

**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

COMMISSIONERS: **Joseph J. Simons, Chairman**
 Maureen K. Ohlhausen
 Noah Joshua Phillips
 Rohit Chopra
 Rebecca Kelly Slaughter

In the Matter of

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

**AARON K. ROBERTS, a/k/a/ Aaron Keith,
individually and as owner and operating
manager of A & O ENTERPRISES INC.**

DECISION AND ORDER

DOCKET NO. C-

DECISION

The Federal Trade Commission (“Commission”) initiated an investigation of certain acts and practices of the Respondents named in the caption. The Commission’s Bureau of Consumer Protection (“BCP”) prepared and furnished to Respondents a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondents with violations of the Federal Trade Commission Act.

Respondents and BCP thereafter executed an Agreement Containing Consent Order (“Consent Agreement”). The Consent Agreement includes: 1) statements by Respondents that they neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, they admit the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission’s Rules.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further

conformity with the procedure prescribed in Commission Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

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 office or place of business is the same as that of A & O Enterprises Inc.
2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

Definitions

For purposes of this Order, the following definitions apply:

- A. “Covered product” means any intravenous therapy, including Respondents’ iV Cocktails, and any intramuscular injection.
- B. “Essentially equivalent product” means a product that contains the identical ingredients, except for inactive ingredients (e.g., inactive binders, colors, fillers, excipients), in the same form and dosage, and with the same route of administration (e.g., intravenous), as the covered product; *provided that* the covered product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field indicates that the amount and combination of additional ingredients are unlikely to impede or inhibit the effectiveness of the ingredients in the essentially equivalent product.
- C. “Intramuscular injection” means the injection of substances, including mixtures of water, vitamins, minerals, amino acids, or other active ingredients, directly into human muscle.
- D. “Intravenous therapy” means the infusion of substances, including mixtures of water, vitamins, minerals, amino acids, or other ingredients, directly into the human bloodstream.
- E. “iV Cocktail” means any intravenous therapy, advertised, promoted, offered for sale, or sold by Respondents, including the Myers Cocktail and the Immune Booster.

- F. “Respondents” means the Corporate Respondent and the Individual Respondent, individually, collectively, or in any combination.
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 placebo-controlled; 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 studies, 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 Provision of this Order 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.

III. Prohibited Misrepresentations Regarding an iV Bars Research Lab

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 misrepresentation, or assist others in making any misrepresentation, expressly or by implication that Respondents:

- A. Assembled physicians, biochemists, or physiologists to create the formulas for their products;
- B. Employ biologists, chemists, pharmacists, medical doctors, naturopathic doctors, or exercise physiologists to test or approve their products; or
- C. Maintain a research facility, including an iV Bars Research Lab.

IV. Prohibited Misrepresentations Regarding Tests, Studies, or Other Research

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 product or service must not make any misrepresentation, or assist others in making any misrepresentation, expressly or by implication:

- A. About the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research, including that studies, research, or trials prove that such product or service is an effective treatment for cancer, angina, cardiovascular disease, congestive heart failure, myocardial infarction, multiple sclerosis, diabetes, fibromyalgia, or neurodegenerative disorders or produces fast, lasting results; or
- B. That any benefit of such product or service is scientifically or clinically proven or otherwise established.

V. 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 Respondents rely to substantiate any claim covered by this Order, Respondents must 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 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.

VI. FDA Approved Claims

IT IS FURTHER ORDERED that nothing in this Order prohibits Respondents, or Respondents' officers, agents, employees, and attorneys, or all other persons in active concert or participation with any of them, from making a representation for any drug that is approved in labeling for such drug under any tentative final or final monograph promulgated by the Food and Drug Administration ("FDA"), or under any new drug application approved by the FDA.

VII. Acknowledgments of the Order

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

- A. Each Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

- 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 personnel. For all others, delivery must occur before they assume their responsibilities.
- C. From each individual or entity to which a Respondent delivered a copy of this Order, that Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

VIII. Compliance Report and Notices

IT IS FURTHER ORDERED that Respondents make timely submissions to the Commission:

- A. One year after the issuance date of this Order, each Respondent must submit a compliance report, sworn under penalty of perjury, in which:
 - 1. Each Respondent 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 Respondent; (b) identify all of that Respondent'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 Respondent (which Individual Respondents must describe if they know or should know due to their own involvement); (d) describe in detail whether and how that Respondent is in compliance with each Provision of this Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.
 - 2. Additionally, the Individual Respondent must: (a) identify all his telephone numbers and all his physical, postal, email and Internet addresses, including all residences; (b) identify all his business activities, including any business for which the Respondent performs services whether as an employee or otherwise and any entity in which the Respondent has any ownership interest; and (c) describe in detail the Respondent's involvement in each the business activity, including title, role, responsibilities, participation, authority, control, and any ownership.

- 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 contact; or (b) the structure of Corporate Respondent or any entity that Respondent 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, the Individual Respondent must submit notice of any change in: (a) name, including alias or fictitious name, or residence address; or (b) title or role in any business activity, including (i) any business for which the Respondent performs services whether as an employee or otherwise and (ii) any entity in which the Respondent has any ownership interest and over which Respondents have direct or indirect control. For each such business activity, also identify its name, physical address, and any Internet address.
- C. Each Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent 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: In re A & O Enterprises Inc.

IX. Recordkeeping

IT IS FURTHER ORDERED that Respondents must create certain records for 10 years after the issuance date of this Order, and retain each such record for 5 years, unless otherwise specified below. Specifically, Corporate Respondent and the Individual Respondent for any business that such Respondent, individually or collectively with any other Respondents, 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, the costs incurred in generating those revenues, and resulting net profit or loss;

- 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. a copy of each unique advertisement or other marketing material making a representation subject to this Order;
- E. for 5 years from the date of the last dissemination of any representation covered by this Order:
 - 1. all materials that were relied upon in making the representation; and
 - 2. all tests, studies, analysis, other research or other such evidence in Respondent's possession, custody, or control that contradicts, qualifies, or otherwise calls into question the representation, or the basis relied upon for the representation; and
- F. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission.

X. Compliance Monitoring

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

- A. Within 10 days of receipt of a written request from a representative of the Commission, each Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.
- B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with each Respondent. Respondents must permit representatives of the Commission to interview anyone affiliated with any Respondent who has agreed to such an interview. The interviewee 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 Respondents or any individual or entity affiliated with Respondents, 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 Respondent, pursuant to Section 604(2) of the Fair Credit Reporting Act, 15 U.S.C. § 1681b(a)(2).

XI. Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate 20 years from the date of its issuance (which date may be stated at the end of this Order, near the Commission's seal), or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Provision in this Order that terminates in less than 20 years;
- B. This Order's application to any Respondent that is not named as a defendant in such complaint; and
- C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Donald S. Clark
Secretary

SEAL:
ISSUED: