UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

In the Matter of

In the Matter of

EFFICIENT LABS, INC.

a corporation, and

AGREEMENT CONTAINING

CONSENT ORDER

BLAS REYES-REYES,

individually and as an officer

of the corporation.

The Federal Trade Commission has conducted an investigation of certain acts and practices of Efficient Labs, Inc., a corporation, and Blas Reyes-Reyes, individually and as an officer of the corporation ("proposed respondents"). Proposed respondents, having been represented by counsel, are willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

IT IS HEREBY AGREED by and between Efficient Labs, Inc., by its duly authorized officer, and Blas Reyes-Reyes, individually and as an officer of the corporation, and counsel for the Federal Trade Commission that:

- 1.a. Proposed respondent Efficient Labs, Inc. is a corporation organized under the laws of the Commonwealth of Puerto Rico, with its principal office or place of business at 413 San Jorge Street, San Juan, Puerto Rico 00912.
- 1.b. Proposed respondent Blas Reyes-Reyes is an officer of the corporate respondent. Individually or in concert with others, he formulates, directs or controls the policies, acts, or practices of the corporation. His principal office or place of business is the same as that of Efficient Labs, Inc.
- 2. Proposed respondents admit all the jurisdictional facts set forth in the draft complaint.

- 3. Proposed respondents waive:
 - a. any further procedural steps;
 - b. the requirement that the Commission's decision contain a statement of findings of fact and conclusions of law; and
 - c. all rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.
- 4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft complaint, will be placed on the public record for a period of sixty (60) days and information about it publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondents, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of the proceeding.
- 5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondents that the law has been violated as alleged in the draft complaint, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.
- This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondents, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other The order shall become final upon service. Delivery of the complaint and the decision and order to proposed respondents by any means specified in Section 4.4 of the Commission's Rules shall constitute service. Proposed respondents waive any right they may have to any other manner of service. The complaint may be used in construing the terms of the order. No agreement, understanding, representation, or interpretation not contained in

the order or in the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondents have read the draft complaint and consent order. They understand that they may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

- 1. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
- 2. Unless otherwise specified, "respondents" shall mean Efficient Labs, Inc., a corporation, its successors and assigns and its officer; Blas Reyes-Reyes, individually and as an officer of the corporation; and each of the above's agents, representatives and employees.
- 3. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondents, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Venoflash or any other product in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, that such product:

A. removes dangerous clogs in the circulatory system;

- B. treats the symptoms of varicose veins; or
- C. treats the symptoms of hemorrhoids.

unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Venoflash or any food, dietary supplement, or drug, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, promoted or used to treat conditions or illnesses related to the circulatory system, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the health benefits, performance, safety, or efficacy of such product, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

Nothing in this order shall prohibit respondents from making any representation for any product that is specifically permitted in the labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

IV.

Nothing in this order shall prohibit respondents from making any representation for any drug that is permitted in the labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

V.

IT IS FURTHER ORDERED that respondent Efficient Labs, Inc., and its successors and assigns, and respondent Blas Reyes-Reyes shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon

request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VI.

IT IS FURTHER ORDERED that respondent Efficient Labs, Inc., and its successors and assigns, and respondent Blas Reyes-Reyes, shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that respondent Efficient Labs, Inc., and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed

change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

VIII.

IT IS FURTHER ORDERED that respondent Blas Reyes-Reyes, for a period of seven (7) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that respondent Efficient Labs, Inc., and its successors and assigns, and respondent Blas Reyes-Reyes shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

Х.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever

comes later; <u>provided</u>, <u>however</u>, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (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 Part.

<u>Provided</u>, <u>further</u>, 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 Part 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.

Signed this	, day of, 1997	
		EFFICIENT LABS, INC.
	ву:	BLAS REYES-REYES President
		BLAS REYES-REYES, individually and as an officer of the corporation.
		JOSE A. ACOSTA-GRUBB Attorney for Respondents

DONALD G. D'AMATO Counsel for the Federal Trade Commission

DENISE V. TIGHE Counsel for the Federal Trade Commission

APPROVED:

MICHAEL JOEL BLOOM Director

New York Regional Office

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

In the Matter of

In the Matter of

EFFICIENT LABS, INC.

a corporation, and

DOCKET NO.

BLAS REYES-REYES,

individually and as an officer

of the corporation.

