

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

FEDERAL TRADE COMMISSION,  
600 Pennsylvania Ave., N.W.  
Washington, D.C. 20004,

Plaintiff,

v.

TRANSDERMAL PRODUCTS INTERNATIONAL  
MARKETING CORPORATION,  
200 Rittenhouse Circle, 2 East Building  
Bristol, Pennsylvania 19007,

and

WILLIAM H. NEWBAUER,  
200 Rittenhouse Circle, 2 East Building  
Bristol, Pennsylvania 19007,

Defendants.

CIVIL ACTION NO.

COMPLAINT

Plaintiff, the Federal Trade Commission ("FTC" or "Commission"), through its undersigned attorneys, alleges as follows:

1. Plaintiff brings this action under Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), to secure a permanent injunction, rescission of contracts, restitution, disgorgement of ill-gotten gains, and other equitable relief against defendants for engaging in deceptive acts or practices and disseminating false advertisements in connection with the advertising and sale of purported weight loss products, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and

## JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over this matter pursuant to 15 U.S.C. §§ 45(a), 52, and 53(b), and 28 U.S.C. §§ 1331, 1337(a), and 1345.
3. Venue in the United States District Court for the Eastern District of Pennsylvania is proper under 15 U.S.C. § 53(b) and 28 U.S.C. §§ 1391(b) and (c).

## THE PARTIES

4. Plaintiff, the **Federal Trade Commission**, is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The Commission enforces Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce. The Commission also enforces Section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits false advertisements for food, drugs, devices, services, or cosmetics in or affecting commerce. The Commission may, through its attorneys, initiate federal district court proceedings to enjoin violations of the FTC Act and to secure such other equitable relief, including rescission of contracts and restitution, and disgorgement of ill-gotten gains, as may be appropriate in each case. 15 U.S.C. § 53(b).
5. Defendant **Transdermal Products International Marketing Corporation** (“Transdermal”) is a Delaware corporation with its principal office or place of business at 200 Rittenhouse Circle, 2 East Building, Bristol, Pennsylvania 19007. At all times relevant to this complaint, acting individually or in concert with others, Transdermal has marketed purported weight loss patches wholesale to product retailers (“trade customers”) for resale to consumers. Transdermal transacts or has transacted business in this district.

6. Defendant **William H. Newbauer** (“Newbauer”) is an officer and director of Transdermal. At all times relevant to this complaint, acting individually or in concert with others, he has formulated, directed, controlled, had the authority to control, or participated in the acts and practices of Transdermal, including the acts or practices set forth in this complaint. His principal office or place of business is the same as that of Transdermal. Newbauer transacts or has transacted business in this district.

### COMMERCE

7. The acts and practices of defendants alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

### DEFENDANTS' COURSE OF CONDUCT

8. Since at least the mid-1990s, defendants have advertised, offered for sale, sold, and distributed various types of purported transdermal skin patches to trade customers. Since about 2000, defendants' products have included, but are not limited to, a purported transdermal skin patch (“patch”) containing the ingredients *Fucus vesiculosus* (sea kelp) (10 mg), guarana extract (2 mg), garcinia extract (2 mg), and menthol (2 mg). Defendants have promoted the patch as effective for weight loss.
9. The patch that defendants have sold to their trade customers is often branded with names including, among others, LePatch, Revo Patch, Revo Patch Plus, Svelt Patch, Dermo Patch, Z Patch, Elupatch, and Redu Patch. Defendants also have sold an unmarked patch for their trade customers to sell under their own brand names. Defendants have offered and sold the patch in “units” comprised of a one-month supply of 30 patches to trade customers for between \$3 and \$6.50 per unit. Since about 2001, defendants have sold

approximately 381,000 units to trade customers for which defendants have billed approximately \$1.75 million. Defendants' trade customers have resold the patch to consumers for \$15.99 to \$119.00 per unit.

