

Office of the Secretary

February 13, 2019

Ms. Jann Bellamy State of Florida

> Re: In the Matter of A & O Enterprises Inc., a corporation, doing business as iV Bars Incorporated and iV Bars, and Aaron K. Roberts, also known as Aaron Keith, individually and as owner and operating manager of A & O Enterprises Inc. File No. 172 3016; Docket No. C-4670

Dr. Ms. Bellamy:

Thank you for your comment of September 24, 2018, regarding the proposed consent agreement accepted by the Federal Trade Commission for public comment in the above-captioned matter. The Commission has placed your comment on the public record pursuant to Commission Rule 4.9(b), 16 C.F.R. § 4.9(b), and has given it serious consideration in connection with its decision to grant final approval to the proposed Decision and Order.

In your comment, you state you are pleased that the Commission has taken action against the respondents and that you "hope this portends future actions against the many companies and practitioners selling unproven remedies like . . . IV treatments [and others]." You further state that the Commission is doing too little to stop medical "quackery."

The Commission rigorously enforces Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which prohibits "unfair or deceptive acts or practices." Further, it places a high priority on preventing deceptive health claims that pose a threat of physical as well as economic harm to consumers. In the instant case, the Commission's proposed complaint alleges that respondents' health claims were false, misleading, or unsubstantiated, and therefore violated Section 5(a). The proposed Decision and Order broadly prohibits express or implied health benefit, efficacy, safety, or side effects claims for proposed respondents' intravenous therapies, unless the representation is non-misleading. In addition, the proposed Decision and Order requires that at the time the representation is made, proposed respondents must possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity to support the claim, based on standards generally accepted by experts in the area.

The Commission has determined that the conduct relief obtained by the proposed Decision and Order will serve to remedy the alleged violations and deter future violations. This action also sends a clear message to the burgeoning iV therapy industry and sellers of all healthcare products that health claims must be supported by competent and reliable scientific evidence. After carefully considering your comment, along with others received in this matter, the Commission has determined that the public interest is best served by issuing the Decision and Order in final form without modification. A copy of the final Decision and Order, and other relevant materials, are available from the Commission's website at <u>www.ftc.gov</u>.

Thank you again for your comment. The Commission is aided in its analysis by hearing from a variety of sources, and we appreciate your interest in this matter.

By direction of the Commission.



Office of the Secretary

February 13, 2019

Robyn Blumner, President and CEO Nicholas Little, Vice President and General Counsel, Legal Director Jason Lemieux, Director of Government Affairs Center for Inquiry 1012 14th Street, NW, Suite 205 Washington, D.C. 20005

> Re: In the Matter of A & O Enterprises Inc., a corporation, doing business as iV Bars Incorporated and iV Bars, and Aaron K. Roberts, also known as Aaron Keith, individually and as owner and operating manager of A & O Enterprises Inc. File No. 172 3016; Docket No. C-4670

Dear Messrs. Blumner, Little, and Lemieux:

Thank you for your comment of October 22, 2018, regarding the proposed consent agreement accepted by the Federal Trade Commission for public comment in the above-captioned matter. The Commission has placed your comment on the public record pursuant to Commission Rule 4.9(b), 16 C.F.R. § 4.9(b), and has given it serious consideration in connection with its decision to grant final approval to the proposed Decision and Order.

In your detailed comment, CFI analyzes the facts of this case, expresses concerns about the "alternative medicine" industry, and recommends that the Commission take action against proposed respondents. CFI supports each of the five core injunctive parts of the proposed Decision and Order, but objects to the proposed consent agreement to the extent that it does not seek monetary restitution for consumers.

The proposed Decision and Order broadly prohibits express or implied health benefit, efficacy, safety, or side effects claims for proposed respondents' intravenous therapies, unless the representation is non-misleading. In addition, the proposed Decision and Order requires that at the time the representation is made, proposed respondents must possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity to support the claim, based on standards generally accepted by experts in the area. Proposed respondents will be subject to the Commission's final Decision and Order for 20 years.

In addition, prior to accepting the proposed Decision and Order, the Commission required proposed respondents to send notices to consumers, who may have relied on the challenged claims. The notices informed consumers, among other things, that: (1) contrary to proposed respondents' marketing materials, scientific studies have not shown that the Myers Cocktail is an effective treatment for any disease, including cancer, angina, cardiovascular disease, congestive

heart failure, myocardial infarction, multiple sclerosis, diabetes, fibromyalgia, or neurodegenerative disorders; and (2) consumers should talk to their doctor or healthcare provider before stopping any treatment they have prescribed.

The Commission considers a number of factors in determining appropriate relief in each case, including the scope of harm, the benefits to consumers of obtaining a quick resolution to stop the deceptive conduct, and the best use of the Commission's scarce resources. In this matter, we carefully considered the facts of this case (including non-public facts), and determined that the conduct relief obtained by the order appropriately remedies the alleged violations of the FTC Act. In addition, the order will deter future violations by respondents, providing for civil penalties of up to \$41,484 per violation should they violate the order, pursuant to Section 5(l) of the FTC Act, 15 U.S.C. § 45(l).

