

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

CASE NO.

FEDERAL TRADE COMMISSION,)
)
Plaintiff,)
)
v.)
)
ALTERNATIVE MEDICAL)
TECHNOLOGIES, INC.,)
and)
JOSE FERNANDEZ,)
)
Defendants.)
)

**STIPULATED FINAL ORDER FOR
PERMANENT INJUNCTIVE AND OTHER EQUITABLE RELIEF
AGAINST ALTERNATIVE MEDICAL TECHNOLOGIES, INC.
AND JOSE FERNANDEZ**

WHEREAS Plaintiff, the Federal Trade Commission (“FTC”), has commenced this action by filing the Complaint herein; defendants Alternative Medical Technologies, Inc., and Jose Fernandez have waived service of the Summons and Complaint; the parties have been represented by the attorneys whose names appear hereafter; and the parties have agreed to settlement of this action upon the following terms and conditions, without adjudication of any issue of fact or law and without defendants admitting liability for any of the matters alleged in the Complaint;

THEREFORE, on the joint motion of plaintiff and defendants, it is hereby ORDERED, ADJUDGED, and DECREED as follows:

1. This Court has jurisdiction over the subject matter of this case and jurisdiction over all parties. Venue in the Southern District of Florida is proper under 28 U.S.C. § 1391(b) and 15 U.S.C. § 53(b).

2. The Complaint states a claim upon which relief can be granted against the defendants under Sections 5(a), 12, and 13(b) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. §§ 45(a), 52, and 53(b).

3. The acts and practices of defendants were, and are, in or affecting commerce, as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

4. Defendants waive all rights to seek judicial review or otherwise challenge or contest the validity of this Order. Defendants also waive any claims that they may have held under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action to the date of this Order.

5. Each party shall bear its own costs and attorneys’ fees.

6. Entry of this Order is in the public interest.

DEFINITIONS

For purposes of this Order, the following definitions apply:

7. “Clearly and prominently” means as follows:

a. In an advertisement communicated through an electronic medium (such as television, video, radio, and interactive media such as the Internet, online services and software), the disclosure must be presented simultaneously in both the audio and visual portions of the advertisement. *Provided, however*, that in any advertisement presented solely through visual or audio means, the disclosure may be made through the same means in which the ad is presented. *Provided, further*, that in any advertisement communicated through interactive media which is

presented predominantly through visual or audio means, the disclosure may be made through the same means in which the ad is predominantly presented. The audio disclosure must be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. The visual disclosure must be of a size and shade, with a degree of contrast to the background against which it appears, and must appear on the screen for a duration and in a location, sufficiently noticeable for an ordinary consumer to read and comprehend it.

- b. In a print advertisement, promotional material, or instructional manual, the disclosure must be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears.
- c. On a product label, the disclosure must be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it and in print that contrasts with the background against which it appears. *Provided, however*, if a disclosure on a bottle label or package label is made in a location other than the principal display panel, the bottle label or package label must (i) include the statement, “**See important safety warning(s) on [insert disclosure location],**” in a type size and location on the principal display panel sufficiently noticeable for an ordinary consumer to read and comprehend it and in print that contrasts with the background against which it appears; and (ii) place the disclosure on the bottle label and, if applicable, the package label, within a border that is a color or shade that contrasts with the background against which it appears. *Provided further*, that in a multi-page insert, the disclosure must appear on the cover page or first page.

- d. The disclosure must be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure can be used in any advertisement or on any label.
- e. In the case of advertisements disseminated by means of an interactive electronic medium, such as software, the Internet, or online services, “in close proximity” means on the same Web page, online service page, or other electronic page, and proximate to the triggering representation, and does not include disclosures accessed or displayed through hyperlinks, pop-ups, interstitials or other means.
- 8. “Commerce” means as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.
- 9. “Competent and reliable scientific evidence” means 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.
- 10. Unless otherwise specified, “defendants” mean Alternative Medical Technologies, Inc. (“AMT”), and its successors and assigns, and Jose Fernandez (“Fernandez”).
- 11. “Endorsement” means as defined in 16 C.F.R. § 255.0(b).
- 12. “Ephedra” means a source of ephedrine alkaloid, including, but not limited to, ephedrine, pseudoephedrine, norephedrine, norpseudoephedrine, N-methylephedrine, and N-methylpseudoephedrine, either derived from natural sources such as the herb *Ephedra sinica* (also called Ma-Huang or Chinese Ephedra) or synthetically produced.
- 13. “Drug” and “cosmetic” mean as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.