10. Through their Internet website [www.transdermalproducts.com](http://www.transdermalproducts.com), prospectus and other means, defendants have furnished advertising copy and purported substantiation materials to their trade customers (to whom defendants sometimes refer as their "distributors") and invited their trade customers to use these materials to market defendants' patches to consumers nationwide and abroad.
11. As part of its evaluation of all then marketed over-the-counter drugs for weight loss, in 1982 the Federal Food and Drug Administration ("FDA") categorized sea kelp as a "category III" ingredient, 47 Fed. Reg. 8466, 8476 (Feb. 26, 1982). This meant that the evidence was not sufficient to categorize the ingredient as generally recognized as safe ("GRAS") and generally recognized as effective ("GRAE") for weight loss. Although industry members were permitted to continue marketing sea kelp for weight loss, they had to demonstrate the safety and effectiveness of the ingredient to FDA to prevent FDA from re-classifying the ingredient as neither GRAS nor GRAE (a "category II" ingredient).
12. In 1991, the FDA determined that sea kelp is neither GRAS nor GRAE for weight loss, 56 Fed. Reg. 37792, 37797 (Aug. 8, 1991). Accordingly, sea kelp cannot be marketed in the United States for weight loss without the seller successfully completing FDA's new drug application ("NDA") process. In a September 2, 1998 warning letter, FDA warned defendants that the patch is a "new drug" and may not be marketed in the United States for weight loss without an approved NDA. Also, FDA's letter stated that labeling the

product for weight loss “is false and misleading.” Despite this, defendants have continued to market the patch for weight loss to their trade customers for resale to U.S. consumers without an approved NDA.

13. To induce trade customers and other consumers to purchase the patch, defendants have disseminated, or caused to be disseminated, advertisements and other promotional materials, including, but not necessarily limited to, the attached Exhibits A through D.

These materials contain the following statements, among others:

- a. **“Amazing Skin Patch Melts Away Body Fat”**  
– the Globe with 7 million US readers

How can you enjoy losing weight and keeping it off?

In Europe one skeptical reporter writes, “To my astonishment, my bathroom scales began to register slow but unmistakable progress. My haphazard eating and exercise habits did not change.”

– Isabel Conway, ELAN  
with 12 million European readers

Exhibit A, TRA 002863  
[Print advertisement]

- b. **Dr. Marvin Kaplan reviews the tremendous success of the Svelt-PATCH™ after 6 years:**

- Test after test shows remarkable and consistent weight loss in country after country – US, England, France, Germany, Italy, Japan
- Over 1,000,000 people use the Svelt-PATCH™ each year.
- Spreading all over the globe. Now in 32 countries.
- Over 400,000 people use the Svelt-PATCH to stay slim year after year.
- Recommended by Doctors, Pharmacists and Nutritionists
- *Say “no” more easily.* Customer surveys make it clear. Because your energy is increased and your appetite-control has an assist, it is easier to say no to indulging foods. And, it is easier to exercise.

Exhibit A, TRA 002863  
[Print advertisement]

c.

### **100% Guarantee**

**You will be thinner and happier.**

We guarantee right here in writing that you will lose a *maximum* amount of fat, and a *minimum* of precious muscle. If you are not completely satisfied, we will send to you a complete, every cent, refund when you return the unused portion of the product.

Traditional weight loss can be very discouraging. We insist that you take no risk.

Why?

1. When you see the pounds melting off, you will want to tell your friends.
2. Because it is easy and risk free, and the Svelt-PATCH works for you, you will reorder.

Exhibit A, TRA 002863

[Print advertisement]

d. **JEAN** absolutely loves the Svelt-PATCH.

\* \* \*

“When I heard about a weight loss patch, I just had to have it. No more bad tasting food. No more forgetting. After only three weeks, 8 pounds were gone. A couple of weeks later I had so much extra energy that I started to walk more.”

“54 pounds were gone after only four months with the Svelt-PATCH. My cravings were almost gone. It was easier to take only a few bites of dessert and to avoid rich snacks.”

Learn on page 2 how the Svelt-PATCH Weight-Loss Plan can help you lose 15, 25, even more than 50 pounds in record time. Increase self confidence. Improve your love life. Feel good inside and out.

### **Jean Saw Two Really Big Issues**

“It was quick and easy to lose weight. That is the first issue. No more months of fighting my own desires! I had more energy without feeling jittery. I felt different, more awake and alive. I felt naturally motivated, more motivated than I had on any other weight loss program.”

