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21	CENTRAL DISTRICT OF CALIFORNIA
22	
)
23	FEDERAL TRADE COMMISSION, Case No. 8:15-CV-1314 DOC (KESx)
24	Plaintiff,)
25)
26	v.) STIPULATED ORDER FOR Y PERMANENT INJUNCTION AND
27	ZADRO HEALTH SOLUTIONS, MONETARY JUDGMENT
	INC. a California corporation,
28	,

1 ZLATKO ZADRO, 2 individually and as an officer of Zadro Health Solutions, Inc., and 3 4 REBECCA ZADRO, aka Becky Zadro, individually and as an officer 5 of Zadro Health Solutions, Inc., 6 7 Defendants. 8 Plaintiff, the Federal Trade Commission ("Commission"), filed its Complaint 10 for Permanent Injunction and Other Equitable Relief in this matter, pursuant to 11 Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 12 13 53(b). The Commission and Defendants stipulate to entry of this Stipulated Order 14 for Permanent Injunction and Monetary Judgment ("Order") to resolve all matters 15 in dispute in this action between them. 16 17 THEREFORE, IT IS ORDERED as follows: 18 **FINDINGS** 19 20 1. This Court has jurisdiction over this matter. 21 2. The Complaint charges that Defendants participated in deceptive acts 22 23 or practices in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) 24 and 52, in connection with the advertising, marketing, distribution, offering for sale, 25 and sale of ultraviolet light disinfection devices, including the Nano-UV 26 27

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Disinfection Scanner, the Nano-UV Wand, and the Nano-UV Water Disinfectant devices.

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

DEFINITIONS

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

- A. "Defendants" means all the Individual Defendants and the Corporate Defendant, individually, collectively, or in any combination.
- B. "Corporate Defendant" means Defendant Zadro Health Solutions, Inc., and its successors and assigns.
- C. "Individual Defendants" means Zlatko Zadro and Rebecca Zadro, aka Becky Zadro.
- D. "Device," as defined in Section 15 of the FTC Act, 15 U.S.C. § 55, means an instrument, apparatus, implement, machine, contrivance, implant, in vitro

reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (3) intended to affect the structure or any function of the body of man or other animals; and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

E. "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.

ORDER

I.

PROHIBITION AGAINST FALSE OR UNSUBSTANTIATIED CLAIMS

IT IS 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,

are permanently restrained and enjoined from making, or assisting others in making,

- A. any misrepresentation, expressly or by implication, in connection with the promoting or offering for sale of any Device, that:
 - 1. the Device kills 99.9%, or any percentage, of bacteria, germs, and viruses, including *E. coli*, *Salmonella*, *Staphyloccocus*Aureus, and the H1N1 virus, on any surface in only 10 seconds or any time period;
 - 2. the Device stops the spread of germs, from the common cold and flu viruses to bacteria, mold, and fungus;
 - 3. the Device kills dust mite populations and eggs, flea eggs, and bed bug eggs in pillows, bedding, and carpet; or
 - 4. the Device eliminates 99.9%, or any percentage, of bacteria, mold, and fungus on water surfaces in only 10 seconds or any time period, or in water in only 40 seconds or any time period; and
- B. any representation, expressly or by implication, about the health benefits, performance, or efficacy of any product or service, unless the representation is non-misleading, and, at the time such representation is made,

 Defendants possess and rely 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 as set forth in the Section entitled 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 REGARDING TESTS OR STUDIES

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 promoting or offering for sale of any product or service, are permanently restrained and enjoined from misrepresenting or assisting others in misrepresenting, in any manner, expressly or by implication:

- A. That the benefits of such product or service are scientifically proven; or
- B. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

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, 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 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 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 shall be documented in

writing and shall contain administrative, technical, and physical safeguards appropriate to 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 shall prohibit Defendants from:

- A. Making any representation for any drug that is permitted in labeling for such drug under any tentative 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. 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 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

V.

MONETARY JUDGMENT

IT IS FURTHER ORDERED that:

- A. Judgment in the amount of Six Hundred Twenty-Nine Thousand Three Hundred and Fifty-Nine Dollars (\$629,359) is entered in favor of the Commission against Corporate Defendant Zadro Health Solutions, Inc., as equitable monetary relief.
- B. Corporate Defendant Zadro Health Solutions, Inc. is ordered to pay to the Commission Two Hundred Twenty-Two Thousand and Twenty-Nine Dollars (\$222,029), 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 the Order by electronic fund transfer in accordance with instructions to be provided by a representative of the Commission. Upon such payment, the remainder of the judgment is suspended, subject to the Subsections below.
- C. The Commission's agreement to the suspension of the judgment is expressly premised upon the truthfulness, accuracy, and completeness of Defendant Zadro Health Solutions, Inc.'s sworn financial statements and related documents (collectively, "financial representations") submitted to the Commission, namely the Financial Statement of Corporate Defendant Zadro Health Solutions, Inc., signed by

corporate president Zlatko Zadro on June 15, 2015, including the attachments.

- D. The suspension of the judgment will be lifted if, upon motion by the Commission, the Court finds that Defendant Zadro Health Solutions, Inc. failed to disclose any material asset, materially misstated the value of any asset, or made any other material misstatement or omission in the financial representations identified above.
- E. If the suspension of the judgment is lifted, the judgment becomes immediately due as to Defendant Zadro Health Solutions, Inc. 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.
- F. 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.
- G. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation or proceeding by or on behalf of the Commission to enforce its rights to any payment or monetary judgment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

- H. 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.
- I. Defendant Zadro Health Solutions, Inc. acknowledges that its

 Taxpayer Identification Number (Employer 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.
- J. 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 the 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.

VI.

CUSTOMER INFORMATION

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, are permanently restrained and enjoined from directly or indirectly 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.

VII.

COOPERATION

IT IS FURTHER ORDERED that Defendants must fully cooperate with representatives of the Commission in this case and in any investigation related to or associated with the transactions or the occurrences that are the subject of the Complaint. Defendants must provide truthful and complete information, evidence, and testimony. Individual Defendants must appear and Corporate Defendant must cause its officers, employees, representatives, or agents to appear for interviews, discovery, hearings, trials, and any other proceedings that a Commission representative may reasonably request upon 5 days written notice, or other

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27 28 reasonable notice, at such places and times as a Commission representative may designate, without the service of a subpoena.

VIII.

ORDER ACKNOWLEDGMENTS

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

- Each Defendant, within 7 days of entry of this Order, must submit to A. the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.
- For 5 years after entry of this Order, each Individual Defendant for any B. business such Defendant, individually or collectively with any other Defendants, 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 approving the advertising, marketing, distribution, offering for sale, and sale of such Defendant's products; 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.

IX.

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 goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Defendant (which Individual Defendants must describe if they know or should know due to their 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, each 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 Defendants' 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 the Corporate Defendant or any entity such 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, each Individual Defendant must report any change in: (a) name, including aliases or fictitious names, 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 direct or indirect control, 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 the 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. Zadro Health Solutions, Inc., et al.

X.

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 and each 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.

XI.

COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Defendants' compliance with this Order, and 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. Each Defendant must permit representatives of the Commission to interview any employee or other person affiliated with the 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,

1	to Defendants or any individual or entity affiliated with Defendants, without the
2	necessity of identification or prior notice. Nothing in this Order limits the
3	Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of
5	the FTC Act, 15 U.S.C. §§49, 57b-1.
6	D. Upon written request from a representative of the Commission, any
7 8	consumer reporting agency must furnish consumer reports concerning Individual
9	Defendants pursuant to Section 604(1) of the Fair Credit Reporting Act, 15 U.S.C.
10	§1681b(a)(1).
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14	RETENTION OF JURISDICTION
15	IT IS FURTHER ORDERED that this Court retains jurisdiction of this matter
16	for purposes of construction, modification, and enforcement of this Order.
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19	IT IS SO ODERED.
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21	DATED.
22	DATED: United States District Judge
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