After carefully considering your comment, along with others received in this matter, the Commission has determined that the public interest is best served by issuing the Decision and Order in final form without modification. A copy of the final Decision and Order, and other relevant materials, are available from the Commission's website at <u>www.ftc.gov</u>.

Thank you again for your comment. The Commission is aided in its analysis by hearing from a variety of sources, and we appreciate your interest in this matter.

By direction of the Commission.



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February 13, 2019

Ms. Amy Crittenden State of Ohio

> Re: In the Matter of A & O Enterprises Inc., a corporation, doing business as iV Bars Incorporated and iV Bars, and Aaron K. Roberts, also known as Aaron Keith, individually and as owner and operating manager of A & O Enterprises Inc. File No. 172 3016; Docket No. C-4670

Dear Ms. Crittenden:

Thank you for your comment of October 2, 2018, regarding the proposed consent agreement accepted by the Federal Trade Commission for public comment in the above-captioned matter. The Commission has placed your comment on the public record pursuant to Commission Rule 4.9(b), 16 C.F.R. § 4.9(b), and has given it serious consideration in connection with its decision to grant final approval to the proposed Decision and Order.

In your comment, you urged the Commission to adopt the proposed consent agreement and state that proposed respondents' "marketing materials are clearly deceptive and misleading, and they should not be permitted to continue this behavior." You also state that proposed respondents "are marketing their product as a drug [and] should be subjected to the same requirements the FDA imposes."

The Commission does not have authority to enforce FDA law or regulation. However, the Commission does rigorously enforce Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), that prohibits "unfair or deceptive acts or practices." In the instant case, the Commission's proposed complaint alleges that proposed respondents' health claims were false, misleading, or unsubstantiated, and therefore violated Section 5(a). Further, the Commission has determined that the conduct relief obtained by the proposed Decision and Order will serve to remedy these alleged violations and deter future violations. Proposed respondents will be subject to the Commission's final Order for 20 years and be liable for civil penalties of up to \$41,484 per violation should they violate that Order, pursuant to Section 5(l) of the FTC Act, 15 U.S.C. § 45(l).

After carefully considering your comment, along with others received in this matter, the Commission has determined that the public interest is best served by issuing the Decision and Order in final form without modification. A copy of the final Decision and Order, and other relevant materials, are available from the Commission's website at <u>www.ftc.gov</u>.

Thank you again for your comment. The Commission is aided in its analysis by hearing from a variety of sources, and we appreciate your interest in this matter.

By direction of the Commission.



Office of the Secretary

February 13, 2019

Ms. Elizabeth de Laperouse State of Missouri

> Re: In the Matter of A & O Enterprises Inc., a corporation, doing business as iV Bars Incorporated and iV Bars, and Aaron K. Roberts, also known as Aaron Keith, individually and as owner and operating manager of A & O Enterprises Inc. File No. 172 3016; Docket No. C-4670

Dear Ms. de Laperouse:

Thank you for your comment of September 24, 2018, regarding the proposed consent agreement accepted by the Federal Trade Commission for public comment in the above-captioned matter. The Commission has placed your comment on the public record pursuant to Commission Rule 4.9(b), 16 C.F.R. § 4.9(b), and has given it serious consideration in connection with its decision to grant final approval to the proposed Decision and Order.

Your comment is generally supportive of the proposed consent agreement and states, "Any facility claiming to help disease should be held to a basic level of proof that the therapy works." In the instant case, the Commission's proposed complaint alleges that respondents' disease claims were false, misleading, or unsubstantiated, and violated Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). The proposed Decision and Order prohibits express or implied health benefit, efficacy, safety, or side effects claims for proposed respondents' intravenous therapies, unless the representation is non-misleading. In addition, the proposed Decision and Order requires that at the time the representation is made, proposed respondents must possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity to support the claim, based on standards generally accepted by experts in the area. The proposed Order further provides that such substantiation must include a randomized, double-blind, and placebo-controlled human clinical trial, when experts generally require such human clinical testing to substantiate the representation.

The Commission has determined that the conduct relief obtained by the proposed Decision and Order will serve to remedy these alleged violations and deter future violations. Proposed respondents will be subject to the Commission's final Order for 20 years and be liable for civil penalties of up to \$41,484 per violation should they violate that Order, pursuant to Section 5(1) of the FTC Act, 15 U.S.C. § 45(1). This action also sends a clear message to the burgeoning iV therapy industry and sellers of all healthcare products, that health claims must be supported by competent and reliable scientific evidence.

After carefully considering your comment, along with others received in this matter, the Commission has determined that the public interest is best served by issuing the Decision and Order in final form without modification. A copy of the final Decision and Order, and other relevant materials, are available from the Commission's website at <u>www.ftc.gov</u>.

