agents purchased reviews of Quality Encapsulations Garcinia Cambogia Extract with HCA sold by Defendants and appearing on the <u>www.amazon.com</u> website. The notification must: (A) be sent by email to an email address to be provided by FTC staff; (B) have the subject line: FTC v. Cure Encapsulations, Inc.; (C) include the Review ID numbers of all Amazon product reviews that were purchased by Defendants or their agents and if Review ID numbers are not available for a purchased review; must include all other information possessed by Defendants identifying the purchased review; (D) attach copies of the Complaint and of this Order; and (E) copy DEbrief@ftc.gov.

## 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 5 years after entry of this Order, Individual Defendant for any business that such Defendant, individually or collectively with any other Defendants, is the majority owner or controls directly or indirectly, and Corporate Defendant, 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 conduct related to the subject matter of the Order and all 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. Ninety days 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 goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Defendant (which 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, Individual Defendant must: (a) identify all telephone numbers and all

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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, 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 any 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: 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, 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 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. Cure Encapsulations, Inc.

## XIII. RECORDKEEPING

IT IS FURTHER ORDERED that Defendants must create certain records for 10 years after entry of the Order, and retain each such record for 5 years. Specifically, Corporate Defendant in connection with any activity subject to this Order and Individual 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. 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. records of all consumer 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.

## XIV. COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Defendants' compliance with this Order, including any failure to transfer any assets as required by 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 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 each Defendant. Defendant 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 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 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.

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

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# **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 \_\_\_\_\_ day of \_\_\_\_\_\_, \_\_\_\_.

UNITED STATES DISTRICT JUDGE

# SO STIPULATED AND AGREED:

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## FOR PLAINTIFF:

## FEDERAL TRADE COMMISSION

Michael Ostheimer, Attorney Federal Trade Commission Washington, DC 20580 202-326-2699 (telephone) 202-326-3259 (fax) mostheimer@ftc.gov

FOR DEFENDANTS:

Date: 10/19/2018

August T. Horvath, Esq. Foley Hoag LLP 1301 Avenue of the Americas, 25th floor New York, NY 10019 (646) 927-5544 (telephone) (646) 927-5599 (fax) ahorvath@foleyhoag.com Counsel for Cure Encapsulations, Inc. and Naftula Jacobowitz

DEFENDANTS: Cure Encapsulations, Inc. and Naftula Jacobowitz

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Date: 10/19/18

Naftula Jacobowitz, Individually and as an Officer of Cure Encapsulations, Inc. Case 1:19-cv-00982-LDH-ST Document 7-1 Filed 02/19/19 Page 22 of 31 PageID #: 54

# ATTACHMENT A

Subject Line: FTC says company deceptively advertised a product you bought

Dear Customer:

Our records show you bought our Quality Encapsulations Garcinia Cambogia Extract with HCA product. The Federal Trade Commission (FTC), the nation's consumer protection agency, has charged us with deceptive advertising. To settle the case, we have agreed to send this notice to people who bought our product.

According to the FTC, we deceptively claimed – among other things – that our product causes significant weight loss, is a powerful appetite suppressant, and blocks the formation of new fat cells. We don't have scientific proof for any of those claims.

You might want to look at the attached National Institutes of Health fact sheet on dietary supplements for weight loss. It discusses common ingredients in weight-loss dietary supplements, including *garcinia cambogia*. It says, "*Garcinia cambogia* has little to no effect on weight loss." The fact sheet also addresses other topics, including whether weight-loss dietary supplements can be harmful and choosing a sensible approach to weight loss.

Sincerely,

Naftula Jacobowitz Chief Executive Officer Cure Encapsulations, Inc. Case 1:19-cv-00982-LDH-ST Document 7-1 Filed 02/19/19 Page 24 of 31 PageID #: 56

# ATTACHMENT B



National Institutes of Health Office of Dietary Supplements

# **Dietary Supplements for Weight Loss** Fact Sheet for Consumers



If you're thinking about taking a dietary supplement to lose weight, talk with your health care provider.

# What are weight-loss dietary supplements and what do they do?

The proven ways to lose weight are eating healthful foods, cutting calories, and being physically active. But making these lifestyle changes isn't easy, so you might wonder if taking a dietary supplement that's promoted for weight loss might help.

This fact sheet describes what's known about the safety and effectiveness of many ingredients that are commonly used in weight-loss dietary supplements. Sellers of these supplements might claim that their products help you lose weight by blocking the absorption of fat or carbohydrates, curbing your appetite, or speeding up your metabolism. But there's little scientific evidence that weight-loss supplements work. Many are expensive, some can interact or interfere with medications, and a few might be harmful.

If you're thinking about taking a dietary supplement to lose weight, talk with your healthcare provider. This is especially important if you have high blood pressure, diabetes, heart disease, liver disease, or other medical conditions.

# What are the ingredients in weight-loss dietary supplements?

Weight-loss supplements contain many ingredients—like herbs, fiber, and minerals in different amounts and in many combinations. Sold in forms such as capsules, tablets, liquids, and powders, some products have dozens of ingredients.

Common ingredients in weight-loss supplements are described below in alphabetical order. You'll learn what's known about whether each ingredient works and is safe. Figuring out whether these ingredients really help you lose weight safely is complicated, though. Most products contain more than one ingredient, and ingredients can work differently when they're mixed together.

You might be surprised to learn that makers of weight-loss supplements rarely carry out studies in people to find out whether their product works and is safe. And when studies are done, they usually involve only small numbers of people who take the supplement for just a few weeks or months. To know whether a weight-loss supplement can help people lose weight safely and keep it off, larger groups of people need to be studied for a longer time.

The next pages provide information on common ingredients found in weight-loss dietary supplements.

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## African mango

African mango seed extract is claimed to curb the formation of fat tissue.

## Does it work?

African mango might help you lose a very small amount of weight.

## Is it safe?

African mango seems to be safe, but its safety hasn't been well studied. It can cause headache, sleeping problems, flatulence, and gas.



## **Beta-glucans**

Beta-glucans are soluble dietary fibers in bacteria, yeasts, fungi, oats, and barley. They might slow down the time it takes for food to travel through your digestive system, making you feel fuller.

## Does it work?

Beta-glucans don't seem to have any effect on body weight.

#### Is it safe?

Beta-glucans seem to be safe (at up to 10 grams [g] a day for 12 weeks). They can cause flatulence.



## Bitter orange

Bitter orange contains synephrine (a stimulant). It's claimed to burn calories, increase fat breakdown, and decrease appetite. Products with bitter orange usually also contain caffeine and other

ingredients. Bitter orange is in some weight loss dietary supplements that used to contain ephedra, another stimulantcontaining herb that was banned from the U.S. market in 2004 (*see the section on Ephedra*).

## Does it work?

Bitter orange might slightly increase the number of calories you burn. It might also reduce your appetite a little, but whether it can help you lose weight is unknown.

#### Is it safe?

Bitter orange might not be safe. Supplements with bitter orange can cause chest pain, anxiety, headache, muscle and bone pain, a faster heart rate, and higher blood pressure.



## Caffeine

Caffeine is a stimulant that can make you more alert, give you a boost of energy, burn calories, and increase fat breakdown. Often added to weight-loss dietary supplements, caffeine is found naturally in tea, guarana, kola

(cola) nut, yerba mate, and other herbs. The labels of supplements that contain caffeine don't always list it, so you might not know if a supplement has caffeine.

## Does it work?

Weight-loss dietary supplements with caffeine might help you lose a little weight or gain less weight over time. But when you use caffeine regularly, you become tolerant of it. This tolerance might lessen any effect of caffeine on body weight over time.

## Is it safe?

Caffeine is safe for most adults at doses up to 400–500 milligrams (mg) a day. But it can make you feel nervous, jittery, and shaky. It can also affect your sleep. At higher doses, it can cause nausea, vomiting, rapid heartbeat, and seizures. Combining caffeine with other stimulant ingredients can increase caffeine's effects.



## Calcium

Calcium is a mineral you need for healthy bones, muscles, nerves, blood vessels, and many of your body's functions. It's claimed to burn fat and decrease fat absorption.

## Does it work?

Calcium—either from food or in weight-loss dietary supplements—probably doesn't help you lose weight or prevent weight gain.

#### Is it safe?

Calcium is safe at the recommended amounts of 1,000 to 1,200 mg a day for adults. Too much calcium (more than 2,000–2,500 mg a day) can cause constipation and decrease your body's absorption of iron and zinc. Also, too much calcium from supplements (but not foods) might increase your risk of kidney stones.

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### Capsaicin

Capsaicin comes from chili peppers and makes them taste hot. It's claimed to help burn fat and calories and to help you feel full and eat less.