14. "Material connection" means any relationship that might materially affect the weight or credibility of an endorsement and would not reasonably be expected by the consumer audience.

15. "Person" means a natural person, organization or other legal entity, including a partnership, corporation, proprietorship, association, cooperative, or any other group acting together as an entity.

16. "Product label" means any label or other written, printed or graphic matter upon any product or accompanying any product, including package labels, bottle labels, and package inserts.

17. The term "including" in this Order means "including, without limitation."

I.

PROHIBITED REPRESENTATIONS

IT IS ORDERED that defendants, and their officers, agents, servants, employees, and attorneys, and all persons and entities in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any corporation, subsidiary, division, or other entity, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of the following products, in or affecting commerce, are hereby permanently enjoined from representing, in any manner, expressly or by implication, including through the use of endorsements or trade name, that:

- A. Any dietary supplement, over-the-counter drug, or cosmetic causes substantial weight loss without the need to increase exercise or reduce caloric intake; or
- B. X-TOX 10, or any substantially similar product, causes substantial weight loss in a short period of time.

II.

REPRESENTATIONS PROHIBITED UNLESS TRUE AND SUBSTANTIATED

IT IS FURTHER ORDERED that defendants, and their officers, agents, servants, employees, and attorneys, and all persons and entities in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any corporation, subsidiary, division, or other entity, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, service, or program, in or affecting commerce, are permanently enjoined from making any representation, expressly or by implication, including through the use of endorsements or trade name:

- A. That any such product, service, or program:
 - 1. Causes weight loss;
 - 2. Causes substantial weight loss in a short period of time;
 - 3. Suppresses appetite;
 - 4. Dissolves or eliminates existing body fat;
 - 5. Causes loss of body fat, not muscle;
 - 6. Reduces cigarette addiction;
 - 7. Reduces the desire to smoke;
 - 8. Eliminates or reduces nicotine or other toxins in the body that result from smoking;
 - 9. Helps users quit smoking;
 - 10. Eliminates or reduces the respiratory or circulatory damage caused by smoking; or

- B. That any such product, service, or program that contains or purports to contain ephedra:
 - 1. Can be taken safely for an indefinite period of time;
 - 2. Can be taken safely with other medicines, including prescription medicines; or
- C. About the benefits, performance, efficacy, safety, or side effects, of any such product, service, or program;

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

III.

PROHIBITED MISREPRESENTATIONS

IT IS FURTHER ORDERED that defendants, and their officers, agents, servants, employees, and attorneys, and all persons and entities in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any corporation, subsidiary, division, or other entity, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, service, or program, in or affecting commerce, are hereby permanently enjoined from making any misrepresentation, expressly or by implication, including through the use of endorsements:

- A. About any material connection, or lack thereof, between an endorser and any of the defendants; or
- B. About the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

IV.

REQUIRED DISCLOSURE: MATERIAL CONNECTION

IT IS FURTHER ORDERED that defendants, and their officers, agents, servants, employees, and attorneys, and all persons and entities in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any corporation, subsidiary, division, or other entity, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution any product, service, or program, in or affecting commerce, must disclose, clearly and prominently, and in close proximity to the endorsement, a material connection, where one exists, between a person providing an endorsement of any product, service, or program, and any defendant, or any other person manufacturing, labeling, advertising, promoting, offering for sale, sale, or distribution of such product, service, or program.

V.