COMPLAINT

The Federal Trade Commission, having reason to believe that Efficient Labs, Inc., a corporation, and Blas Reyes-Reyes, individually and as an officer of the corporation ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

- 1. Respondent Efficient Labs, Inc. is a corporation organized under the laws of the Commonwealth of Puerto Rico, with its principal office or place of business at 413 San Jorge Street, San Juan, Puerto Rico 00912.
- 2. Respondent Blas Reyes-Reyes is an officer of the corporate respondent. Individually or in concert with others, he formulates, directs, participates in, or controls the policies, acts, or practices of the corporation, including the acts or practices alleged in this complaint. His principal office or place of business is the same as that of Efficient Labs, Inc.
- 3. Respondents have advertised, offered for sale, sold, and distributed products to the public, including "Venoflash," a nutritional supplement with ingredients that include Niacin U.S.P.; Vitamins B-1, B-6, B-12, C, and E; and various plant derivatives. Venoflash purportedly, among other things, treats the symptoms of varicose veins and hemorrhoids. "Venoflash" is a

"food" and/or "drug" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act, 15 U.S.C. §§ 52,55.

- 4. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.
- 5. Respondents have disseminated or have caused to be disseminated print and television advertisements for Venoflash that have appeared in Miami's El Nuevo Herald, and have been broadcast and cablecast on Telemundo de Puerto Rico, Univision 41(WXTV-New York), Telemundo (T47/WNJU New York), Univision 23 (WLTV-Miami), and Telemundo de Florida . These print and television advertisements, including but not necessarily limited to the attached Exhibit A (transcript of a television advertisement), contain the following statements:

"Clogged, Clogged!

When your blood circulation feels like it's clogging, look for the Venoflash aid.

If you suffer from varicose veins, Venoflash can help you! If you suffer from hemorrhoids, Venoflash can help you!

To order, 1-800-272-8964.

Venoflash can help if your extremities become numb as a result of problems in your veins and capillaries.

Defend yourself from those dangerous clogs in your circulatory system and recover your lost agility taking Venoflash.

Venoflash can help you!"

(Exhibit A)

- 6. Through the means described in Paragraph 5, respondents have represented, expressly or by implication, that:
 - A. Venoflash removes dangerous clogs in the circulatory system;
 - B. Venoflash treats the symptoms of varicose veins; and
 - C. Venoflash treats the symptoms of hemorrhoids.

- 7. Through the means described in Paragraph 5, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 6 at the time the representations were made.
- 8. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 6 at the time the representations were made. Therefore, the representation set forth in Paragraph 7 was, and is, false or misleading.
- 9. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this day of , has issued this complaint against respondents.

By the Commission.

Donald S. Clark Secretary

SEAL:

[Exhibit A attached to paper copies of complaint, but not available in electronic form.]

ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission has accepted an agreement to a proposed consent order from Efficient Labs, Inc. and Blas Reyes-Reyes.

The proposed consent order has been placed on the public record for sixty (60) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

The Commission's complaint alleges that the proposed respondents made the following unsubstantiated representations about Venoflash: it removes dangerous clogs in the circulatory system; it treats the symptoms of varicose veins; and it treats the symptoms of hemorrhoids.

The proposed order contains provisions designed to remedy the violations charged and to prevent proposed respondents from engaging in similar acts in the future.

Paragraph I of the proposed order prohibits proposed respondents from representing that Venoflash or any other product removes dangerous clogs in the circulatory system; treats the symptoms of varicose veins; and treats the symptoms of hemorrhoids, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Paragraph II of the proposed order prohibits proposed respondents from making any representation about the health benefits, performance, safety, or efficacy of Venoflash, or any food, dietary supplement, or drug, promoted or used to treat conditions or illnesses related to the circulatory system, unless, at the time the representation is made, proposed respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Paragraph III of the proposed order provides that nothing in this order shall prohibit proposed respondents from making any representation for any product permitted by the Food and Drug Administration. Paragraph IV of the proposed order provides that nothing in this order shall prohibit proposed respondents from making any representation for any drug permitted by the Food and Drug Administration.

Paragraph V of the proposed order requires the proposed respondents to keep and maintain all advertisements and promotional materials containing any representation, and all materials that were relied upon in disseminating the representations, covered by the proposed order. Additionally, Paragraph VI requires distribution of a copy of the consent order to current and future officers and agents. Further, Paragraph VII provides for Commission notification upon a change in the corporate respondent, and Paragraph VIII requires Commission notification when the individual respondent changes his present business or employment. Paragraph IX requires proposed respondents to file compliance reports with the Commission.

Lastly, Paragraph X provides for the termination of the order after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.