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UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION

Joseph J. Simons, Chairman Noah Joshua Phillips **COMMISSIONERS:**

Rohit Chopra

Rebecca Kelly Slaughter Christine S. Wilson

In the Matter of

A & O ENTERPRISES INC, a corporation, d/b/a iV BARS INCORPORATED and

ElaJ 0 Tc 0 Tw 17.92 0 Td ()Tj EMC ARbN 0 6T1 115(C)a R

Findings

1. The Respondents are:

- a. Respondent A & O Enterprises Inc, a Wyoming corporation, also doing business as iV Bars Incorporated and iV Bars, with its principal office or place of business at 4101 Centurion Way, Addison, Texas 75001.
- b. Respondent Aaron K. Roberts, also known as Aaron Keith, the owner and operating manager of A & O Enterprises Inc. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of A & O Enterprises Inc. His principal

- 1. "Corporate Respondent" means A & O Enterprises Inc, also doing business as iV Bars Incorporated and iV Bars, and its successors and assigns.
- 2. "Individual Respondent" means Aaron K. Roberts, also known as Aaron Keith.

Provisions

I. Prohibited Disease Claims

IT IS ORDERED that Respondents, and Respondents' 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 advertising, promotion, offering for sale, or sale of any covered product must not make any representation, or assist others in making any representation, expressly or by implication, that such product:

- A. Is an effective treatment for cancer;
- B. Is an effective treatment for angina, cardiovascular disease, congestive heart failure, or myocardial infarction;
- C. Is an effective treatment for multiple sclerosis;
- D. Is an effective treatment for diabetes:
- E. Is an effective treatment for fibromyalgia;
- F. Is an effective treatment for neurodegenerative disorders;
- G. Produces fast, lasting results; or
- H. Cures, mitigates, or treats any disease;

unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true. For purposes of this Provision, "competent and reliable scientific evidence" means 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 (1) be randomized, double-blind, and placebocontrolled; and (2) be 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 relevant field as relevant to an assessment of such testing as described in the Provision titled Preservation of Records Relating to Competent and Reliable Human Clinical

Tests or Studies must be available for inspection and production to the Commission. Respondents will have the burden of proving that a product satisfies the definition of an essentially equivalent product.

II. Prohibited Health Benefit and Safety Claims

IT IS FURTHER ORDERED that Respondents, and Respondents' 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 advertising, promotion, offering for sale, or sale of any covered product must not make any representation, or assist others in making any representation, other than representations covered under the Provision titled Prohibited Disease Claims, expressly or by implication, about the health benefits, efficacy, safety, or side effects of such product, unless the representation is non-misleading, including that, at the time such representation is made, 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 Provision, "competent and reliable scientific evidence" means tests, analyses, research, or studies that (1) 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

- A. Assembled physicians, biochemists, or physiologists to create the formulas for their products;
- B. Employ

- 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 Respondent; (2) any Respondent's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Respondent; (4) any person or entity affiliated with or acting on behalf of any Respondent; (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 Provision, "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 Respondents, Respondents 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 Respondents' size and complexity, the nature and scope of Respondents' activities, and the sensitivity of the personal information collected from or about the participants.

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B. For 10 years after the issuance date of this Order, Individual Respondent for any business that such Respondent, individually or collectively with any other Respondents, is the majority owner or controls directly or indirectly, and Corporate Respondent, 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 Provision titled Compliance Reports and Notices. Delivery must occur within 10 days after the effective date of this Order for current

- B. For 10 years after the issuance date of this Order, each Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:
 - 1. Each Respondent must submit notice of any change in: (a) any designated point of

- B. personnel records showing, for each person providing services in relation to any aspect of the Order, 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. copies or records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;

D.