JS-6 DAVID C. SHONKA Acting General Counsel AMY C. HOCEVAR (Ohio Bar #0075510) ahocevar@ftc.gov NICOLE J. GUINTO (Ohio Bar #0089319) nguinto@ftc.gov DANA C. BARRAGATE (Ohio Bar #0065748) dbarragate@ftc.gov Federal Trade Commission 1111 Superior Avenue, Suite 200 Cleveland, Ohio 44114 Hocevar Phone: (216) 263-3409 Guinto Phone: (216) 263-3435 Barragate Phone: (216) 263-3402 Fax: (216) 263-3426 Local Counsel THOMAS J. SYTA (California Bar #116286) tsyta@ftc.gov Federal Trade Commission 10877 Wilshire Blvd., Suite 700 Los Angeles, CA 90024 Phone: (310) 824-4343 Fax: (310) 824-4380 Attorneys for Plaintiff FEDERAL TRADE COMMISSION UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA Case No. 8:16-cv-2147-DOC FEDERAL TRADE COMMISSION. (KESx) Plaintiff, ORDER FOR PERMANENT INJUNCTION AND v. MONETARY JUDGMENT [3] AURA LABS, INC., a corporation, also d/b/a AuraLife and AuraWare, and RYAN ARCHDEACON, individually and as an officer of AURA LABS, INC., Defendants. Page 1 of 25

28

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

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

4. Defendants waive any claim that they may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date of this Order, and agree to bear their own costs and attorney fees.

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

### DEFINITIONS

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

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

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

the communication even if the representation requiring the disclosure is made in only one means.

2. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.

3. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.

4. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.

5. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the representation that requires the disclosure appears.

6. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.

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. "**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. The party whose opinions, beliefs, findings, or experiences

the message appears to reflect will be called the endorser and may be an individual, group, or institution.

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

G. "**Measure**" or "**Measures**" means to calculate, approximate, estimate, predict, or otherwise ascertain the value, number, quantity, amount, or degree of something.

H. "**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.

I. "**Reliably Reported**," for a human clinical test or study, means a report of the test or study has been published in a peer-reviewed journal, and such published report provides sufficient information about the test or study for experts in the relevant field to assess the reliability of the results.

## ORDER

## I. PROHIBITED REPRESENTATIONS REGARDING BLOOD PRESSURE

IT IS ORDERED that Defendants, Defendants' officers, agents,

employees, and attorneys, and all other Persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, are permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product or program name, Endorsement, depiction, or illustration, any representation that such product:

A. Serves as a replacement for a traditional blood pressure cuff;

B. Measures blood pressure;

C. Measures blood pressure as accurately as a traditional blood pressure cuff; or

D. Measures blood pressure with a specified degree of accuracy,

1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
26	Page 9 of 25
27	
28	

## II. PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, employees, and attorneys, and all other Persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Device, are permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product or program name, Endorsement, depiction, or illustration, any representation, other than representations covered under Section I of this Order, about the health benefits or health efficacy of any Device, unless the representation is non-misleading, and, at the time of making such representation, 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 experts; (2) that are generally accepted by qualified experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Device, when qualified 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.

### **III. DECEPTIVE USE OF 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 manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Device, must not:

1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		
26	Page 12 of 25	
27		
28		

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 contracts and communications 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 Corporate Defendant's size and complexity, the nature and scope of Defendants' activities, and the sensitivity of the personal information collected from or about the participants.

# V. MONETARY JUDGMENT AND SUSPENSION IT IS FURTHER ORDERED that:

A. Judgment in the amount of Five Hundred Ninety-Five Thousand, Nine Hundred Forty-Five Dollars and Twenty-Seven Cents (\$595,945.27) is entered in favor of the Commission against Defendants, jointly and severally, as equitable monetary relief.

B. The judgment is suspended subject to the Subsections below.

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

> 1. the Financial Statement of Individual Defendant Ryan Archdeacon, signed on June 23, 2016, including the attachments;

2. the Financial Statement of Corporate Defendant Aura Labs, Inc., signed on June 20, 2016, including the attachments.

The suspension of the judgment will be lifted as to any Defendant if, upon D. 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 Compla

1	pursuant to this Section, plus interest computed from the date of entry of this
2	Order.
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	$\mathbf{D}_{\mathbf{r}} = 16  \text{of}  25$
26	Page 16 of 25
27	
28	

All money paid to the Commission pursuant to this Order may be deposited J. 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.

### **VI. 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, whether acting directly or indirectly, are permanently restrained and enjoined from failing to provide sufficient customer information to enable the Commission to efficiently

administer consumer redress. Defendants represent that they have provided this redress information to the Commission. If a representative of the Commission requests in writing any information related to redress, Defendants must provide it, in the form prescribed by the Commission, within 14 days.

#### VII. 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 Individual Defendant, individually or collectively with Corporate Defendant, 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, agents, and representatives who participate in conduct related to the subject matter of this 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 within 10days after 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.

## VIII. COMPLIANCE REPORTING

involvement of any other Defendant (which Individual Defendant must describe if he knew 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 OrderAcknowledgment obtained pursuant to this Order, unless previously submitted to the Commission.

2. Additionally, Individual Defendant must: (a) identify all telephone numbers and all physical, postal, email and Internet addresses, including all residences; (b) identify all business activities, including any business for which such Defendant performs services, whether as an employee or otherwise, and any entity in which such Defendant has any ownership interest; and (c) describe in detail such Defendant's involvement in each such business, including title, role, responsibilities, participation, authority, control, and any ownership.

B. For 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:

Page 20 of 25

 Each Defendant must report any change in: (a) any designated point of contact; or (b) the structure of 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.
 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
Individual Defendant performs services, whether as an employee or
otherwise, and any entity in which Individual 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

Page 21 of 25

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.

C.

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;

records of all complaints and refund requests, whether received directly or

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 provided that Defendants, after attempting to resolve a dispute without court action and for good cause shown, may file a motion with this Court seeking an order for one or more of the protections set forth in Rule 26(c).

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. § 1681(b)(a)(1).

## XI. RETENTION OF JURISDICTION

## **IT IS FURTHER ORDERED**