REQUIRED DISCLOSURES: EPHEDRA PRODUCT OR SERVICE

IT IS FURTHER ORDERED that defendants, and their officers, agents, servants, employees, and attorneys, and all persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, whether acting directly or through any corporation, subsidiary, division, or other device:

- A. In any advertisement (other than a television or radio advertisement), promotional material, or product label for any product, service, or program that contains or purports to contain ephedra, and during any discussion relating to the use of such product, service, or program, communicated via electronic mail or any telephone line, must make clearly and prominently, the following disclosure:

WARNING: This product contains ephedra or ephedrine alkaloids, which can have dangerous effects on the central nervous system and heart and can result in serious injury. Risk of injury can increase with dose, and may even include heart attack, stroke, seizure or death. Consult a health care provider prior to use if you have high blood pressure, heart or thyroid disease, diabetes, difficulty urinating, prostate enlargement, or glaucoma, or are using any prescription drug. Do not use if you are taking a MAO inhibitor or any allergy, asthma, or cold medication containing ephedrine, pseudoephedrine or phenylpropanolamine. Discontinue use if you experience rapid heart beat, chest pain, severe headache, shortness of breath, dizziness, sleeplessness or nausea. This product is not recommended for use if you are or could be pregnant unless a qualified health care provider tells you to use it.

The product may not be safe for your developing baby.

unless defendants possess competent and reliable scientific evidence that such product is safe and produces no adverse side effects.

- B. In any television or radio advertisement for any product, service, or program containing ephedra, must make, clearly and prominently, the following disclosure:

WARNING: This product contains [insert name of ephedrine alkaloids contained in product, *e.g.*, Mahuang] which can have dangerous effects on the central nervous system and heart and can

result in serious injury. Risk of injury increases with increased dosage.

unless defendants possess competent and reliable scientific evidence that such product is safe and produces no adverse side effects.

Provided, however, that in the event that the Food and Drug Administration issues a final rule requiring a warning on the labeling of products containing ephedrine alkaloids, defendants may substitute that warning for the disclosures required under Subparts A and B above.

VI.

FOOD AND DRUG ADMINISTRATION

IT IS FURTHER ORDERED that nothing in this Order prohibits defendants from:

- A. Making any representation for any drug that is permitted in 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; and
- B. Making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

VII.

RIGHT TO REOPEN

IT IS FURTHER ORDERED that:

- A. The Commission's agreement to this Order is expressly premised on the truthfulness, accuracy, and completeness of defendants' sworn financial statements and supporting documents submitted to the Commission, including:

1. The Financial Statement of Alternative Medical Technologies, Inc. dated January 12, 2004; the letter from Ray Garcia, Esq., dated January 27, 2004, including balance sheets and income statements attached thereto; and the letter from Ray Garcia, Esq., dated August 22, 2003, including U.S. Income Tax Returns and other financial disclosures attached thereto.
2. The Financial Statement of Jose Fernandez dated February 16, 2004; and the letter from Jose Fernandez dated December 12, 2003, including the U.S. Income Tax Return attached thereto.

Such financial statements and supporting documents contain material information upon which the Commission relied in negotiating and agreeing to this Order.

- B. If, upon motion by the Commission, a Court finds that any defendant has failed to disclose any material asset, or made any other material misrepresentation or omission in the financial statements and related documents described in Paragraph VII (A) above, the Court shall enter judgment against defendants, jointly and severally, in favor of the Commission, in the amount of \$376,000 (three hundred and seventy six thousand dollars) in U.S. currency, which amount would be rendered immediately due and payable. Interest computed at the rate prescribed in 28 U.S.C. § 1961 shall immediately begin to accrue on the balance. For the purposes of this Paragraph and any subsequent proceedings to enforce payment, the Defendants waive any right to contest any of the allegations in the Complaint filed in this action. *Provided however*, that in all other respects this Stipulated Final Order

remains in full force and effect unless otherwise ordered by the Court; and *provided further*, that proceedings instituted under this Paragraph VII are in addition to, and not in lieu of, any other civil or criminal remedies that may be provided by law, including any other proceedings the Commission may initiate to enforce this Order.

