

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:

1. "Commerce" means as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

2. "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.

3. Unless otherwise specified, "Defendants" mean Transdermal Products International Marketing Corporation and its successors and assigns ("Transdermal") and William H. Newbauer ("Newbauer").

4. "Drug," "device" and "cosmetic" mean as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.

5. "Endorsement" means as defined in 16 C.F.R. § 255.0(b).

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

7. "Transdermal product" means any product applied to the skin to deliver the product's ingredients into the body.

I.

PROHIBITED BUSINESS ACTIVITIES

Unless otherwise permitted by the provisions of Part VI of this Order, **IT IS HEREBY ORDERED** that:

- A. Defendants, whether acting directly or through any corporation, subsidiary, division, or other entity, are hereby permanently enjoined from engaging, participating, or assisting, in any manner whatsoever, directly or indirectly, in the labeling, advertising, marketing, promotion, offering for sale, distribution, or sale of any transdermal product for the purpose of losing or controlling weight; and
- B. Defendants and their officers, agents, servants, employees, 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 dietary supplement, drug, device or cosmetic, in or affecting commerce, are hereby permanently enjoined from making, or assisting others in making, expressly or by implication, including through the use of endorsements or any trade name, any oral or written representation that:

- 1. Any such product causes substantial weight loss without reducing calories

or increasing exercise;

2. Any such product safely enables users to lose more than three pounds per week for a period of more than four weeks; or
3. Any such product causes permanent weight loss.

II.

PROHIBITED MISREPRESENTATIONS

IT IS FURTHER ORDERED that Defendants, and their officers, agents, servants, employees, 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 transdermal product, dietary supplement, food, drug, device or cosmetic, in or affecting commerce, are hereby permanently enjoined from making or assisting others in making any false or misleading statement of material fact, expressly or by implication, including through the use of endorsements, that any transdermal product, dietary supplement, food, drug, device or cosmetic has been approved or is awaiting approval by the Food and Drug Administration for any purpose.

III.

REPRESENTATIONS PROHIBITED UNLESS TRUE AND SUBSTANTIATED

IT IS FURTHER ORDERED that Defendants, and their officers, agents, servants, employees, 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 transdermal

product, dietary supplement, food, drug, device or cosmetic, in or affecting commerce, are permanently enjoined from making or assisting others in making any representation, expressly or by implication, of material fact, including through the use of endorsements or trade names:

- A. That any such product:
 - 1. Causes weight loss;
 - 2. Melts away or burns body fat (or words of similar import), or otherwise affects the body's metabolism of fat; or
- B. About the benefits, performance, efficacy, safety, or side effects of any such product;

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.

IV.

PROHIBITED MISREPRESENTATIONS ABOUT TESTS, STUDIES, AND RESEARCH

IT IS FURTHER ORDERED that Defendants, and their officers, agents, servants, employees, 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 transdermal product, dietary supplement, food, drug, device or cosmetic, in or affecting commerce, are hereby permanently enjoined from making or assisting others in making any false or misleading statement, expressly or by implication, of material fact, including through the use of endorsements, about the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

V.

MEANS AND INSTRUMENTALITIES

IT IS FURTHER ORDERED that Defendants, and their officers, agents, servants, employees, 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 transdermal product, dietary supplement, food, drug, device or cosmetic, in or affecting commerce, are hereby permanently enjoined from providing the means and instrumentalities with which to make, expressly or by implication, any false or misleading statement of material fact, including, but not limited to, the representations contained in Sections I - IV above. For purposes of this Part, "means and instrumentalities" shall mean any information, including but not necessarily limited to any advertising, labeling, promotional, or purported substantiation materials, for use by trade customers in their marketing of any transdermal product, dietary supplement, food, drug, device or cosmetic, in or affecting commerce.

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, at the time the representation is made, 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, at the time the representation is

made, specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration.

VII.