“The other big issue is even more important to me. **Keep that weight off!** And, the Patch has.”

Exhibit A, TRA 002863

[Print advertisement]

e. **Does the Svelt-PATCH Really ‘Melt Fat’?**

Yes. Your body changes.

Your body uses (melts) existing fat to turn it into energy for you to use. And, your body takes much of the food that it used to store as fat and uses it right away. That is ‘faster metabolism’. It’s exciting.

The safe, natural herb in the patch re-sets your metabolism.

Exhibit A, TRA 002863  
[Print advertisement]

f. ***How does the Svelt-PATCH™ work?***

It is so simple that it is exciting. Anywhere on you [sic] skin, just stick on the patch. The natural, concentrated, herb called fucus releases continually into your body. Unlike other products, which work for a few hours — the fucus is constantly feeding your body, gently telling you [sic] body to process food with a faster metabolism. So, your body *burns fat even while you sleep*.

Exhibit A, TRA 002864  
[Print advertisement]

g. **“The Svelt-PATCH Speeds Up The Body’s Metabolism and Burns up Fat”**

— Thomas Angelean for 7 million US readers

Forget working out, counting calories or swallowing food supplements. Consider some of the research that proves you can lose weight easily and with no diet or exercise changes

**RESEARCH PROVES IT**

Scientific studies and customer surveys in US, Germany, England and country after country show the surprising results again and again.

In one scientific study 100 obese people participated under Dr. Kaplan’s direction. He explains, “We tested overweight men and women for 60 days, without having them change their normal lifestyle in any way.”

“Every one of these people were unsuccessful with a variety of diet and weight loss plans. Over one half lost more than 20 pounds. Every one of them lost weight after no more than 4 weeks.”

Exhibit A, TRA 002864  
[Print advertisement]

h. **“18 Pounds in 4 Weeks: with Patches, without Dieting or Exercise”**

– Bunte Magazine, with 3 Million German readers, ran this headline in a 7 page article featuring six customers and thorough test results

Exhibit A, TRA 002864  
[Print advertisement]

i. **The average loss for men was 4.7 lbs the first week, 15.7 lbs the first month and 25.1 lbs in two months in one major study.**

Exhibit A, TRA 002864  
[Print advertisement]

j. **You could be losing weight and keeping it off, right now.**

“I sit around the office all day. Two months ago I had 60 pounds to lose. I decided to try the Patch even though I thought counting calories was the only way. I’m already down to 136 with only 14 more pounds to go.”

– Jane C. in rural Kansas

“In 6 weeks my weight dropped from 198 to my target of 183. Five of that came off the first week. Now I keep it off with the Patch.”

– Ralph J., in Boston

“I have to look good. I work in the film industry. My weight seems to climb by itself. Now with the Patch it is not a struggle any more.”

– Francine S. in the LA area

Exhibit A, TRA 002864  
[Print advertisement]

k. European éLAN

– COVER STORY –

**THE FAT PATCH**

\* \* \*

Full of scepticism I fixed it to my thigh and, armed with a supply of chocolate bars for moral support, awaited results. As a gesture of goodwill I gave up alcohol for the first two weeks, but filled the void with sweets and puddings. I drank the recommended eight glasses of water a day but otherwise my haphazard eating and exercise habits did not change.

Too [sic] my astonishment, my bathroom scales began to register a slow but unmistakable progress. After two months I had shed 9 kg and there was visibly less flab in my thighs and upper arms where it is usually most stubborn. As with



any weight reduction method the loss rate varied from a peak of 2 kg in the first week to just 0.5 kg in week seven.

Such a simple remedy after so many years of research and experiment sounds too good to be true, so what are the catches?

Although the patch has been slowly percolating through Europe in the last six months, no medical research has been done this side of the Atlantic.

“There was no need,” said Paul Bone of Promades, the distributors in Belgium where over 80,000 patches have been sold in six months. “*Fucus* is registered as a food additive and a category III ingredient for weight control products by the US Food and Drug Administration (FDA), and that for me is as good as the Bible.”

The only claimed proof that the drug has any effect comes from its manufacturer. Transdermal Products points to trials it organised [sic] in the US, during which 100 overweight men and women tried out the patch over 60 days without any radical alteration to their lifestyle. All had spent years on fruitless weight-loss programmes and all admitted that it was lack of willpower that had let them down.