VIII.

ACKNOWLEDGMENT OF RECEIPT OF ORDER

IT IS FURTHER ORDERED that defendants, within five (5) business days of receipt of this Order as entered by the Court, must each execute and submit to the Commission a truthful sworn statement acknowledging receipt of this Order.

IX.

DISTRIBUTION OF ORDER

IT IS FURTHER ORDERED that, for a period of five (5) years from the date of entry of this Order:

- A. Defendant AMT, and its successors and assigns, must deliver a copy of this Order to all principals, officers, directors, managers, employees, agents, and representatives, including AMT distributors, having responsibilities with respect to the subject matter of this Order, and must secure from each such person a signed and dated statement acknowledging receipt of the Order. Defendant AMT, and its successors and assigns, must deliver this Order to current personnel within thirty (30) days after the date of service of this Order, and to new personnel within thirty (30) days after the person assumes such position or responsibilities.

- B. Defendant Fernandez must deliver a copy of this Order to the principals, officers, directors, managers and employees under defendant Fernandez's control for any business that (a) hires defendant Fernandez as an employee, consultant or independent contractor and (b) has responsibilities with respect to the subject matter of this Order. Defendant Fernandez must secure from each such person a signed and dated statement acknowledging receipt of the Order within thirty (30) days after the date of service of the Order or the commencement of the employment relationship.

X.

COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring and investigating compliance with any provision of this Order:

- A. Within ten (10) days of receipt of written notice from a representative of the Commission, defendants each must submit additional written reports, sworn to under penalty of perjury; produce documents for inspection and copying; appear for deposition; and/or provide entry during normal business hours to any business location in such defendant's possession or direct or indirect control to inspect the business operation;
- B. In addition, the Commission is authorized to monitor compliance with this Order by all other lawful means, including but not limited to the following:
1. Obtaining discovery from any person, without further leave of court, using the procedures prescribed by Fed. R. Civ. P. 30, 31, 33, 34, 36, and 45;

2. Posing as consumers and suppliers to defendants, defendants' employees, or any other entity managed or controlled in whole or in part by defendants, without the necessity of identification or prior notice;

Provided that 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, to obtain any documentary material, tangible things, testimony, or information relevant to unfair or deceptive acts or practices in or affecting commerce (within the meaning of 15 U.S.C. § 45(a)(1)).

- C. Defendants must permit representatives of the Commission to interview any employer, consultant, independent contractor, representative, agent, or employee who has agreed to such an interview, relating in any way to any conduct subject to this Order. The person interviewed may have counsel present.

XI.

COMPLIANCE REPORTING

IT IS FURTHER ORDERED that, in order that compliance with the provisions of this Order may be monitored:

- A. For a period of five (5) years from the date of entry of this Order,
 1. Defendant Fernandez must notify the Commission of the following:
 - a. Any changes in his residence, mailing addresses, and telephone numbers, within ten (10) days of the date of such change;
 - b. Any changes in his employment status (including self-employment) within ten (10) days of the date of such change.Such notice must include the name and address of each business that he is affiliated with, employed by, or performs services for; a

statement of the nature of the business; and a statement of his duties and responsibilities in connection with the business;

c. Any changes in his name or use of any aliases or fictitious names; and

2. Defendant AMT, and its successors and assigns, must notify the Commission of any changes in corporate structure 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 filing of a bankruptcy petition; or a change in the corporate name or address, at least thirty (30) days prior to such change, *provided* that, with respect to any proposed change in the corporation about which defendant AMT learns less than thirty (30) days prior to the date such action is to take place, defendant AMT must notify the Commission as soon as is practicable after obtaining such knowledge.

B. One hundred eighty (180) days after the date of entry of this Order, defendants each must provide a written report to the FTC, sworn to under penalty of perjury, setting forth in detail the manner and form in which they have complied and are complying with this Order. This report must include, but not be limited to:

1. Any changes required to be reported pursuant to Subparagraph A above; and
2. A copy of each acknowledgment of receipt of this Order obtained by defendants pursuant to Paragraph IX.