MONETARY JUDGMENT AND CONSUMER REDRESS

IT IS FURTHER ORDERED that Judgment is hereby entered against Defendants, jointly and severally, in the amount of one hundred eighty thousand dollars (\$180,000) to be paid to the Federal Trade Commission, as follows:

A. Sixty thousand dollars (\$60,000) on or before July 31, 2007; sixty thousand dollars (\$60,000) on or before July 31, 2008; and sixty thousand dollars (\$60,000) on or before January 30, 2009. Defendants shall make such payments by certified cashier's check made payable to the Federal Trade Commission, Division of Finance, 600 Pennsylvania Ave., NW, Washington, DC 20580, Reference Information FTC v. Transdermal Products International Marketing Corporation, et al., Matter No. X050023, or by wire transfer in accord with directions provided by the FTC.

B. In the event of any default in payment, interest shall accrue, computed pursuant to 28 U.S.C. § 1961 from the date of default to the date of payment. If such default continues beyond 15 calendar days, then defendants consent to entry of judgment, immediately due and payable, in the amount of nine hundred thousand dollars (\$900,000), representing the total sales at issue in this matter, less any amount already paid.

C. While defendants do not admit any of the facts alleged in the Complaint other than jurisdictional facts, defendants agree that the facts as alleged in the Complaint shall be taken as true in the event of any subsequent litigation to collect amounts due pursuant to this Order, including but not limited to a nondischargeability complaint in any bankruptcy case.

D. The judgment entered pursuant to this Section VII is equitable monetary relief, solely remedial in nature, and not a fine, penalty, punitive assessment or forfeiture.

E. Defendants acknowledge and agree that any money paid pursuant to this Order is irrevocably paid to the FTC for purposes of settlement between the FTC and defendants, and defendants relinquish all rights, title, and interest to such money.

F. Unless they have done so already, defendants are hereby required, in accordance with 31 U.S.C. § 7701, to furnish to the FTC their tax identification numbers, which shall be used for purposes of collecting and reporting on any delinquent amount arising out of this Order.

VIII.

RIGHT TO REOPEN

IT IS FURTHER ORDERED that, within five (5) business days after entry of this Order, Defendants each shall submit to the FTC a truthful sworn statement that shall acknowledge receipt of this Order and shall reaffirm and attest to the truth, accuracy and completeness of the financial statements previously submitted to the FTC. The FTC's agreement to this Order and the Court's approval are expressly premised on the truthfulness, accuracy and completeness of the financial statements and supporting documents submitted to the FTC and dated December 8, 2005, December 12, 2005, and August 2, 2006. If, upon motion by the FTC, the Court finds that the financial statements or supporting documents of any Defendant contain any material misrepresentation or omission, then judgment shall be entered in the amount of nine hundred thousand dollars (\$900,000), immediately due and payable (less any amounts turned over to the FTC pursuant to Section VII of this Order); *provided, however*, that in all other respects this Order shall remain in full force and effect unless otherwise ordered by the Court; and, *provided further*, that proceedings instituted under this provision would be in addition to,

and not in lieu of, any other civil or criminal remedies as may be provided by law, including any other proceedings that the FTC may initiate to enforce this Order. For purposes of this Section VIII, Defendants waive any right to contest any of the allegations in the Complaint.

IX.

DISTRIBUTION OF ORDER

IT IS FURTHER ORDERED that, for a period of three (3) years from the date of entry of this Order, Defendants shall deliver copies of the Order as directed below:

- A. **Corporate Defendant:** Defendant Transdermal must deliver a copy of this Order to all of its principals, officers, directors, and managers. Transdermal also must deliver copies of this Order to all of its employees, agents, and representatives who engage in conduct related to the subject matter of the Order. For current personnel, delivery shall be within five (5) days of service of this Order upon Defendant. For new personnel, delivery shall occur prior to them assuming their responsibilities.
- B. **Individual Defendant as Control Person:** For any business that Defendant Newbauer controls, directly or indirectly, or in which Newbauer has a majority ownership interest, Newbauer must deliver a copy of this Order to all principals, officers, directors, and managers of that business. Defendant Newbauer must also deliver copies of this Order to all employees, agents, and representatives of that business who engage in conduct related to the subject matter of the Order. For current personnel, delivery shall be within five (5) days of service of this Order upon Defendant. For new personnel, delivery shall occur prior to them assuming their responsibilities.