### Does it work?

Capsaicin hasn't been studied

enough to know if it will help you lose weight.

#### Is it safe?

Capsaicin is safe (at up to 33 mg a day for 4 weeks or 4 mg a day for 12 weeks), but it can cause stomach pain, burning sensations, nausea, and bloating.

## Carnitine

Your body makes carnitine, and it's also found in meat, fish, poultry, milk, and dairy products. In your cells, it helps break down fats.

## Does it work?

Carnitine supplements might help you lose a small amount of weight.

#### Is it safe?

Carnitine supplements seem to be safe (at up to 2 g a day for 1 year or 4 g a day for 56 days). They can cause nausea, vomiting, diarrhea, abdominal cramps, and a fishy body odor.



#### Chitosan

Chitosan comes from the shells of crabs, shrimp, and lobsters. It's claimed to bind fat in the digestive tract so that your body can't absorb it.

## Does it work?

Chitosan binds only a tiny

amount of fat, not enough to help you lose much weight.

### Is it safe?

Chitosan seems to be safe (at up to 15 g a day for 6 months). But it can cause flatulence, bloating, mild nausea, constipation, indigestion, and heartburn. If you're allergic to shellfish, you could have an allergic reaction to chitosan.

## Chromium

Chromium is a mineral that you need to regulate your blood sugar levels. It's claimed to increase muscle mass and fat loss and decrease appetite and food intake.

#### Does it work?

Chromium might help you lose a very small amount of weight and body fat.

#### Is it safe?

Chromium in food and supplements is safe at recommended amounts, which range from 20 to 45 micrograms a day for adults. In larger amounts, chromium can cause watery stools, headache, weakness, nausea, vomiting, constipation, dizziness, and hives.



## Coleus forskohlii

*Coleus forskohlii* is a plant that grows in India, Thailand, and other subtropical areas. Forskolin, made from the plant's roots, is claimed to help you lose weight by decreasing your appetite and increasing the

breakdown of fat in your body.

### Does it work?

Forskolin hasn't been studied much. But so far, it doesn't seem to have any effect on body weight or appetite.

#### Is it safe?

Forskolin seems to be safe (at 500 mg a day for 12 weeks), but it hasn't been well studied. It can cause frequent bowel movements and loose stools.



# Conjugated linoleic acid (CLA)

CLA is a fat found mainly in dairy products and beef. It's claimed to reduce your body fat.

## Does it work?

CLA may help you lose a very

small amount of weight and body fat.

### Is it safe?

CLA seems to be safe (at up to 6 g a day for 1 year). It can cause an upset stomach, constipation, diarrhea, loose stools, and indigestion.

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#### Fucoxanthin

Fucoxanthin comes from brown seaweed and other algae. It's claimed to help with weight loss by burning calories and decreasing fat.

## Does it work?

Fucoxanthin hasn't been

studied enough to know if it will help you lose weight. Only one study in people included fucoxanthin (the other studies were in animals).

#### Is it safe?

Fucoxanthin seems to be safe (at 2.4 mg a day for 16 weeks), but it hasn't been studied enough to know for sure.



#### Garcinia cambogia

*Garcinia cambogia* is a tree that grows throughout Asia, Africa, and the Polynesian islands. Hydroxycitric acid in the fruit is claimed to decrease the number of new fat cells your body makes, suppress your appetite

and thus reduce the amount of food you eat, and limit the amount of weight you gain.

#### Does it work?

Garcinia cambogia has little to no effect on weight loss.

#### Is it safe?

*Garcinia cambogia* seems to be fairly safe. But it can cause headache, nausea, and symptoms in the upper respiratory tract, stomach, and intestines.

#### Glucomannan

Glucomannan is a soluble dietary fiber from the root of the konjac plant. It's claimed to absorb water in the gut to help you feel full.

#### Does it work?

Glucomannan has little to no effect on weight loss. But it might help lower total cholesterol, LDL ("bad") cholesterol, triglycerides, and blood sugar levels.

#### Is it safe?

Most forms of glucomannan seem to be safe (at up to 15.1 g a day for several weeks in a powder or capsule form). It can cause loose stools, flatulence, diarrhea, constipation, and abdominal discomfort.

### Green coffee bean extract

Green coffee beans are unroasted coffee beans. Green coffee bean extract is claimed to decrease fat accumulation and help convert blood sugar into energy that your cells can use.

#### Does it work?

Green coffee bean extract might help you lose a small amount of weight.