- C. For the purposes of this Order, defendants must, unless otherwise directed by the Commission's authorized representatives, mail all written notifications to the Commission to: Associate Director for Enforcement, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, DC 20580. Attn: FTC v. Alternative Medical Technologies, Inc. et al., (S.D. Fla.).
- D. For purposes of the compliance reporting required by this Part, the Commission is authorized to communicate directly with defendants.

XII.

RECORD KEEPING PROVISIONS

IT IS FURTHER ORDERED that, for a period of eight (8) years from the date of entry of this Order, defendant AMT, and defendant Fernandez in connection with any business where (1) he is the majority owner, an officer, or director of the business, or directly or indirectly manages or controls the business and where (2) the business engages in, or assists others engaged in, the manufacturing, advertising, promotion, offering for sale, distribution or sale of any product, service, or program, each must maintain, and upon request, make available to the Commission, copies of all business records demonstrating compliance with the terms and provisions of this Order, including, but not limited to the following:

- A. Accounting records that reflect the cost of products, services, or programs sold, revenues generated, and the disbursement of such revenues;
- B. Personnel records accurately reflecting the name, address, and telephone number of each person employed in any capacity by such business, including as an independent contractor; that person's job title or position; the date upon which the person commenced work; and the date and reason for the person's termination, if applicable;

- C. Customer files containing the names, addresses, telephone numbers, dollar amounts paid, quantity of products, services, or programs purchased, and description of products, services, or programs purchased, to the extent such information is obtained in the ordinary course of business;
- D. Complaints and refund requests (whether received directly, indirectly, or through any third party) and any responses to those complaints or requests;
- E. Copies of all advertisements, promotional materials, sales scripts, training materials, or other materials utilized in the advertising, labeling, promotion, offering for sale, distribution or sale of any product, service, or program;
- F. All materials that were relied upon in making any representations contained in the materials identified in Subpart E;
- G. All other documents evidencing or referring to the accuracy of any claim therein or to the safety or efficacy of any product, service, or program, including, but not limited to, all tests, reports, studies, demonstrations, or other evidence that confirm, contradict, qualify, or call into question the safety or efficacy of any such product, service, or program; and
- H. Records accurately reflecting the name, address, and telephone number of each manufacturer or laboratory engaged in the development or creation of any testing obtained for the purpose of advertising, labeling, promoting, offering for sale, distributing, or selling any product, service, or program.

XIII.

RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court retains jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

XIV.

SCOPE OF ORDER

IT IS FURTHER ORDERED that this Order resolves only claims against the named defendants and does not preclude the Commission from initiating further action or seeking any remedy against any other persons or entities, including without limitation persons or entities who may be subject to portions of this Order by virtue of actions taken in concert or participation with defendants, and persons or entities in any type of indemnification or contractual relationship with defendants.

/

/

/

/

/

/

/

/

/

/

/

/

/

SO STIPULATED:

JUDGMENT IS THEREFORE ENTERED in favor of plaintiff and against defendants,
pursuant to all the terms and conditions recited above.

Dated this _____ day of _____, 2004

[NAME]
UNITED STATES DISTRICT JUDGE

FOR THE FEDERAL TRADE COMMISSION:

ELAINE D. KOLISH
Associate Director for Enforcement

JONI LUPOVITZ
Assistant Director for Enforcement

ANGELA FLOYD

HAMPTON NEWSOME
Attorneys
Federal Trade Commission
600 Pennsylvania Ave.
Washington, D.C. 20580
(202) 326-2237 (Floyd telephone)
(202) 326-2889 (Newsome telephone)
(202) 326-2559 (facsimile)

FOR THE DEFENDANTS:

ALTERNATIVE MEDICAL
TECHNOLOGIES, INC.

By: _____

JOSE FERNANDEZ,
Individually and as an officer of
Alternative Medical Technologies, Inc.

CONCUR AS TO FORM:

RAY GARCIA
SPIEGEL & UTRERA
Attorney for Defendants