- C. **Individual Defendant as Employee or Non-control Person:** For any business where Defendant Newbauer is not a controlling person of a business but otherwise engages in conduct related to the subject matter of this Order, Newbauer must deliver a copy of this Order to all principals and managers of such business before engaging in such conduct.
- D. Defendants Transdermal and Newbauer must use all reasonable means and efforts to secure a signed and dated statement acknowledging receipt of the Order, within thirty (30) days of delivery, from all persons receiving a copy of the Order pursuant to this Section.

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 shall 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 actual or prospective consumers, trade customers or 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; and

C. Defendants shall 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.

Provided, however, that nothing in this Order shall limit 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)).

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 three (3) years from the date of entry of this Order,
 - 1. Defendant Newbauer shall 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), and any change in his ownership in any business

entity, within ten (10) days of the date of such change. Such notice must include the name and address of each business that Newbauer is affiliated with, employed by, creates or forms, 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 or employment; and

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

2. Defendants shall notify the Commission of any changes in corporate structure, and any changes in any business entity that they or either of them directly or indirectly control(s), or has an ownership interest in, 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 entity; 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 Defendants learn less than thirty (30) days prior to the date such action is to take place, Defendants shall notify the Commission as soon as is practicable after obtaining such knowledge.

B. Ninety (90) days after the date of entry of this Order, Defendants each shall 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. For Defendant Newbauer:
 - a. The then-current residence address, mailing addresses, and telephone numbers of Newbauer; and
 - b. The then-current employment and business addresses and telephonic numbers of Newbauer, a description of the business activities of each such employer or business, and the title and responsibilities of Newbauer for each such employer or business.
 2. For Defendants Transdermal and Newbauer:
 - a. A copy of each acknowledgment of receipt of this Order, obtained pursuant to Section EX; and
 - b. Any other changes required to be reported under Part A of this Section.
- C. For the purposes of this Order, Defendants shall, 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. Transdermal International Products Marketing Corp. et al., Matter No. X050023.
- D. For purposes of the compliance reporting required by this Order, the Commission is authorized to communicate directly with Defendants.

XII.

RECORD KEEPING PROVISIONS

IT IS FURTHER ORDERED that, for a period of six (6) years from the date of entry of this Order, Defendant Transdermal and its successors and assigns, and Defendant Newbauer 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 (2) the business engages in, or assists others engaged in, the manufacturing, advertising, promotion, offering for sale, sale, or distribution of any transdermal product, dietary supplement, drug, device or cosmetic, and their agents, employees, officers, corporations, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby restrained and enjoined from failing to create and retain the following records:

- A. Accounting records that reflect the cost of goods, 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 goods, services, or programs purchased, and description of goods, 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 sales scripts, training materials, advertisements, promotional materials, or other marketing materials;
 - F. All materials that were relied upon in making any representations contained in the materials identified in Part E of this Section;
 - G. All other documents evidencing or referring to the accuracy of any claim therein or to the safety or efficacy of any transdermal product, dietary supplement, drug, device or cosmetic, 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;
 - H. Records accurately reflecting the name, address, and telephone number of each person or entity engaged in the development or creation of any testing obtained for the purpose of advertising, labeling, promoting, offering for sale, distributing, or selling any transdermal product, dietary supplement, drug, device or cosmetic; and
 - I. All records and documents necessary to demonstrate full compliance with each provision of this Order, including but not limited to, copies of acknowledgments of receipt of this Order, required by Sections VIII and IX, and all reports submitted to the FTC pursuant to Section XI.

XIII.

RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court shall retain 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 ORDERED this 24 day of July, 2007.

Thomas N. O'Neill, Jr.
THOMAS N. O'NEILL, JR.
United States District Judge
Eastern District of Pennsylvania

SO STIPULATED:

JAMES A. KOHM
Associate Director for Enforcement

Lemuel W. Dowdy
LEMUEL W. DOWDY

TRANSDERMAL PRODUCTS
INTERNATIONAL MARKETING
CORPORATION

By: William H. Newbauer
WILLIAM H. NEWBAUER, President

William H. Newbauer
WILLIAM H. NEWBAUER
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