“A quarter had no faith in the patch, but most emerged from the trial on average 10kg lighter,” said Newbauer. “Since then we began selling them in tens of thousands.”

Exhibit B, TRA 002865-6  
[Reprint of news article]

1. **TRANSDERMAL PRODUCTS INTERNATIONAL  
MARKETING CORP.**

**Home**

\* \* \*

Potential distributors have an opportunity for a highly successful and profitable product line. Support from Transdermal Products Marketing Corporation with custom manufacturing and marketing can often help a new distributor become profitable.

\* \* \*

**Weight Control Patch**

This pioneer weight loss patch contains 100% *fucus vesiculosus* as its active ingredient, “which has long been recognized as a remedy for obesity.” Per maximum results the patch should be used in conjunction with a sensible, daily exercise program, water intake (at least eight glass [sic] every day) and a balanced nutritional diet. By following this program the user is virtually guaranteed success in his or her weight loss objectives. The weight control patch practically

eliminates hunger pangs and other symptoms generally associated with weight reduction. One patch per day, with all-natural ingredient, is a completely safe and effective way for controlling weight. The patch is painless and harmless. The patch goes to work automatically while the user lives a normal life.

Exhibit C, TRA 00016, 00020  
[Website]

m.

**WEIGHT CONTROL PATCH:**

The company's original product was the transdermal weight loss patch. Transdermal Products International Marketing Corporation was the first weight control patch in the market where the ingredients were blended into the adhesives allowing timed release of ingredients all day. This original patch contained 100% fucus Vesiculosus. The predominant reason for the success of this patch is that "it works while you wear it, all day, every day." Undoubtedly the most convenient, effective weight control product ever devised.

\* \* \*

The weight control patch practically eliminates hunger pangs and other symptoms generally associated with weight reduction. One patch per day, with its all-natural ingredient, is a completely safe and effective way for controlling weight. Application is simple. The patch is placed on the wrist or arm or some other smooth part of the body just like a first aid strip. The special formula is absorbed immediately into the skin and goes right into the bloodstream where it goes to work at once. The user will eat less, feel full, and quickly loose weight.

Exhibit D, TRA 00080  
[Prospectus]

n.

**CONSIDER TRANSDERMAL PRODUCTS INTERNATIONAL  
MARKETING CORPORATION**

We are here to help our distributors. By talking with distributors that are already very successful with our products, we have a lot to share. You can receive marketing materials used in other countries from us. We can even provide where you have permission to reuse the materials with no additional work.

Exhibit D, TRA 00093  
[Prospectus]

14. In promoting the patch to defendants' trade customers, defendants have provided them with purported substantiation materials including an alleged weight loss study by Marvin Kaplan, Ph.D., and/or a summary of the results of that study prepared by defendants (both referred to as the "2000 Kaplan study," attached as Exhibit E). According to the purported 2000 Kaplan study protocol, the patch was allegedly administered to 100 male and female adult subjects between June 2000 and October 2000. The study did not include a control group. Under the heading "Effectiveness," the 2000 Kaplan study states: "At the conclusion of the 60-day period the investigator reports a mean weight loss of all participants of 13.02% of baseline average weight." Exhibit E at TRA 001646.
- Defendants have relied upon the 2000 Kaplan study to substantiate the advertising described in Paragraph 13 above, and defendants' trade customers have relied on the Kaplan study to substantiate their own advertising.
15. The 2000 Kaplan study's entire text, protocol, patient description and results (except for such things as the study date, some recommended diets and the product description) are a verbatim copy of a report for a study purportedly conducted in 1991-92 on a differently formulated patch ("1991 Kaplan study"). The 1991 Kaplan study is attached as Exhibit F.

#### **DEFENDANTS' VIOLATIONS OF THE FTC ACT**

16. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits unfair or deceptive acts or practices in or affecting commerce. Section 12(a) of the FTC Act, 15 U.S.C. § 52(a), prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics. For purposes of Section 12 of the FTC Act, 15 U.S.C. § 52,

Transdermal's purported weight loss patch is either a "drug" or "device" as defined in Section 15 of the FTC Act, 15 U.S.C. § 55. As set forth below, defendants have engaged and are continuing to engage in such unlawful practices in the marketing and sale of purported weight loss patches.