#### Is it safe?

Green coffee bean extract seems to be safe (at up to 200 mg a day for 12 weeks). It might cause headache and urinary tract infections. Green coffee beans contain the stimulant caffeine, which can cause problems at high doses or when it's combined with other stimulants (*see the section on Caffeine*).



# Green tea and green tea extract

Green tea (also called *Camellia sinensis*) is a common beverage all over the world. Green tea and green tea extract in some weight-loss supplements are claimed to reduce body

weight by increasing the calories your body burns, breaking down fat cells, and decreasing fat absorption and the amount of new fat your body makes.

#### Does it work?

Green tea might help you lose a small amount of weight.

#### Is it safe?

Drinking green tea is safe, but taking green tea extract might not be. Green tea extract can cause constipation, abdominal discomfort, nausea, and increased blood pressure. In some people, it has been linked to liver damage.

#### Guar gum

Guar gum is a soluble dietary fiber in some dietary supplements and food products. It's claimed to make you feel full, lower your appetite, and decrease the amount of food you eat.

#### **Does it work?**

Guar gum probably doesn't help you lose weight.

#### Is it safe?

Guar gum seems to be safe (at up to 30 g a day for 6 months) when it is taken with enough fluid. But it can cause abdominal pain, flatulence, diarrhea, nausea, and cramps.

#### Guarana (see the section on Caffeine)

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## Hoodia

Hoodia is a plant from southern Africa, where it's used as an appetite suppressant.

#### Does it work?

There hasn't been much research on hoodia, but it probably won't help you eat less or lose weight.

Analyses showed that some "hoodia" supplements sold in the past contained very little hoodia or none at all. It's not known whether this is true of hoodia supplements sold today.

#### Is it safe?

Hoodia might not be safe. It can cause rapid heart rate, increased blood pressure, headache, dizziness, nausea, and vomiting.

#### Kola (or cola) nut (see the section on Caffeine)

**Mate** (see the section on Caffeine)

#### **Probiotics**

Probiotics are microorganisms in foods, such as yogurt, that help maintain or restore beneficial bacteria in your digestive tract.

## Does it work?

Probiotic supplements seem to have little to no effect on weight loss, but they haven't been well studied.

#### Is it safe?

Probiotics are safe but may cause gas or other gastrointestinal problems.

### Pyruvate

Pyruvate is naturally present in your body. Pyruvate in weightloss supplements is claimed to increase fat breakdown, reduce body weight and body fat, and improve exercise performance.

#### Does it work?

Pyruvate in supplements might help you lose a small amount of weight.

#### Is it safe?

Pyruvate seems to be safe (at up to 30 g a day for 6 weeks). It can cause diarrhea, gas, bloating, and rumbling noises in the intestines due to gas.



#### **Raspberry ketone**

Raspberry ketone, found in red raspberries, is claimed to be a "fat burner."

#### Does it work?

Raspberry ketone has only been studied as a weight-loss aid in combination with other ingredi-

ents and not alone. Its effects on body weight are unknown.

#### Is it safe?

Raspberry ketone hasn't been studied enough to tell if it's safe.

#### Vitamin D

Your body needs vitamin D for good health and strong bones. People who are obese tend to have lower levels of vitamin D, but there is no known reason why taking vitamin D would help people lose weight.

#### Does it work?

Vitamin D doesn't help you lose weight.

#### Is it safe?

Vitamin D from foods and dietary supplements is safe at the recommended amounts of 600–800 IU a day for adults. Too much vitamin D (more than 4,000 IU a day) can be toxic and cause nausea, vomiting, poor appetite, constipation, weakness, and irregular heartbeat.



## White kidney bean/ bean pod

White kidney bean or bean pod (also called *Phaseolus vulgaris*) is a legume grown around the world. An extract of this bean is claimed to block the absorption of carbohydrates and suppress your appetite.

#### Does it work?

*Phaseolus vulgaris* extract might help you lose a small amount of weight and body fat.

#### Is it safe?

*Phaseolus vulgaris* seems to be safe (at up to 3,000 mg a day for 12 weeks). But it might cause headaches, soft stools, flatulence, and constipation.

Yerba mate (see the section on Caffeine)

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#### Yohimbe

Yohimbe is a West African tree. Yohimbe extract is an ingredient in supplements used to improve libido, increase muscle mass, and treat male sexual dysfunction. Yohimbe is also found in some weight-loss supplements and is

claimed to increase weight loss.

#### Does it work?

Yohimbe doesn't help you lose weight.

#### Is it safe?

Yohimbe might not be safe (especially at doses of 20 mg or higher). Use it only with guidance from your healthcare provider because the side effects can be severe. Yohimbe can cause headaches, high blood pressure, anxiety, agitation, rapid heartbeat, heart attack, heart failure, and death.

# Ephedra, an ingredient banned from dietary supplements?

Ephedra (also called má huáng) is a plant containing substances that can stimulate your nervous system, increase the amount of energy you burn, increase weight loss, and suppress your appetite. In the 1990s, ephedra was a popular ingredient in dietary supplements sold for weight loss and to enhance athletic performance. In 2004, the U.S. Food and Drug Administration (FDA) banned ephedra in dietary supplements, concluding that it isn't safe. Ephedra can cause nausea, vomiting, anxiety, mood changes, high blood pressure, abnormal heartbeat, stroke, seizures, heart attack, and death.

# How are weight-loss dietary supplements regulated?

The FDA is the federal agency that oversees dietary supplements in the United States. Unlike over-the-counter and prescription drugs—which must be approved by the FDA before they can be sold—dietary supplements don't require review or approval by the FDA before they are put on the market. Also, manufacturers don't have to provide evidence to the FDA that their products are safe or effective before selling these products.

When the FDA finds an unsafe dietary supplement, it can remove the supplement from the market or ask the supplement maker to recall it. The FDA and the Federal Trade Commission can also take enforcement action against companies that make false weight-loss claims about their supplements; add pharmaceutical drugs to their supplements; or claim that their supplements can diagnose, treat, cure, or prevent a disease.

For more information about dietary supplement regulations, see the Office of Dietary Supplements publication, *Dietary Supplements: What You Need to Know.* 

# Can weight-loss dietary supplements be harmful?

Weight-loss supplements, like all dietary supplements, can have harmful side effects and might interact with prescription and over-the-counter medications. Many weight-loss supplements have ingredients that haven't been tested in combination with one another, and their combined effects are unknown. Tell your healthcare providers about any weight-loss supplements or other supplements you take. This information will help them work with you to prevent supplement-drug interactions, harmful side effects, and other risks..

# Fraudulent and adulterated products

Be very cautious when you see weight-loss supplements with tempting claims, such as "magic diet pill," "melt away fat," and "lose weight without diet or exercise." If the claim sounds too good to be true, it probably is. These products might not help you lose weight—and they could be dangerous.

Weight-loss products marketed as dietary supplements are sometimes adulterated with prescription drugs or controlled substances. These ingredients won't be listed on the product label, and they could harm you. The FDA puts out public notifications about tainted weight-loss products.

## Interactions with medications

Like most dietary supplements, some weight-loss supplements can interact or interfere with other medicines or supplements you take. If you take dietary supplements and medications on a regular basis, be sure to talk about this with your healthcare provider.

# Choosing a Sensible Approach to Weight Loss

Weight-loss supplements can be expensive, and they might not work. The best way to lose weight and keep it off is to follow a healthy eating plan, reduce calories, and exercise regularly under the guidance of your healthcare provider.

As a bonus, lifestyle changes that help you lose weight might also improve your mood and energy level and lower your risk of heart disease, diabetes, and some types of cancer.

# Where can I find out more?

# For general information on weight-loss dietary supplements:

- Office of Dietary Supplements Health Professional Fact Sheet on Weight-Loss Dietary Supplements
- Weighing the Claims in Diet Ads, Federal Trade Commission

# For publications about weight control, obesity, physical activity, and nutrition:

- The Weight-control Information Network, National Institute of Diabetes and Digestive and Kidney Diseases, NIH
- Weight Control, MedlinePlus, NIH

## For more advice on buying dietary supplements:

• Office of Dietary Supplements Frequently Asked Questions: Which brand(s) of dietary supplements should I purchase?

## For information about building a healthy diet:

- Dietary Guidelines for Americans
- MyPlate

## Disclaimer

This fact sheet by the Office of Dietary Supplements (ODS) provides information that should not take the place of medical advice. We encourage you to talk to your healthcare providers (doctor, registered dietitian, pharmacist, etc.) about your interest in, questions about, or use of dietary supplements and what may be best for your overall health. Any mention in this publication of a specific product or service, or recommendation from an organization or professional society, does not represent an endorsement by ODS of that product, service, or expert advice.





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