Thank you again for your comment. The Commission is aided in its analysis by hearing from a variety of sources, and we appreciate your interest in this matter.

By direction of the Commission.



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February 13, 2019

Ms. Carol Mathews State of California

> Re: In the Matter of A & O Enterprises Inc., a corporation, doing business as iV Bars Incorporated and iV Bars, and Aaron K. Roberts, also known as Aaron Keith, individually and as owner and operating manager of A & O Enterprises Inc. File No. 172 3016; Docket No. C-4670

Dear Ms. Mathews:

Thank you for your comment of October 2, 2018, regarding the proposed consent agreement accepted by the Federal Trade Commission for public comment in the above-captioned matter. The Commission has placed your comment on the public record pursuant to Commission Rule 4.9(b), 16 C.F.R. § 4.9(b), and has given it serious consideration in connection with its decision to grant final approval to the proposed Decision and Order.

In your comment, you support the proposed consent agreement and state that "IV vitamin and mineral injections not specifically for people with known deficiencies are quackery" and "infections and allergic reactions can kill." The Commission's proposed complaint in this matter, in fact, alleged that certain of proposed respondents' health *and* safety claims violated Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). The Commission has determined that the conduct relief obtained by the proposed Decision and Order will serve to remedy these alleged violations and deter future violations. Proposed respondents will be subject to the Commission's final Order for 20 years and be liable for civil penalties of up to \$41,484 per violation should they violate that Order, pursuant to Section 5(1) of the FTC Act, 15 U.S.C. § 45(1).

After carefully considering your comment, along with others received in this matter, the Commission has determined that the public interest is best served by issuing the Decision and Order in final form without modification. A copy of the final Decision and Order, and other relevant materials, are available from the Commission's website at <u>www.ftc.gov</u>.

Thank you again for your comment. The Commission is aided in its analysis by hearing from a variety of sources, and we appreciate your interest in this matter.

By direction of the Commission.



Office of the Secretary

February 13, 2019

Mr. Max Parker State of California

> Re: In the Matter of A & O Enterprises Inc., a corporation, doing business as iV Bars Incorporated and iV Bars, and Aaron K. Roberts, also known as Aaron Keith, individually and as owner and operating manager of A & O Enterprises Inc. File No. 172 3016; Docket No. C-4670

Dear Mr. Parker:

Thank you for your comment of October 11, 2018, regarding the proposed consent agreement accepted by the Federal Trade Commission for public comment in the above-captioned matter. The Commission has placed your comment on the public record pursuant to Commission Rule 4.9(b), 16 C.F.R. § 4.9(b), and has given it serious consideration in connection with its decision to grant final approval to the proposed Decision and Order.

In your comment, you object to the proposed consent agreement to the extent that it does not criminally charge proposed respondents, Aaron K. Roberts and A & O Enterprises Inc. The Commission's complaint alleges violations of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). The FTC Act does not provide for criminal penalties, and the Commission has no criminal prosecutorial authority. You also raise concern as to whether proposed respondents were licensed to give iV injections.¹ The Commission does not license healthcare providers and does not have the authority to enforce state licensure laws.

Like you, the Commission was concerned that cancer patients and others suffering from serious health conditions not forgo proven treatments because of proposed respondents' allegedly false, misleading, or unsubstantiated health claims. Therefore, prior to accepting the proposed consent agreement in this matter, the Commission required proposed respondents to send notices to consumers who may have relied on the challenged claims. The notices informed consumers, among other things, that: (1) contrary to proposed respondents' marketing materials, scientific studies have not shown that the Myers Cocktail is an effective treatment for any disease, including cancer, angina, cardiovascular disease, congestive heart failure, myocardial infarction, multiple sclerosis, diabetes, fibromyalgia, or neurodegenerative disorders; and (2) consumers should talk to their doctor or healthcare provider before stopping any treatment they have prescribed.

¹ Please note, proposed respondents' iV "Cocktails" contain a mixture of water, vitamins, minerals, and amino acids, not alcoholic beverages, as your comment suggests.

The Commission has determined that the conduct relief obtained by the proposed Decision and Order will serve to remedy the alleged violations of the FTC Act by proposed respondents and deter future violations. It is important to note that proposed respondents will be subject to the Commission's final Order for 20 years and be liable for civil penalties of up to \$41,484 per violation should they violate that Order, pursuant to Section 5(1) of the FTC Act, 15 U.S.C. § 45(1).

After carefully considering your comment, along with others received in this matter, the Commission has determined that the public interest is best served by issuing the Decision and Order in final form without modification. A copy of the final Decision and Order, and other relevant materials, are available from the Commission's website at <u>www.ftc.gov</u>.

Thank you again for your comment. The Commission is aided in its analysis by hearing from a variety of sources, and we appreciate your interest in this matter.

By direction of the Commission.