## COUNT I

### False Claims

17. Paragraphs 1-16 are incorporated herein by reference.
18. Through the means described in Paragraph 13 above, defendants have represented, expressly or by implication, that:
  - a. The patch causes substantial weight loss;
  - b. The patch causes substantial weight loss without reducing calories or increasing exercise;
  - c. The patch safely enables users to lose more than three pounds per week for a period of more than four weeks;
  - d. The patch causes permanent weight loss;
  - e. Scientific research demonstrates that the patch causes substantial weight loss; and
  - f. FDA has approved sea kelp (*Fucus vesiculosus*), the principal ingredient in the patch, as effective for controlling weight.
19. In truth and in fact:
  - a. The patch does not cause substantial weight loss;
  - b. The patch does not cause substantial weight loss without reducing calories or increasing exercise;

- c. The patch does not safely enable users to lose more than three pounds per week for a period of more than four weeks;
- d. The patch does not cause permanent weight loss;
- e. Scientific research does not demonstrate that the patch causes substantial weight loss; and
- f. FDA has not approved sea kelp (*Fucus vesiculosus*) as effective for controlling weight.

Therefore, defendants' representations set forth in Paragraph 18 above are false or misleading and constitute deceptive acts or practices, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

## **COUNT II**

### **Unsubstantiated Claims**

- 20. Paragraphs 1-16 are incorporated herein by reference.
- 21. Through the means described in Paragraph 13 above, defendants have represented, expressly or by implication, that:
  - a. The patch causes weight loss; and
  - b. The patch "melts away" or burns body fat by taking food that the body would otherwise store and using it right away.
- 22. Defendants did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 21 above at the time the representations were made. Therefore, defendants' making of the representations set forth in Paragraph 21 constitutes

a deceptive act or practice, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

### **COUNT III**

#### **Means and Instrumentalities**

23. Paragraphs 1-16 are incorporated herein by reference.
24. Defendants have provided to their trade customers the advertising and promotional materials referred to in Paragraph 13, and the purported substantiation materials referred to in Paragraph 14, containing false and misleading representations, as described above.
25. By providing to their trade customers these advertising, promotional and substantiation materials, defendants have provided them with the means and instrumentalities for the commission of deceptive acts or practices. Therefore, defendants' practices, as described in Paragraph 24, constitute deceptive acts or practices, and the making of false advertisements, in violation of Sections 5(a) and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45(a) and 52.

#### **CONSUMER INJURY**

26. Consumers throughout the United States have suffered and continue to suffer substantial monetary loss and other injury as a result of defendants' unlawful acts or practices. In addition, defendants have been unjustly enriched as a result of their unlawful acts or practices. Absent injunctive relief by this Court, defendants are likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.

#### **THIS COURT'S POWER TO GRANT RELIEF**

27. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to grant injunctive

and such other relief as the Court may deem appropriate to halt and redress violations of the FTC Act. The Court, in the exercise of its equitable jurisdiction, may award other ancillary relief, including, but not limited to, rescission of contracts and restitution, and the disgorgement of ill-gotten gains, to prevent and remedy injury caused by defendants' law violations.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff Federal Trade Commission, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and the Court's own equitable powers, requests that this Court:

(1) Temporarily, preliminarily and permanently enjoin defendants from violating Sections 5(a) and 12 of the FTC Act, as alleged herein, including committing such violations in connection with the offering for sale, sale, or distribution of food, drugs, dietary supplements, devices, cosmetics, or other products, services, or programs;

(2) Award such equitable relief as the Court finds necessary to redress injury to consumers resulting from defendants' violations of the FTC Act, including, but not limited to, rescission of contracts and restitution, and the disgorgement of ill-gotten gains; and

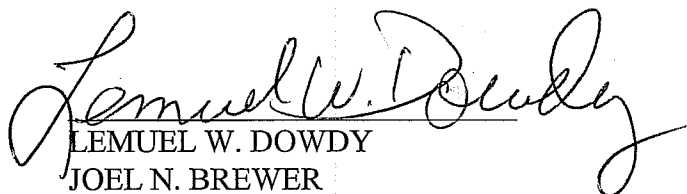
(3) Award Plaintiff the costs of bringing this action and such other equitable relief as the

Court may determine to be just and proper.

Dated: 12-06-04

Respectfully submitted,

WILLIAM E. KOVACIC  
General Counsel



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Attorneys for Plaintiff



**Exhibit A**

# "Amazing Skin Patch Melts Away Body Fat"

— the Globe with 7 million US readers

*How can you  
enjoy losing  
weight and  
keeping it off?*

In Europe one skeptical reporter writes, "To my astonishment, my bathroom scales began to register slow but unmistakable progress. My haphazard eating and exercise habits did not change."

— Isabel Conway, ELAN  
with 12 million European readers



*The Svelt-PATCH  
helps me keep my  
weight off.*

*Learn in this ad how Jean lost 54 pounds and easily keeps it off.*

## Dr. Marvin Kaplan reviews the tremendous success of the Svelt-PATCH™ after 6 years:

- Test after test shows remarkable and consistent weight loss in country after country - US, England, France, Germany, Italy, Japan
- Over 1,000,000 people use the Svelt-PATCH™ each year.
- Spreading all over the globe. Now in 32 countries.
- Over 400,000 people use the Svelt-PATCH to stay slim year after year.
- Recommended by Doctors, Pharmacists and Nutritionists
- Say "no" more easily. Customer surveys make it clear. Because your energy is increased and your appetite-control has an assist, it is easier to say no to indulging foods. And, it is easier to exercise.

Is the once-a-day Svelt-PATCH™ really so unique? And does it give the promised results? Read on to see what customers and studies show, to learn how the Svelt-PATCH works.

**JEAN** absolutely loves the Svelt-PATCH. Living outside of Chicago, she has a very busy schedule. Jean explains.

"Losing weight was very difficult for me. And I felt tired all the time. I did not feel like I ever could really completely wake up. I tried many diets and weight loss programs. Even if it worked, my weight just went right back up."

"When I heard about a weight loss patch, I just had to have it. No more bad tasting food. No more forgetting. After only three weeks, 8 pounds were gone. A couple of weeks later I had so much extra energy that I started to walk more."

"54 pounds were gone after only four months with the Svelt-

PATCH. My cravings were almost gone. It was easier to take only a few bites of dessert and to avoid rich snacks."

Learn on page 2 how the Svelt-PATCH Weight-Loss Plan can help you lose 15, 25, even more than 50 pounds in record time. Increase self-confidence. Improve your love life. Feel good inside and out.

### **Jean Saw Two Really Big Issues**

"It was quick and easy to lose weight. That is the first issue. No more months of fighting my own desires! I had more energy without feeling jittery. I felt different, more awake and alive. I felt naturally

motivated, more motivated than I had on any other weight loss program."

"The other big issue is even more important to me. **Keep that weight off!** And, the Patch has."

"My cousin in Italy was the first to tell me about the patch. You should have seen her before. Now she has kept slim for three years. When the weight goes up, the patch goes back on. It is that simple."

**Just call  
800-299-2993  
any time to try the  
Svelt-PATCH risk-free.**

### **Motivation is Critical**

'No! Don't eat that cookie.' Do you fight your own desires?

Stop! Make it easier, much easier. Just let the patch help to change your body.

When your body has a faster metabolism and more energy, your whole life changes and becomes easier.

### **Does the Svelt-PATCH Really 'Melt Fat'?**

Yes. Your body changes.

Your body uses (melts) existing fat to turn it into energy for you to use. And, your body takes much of

## **100% Guarantee**

**You will be thinner  
and happier.**

We guarantee right here in writing that you will lose a *maximum* amount of fat, and a *minimum* of precious muscle. If you are not completely satisfied, we will send to you a complete, every cent, refund when you return the unused portion of the product.

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**Why?**

1. When you see the pounds melting off, you will want to tell your friends.
2. Because it is easy and risk free, and the Svelt-PATCH works for you, you will reorder.

the food that it used to store as fat and uses it right away. That is 'faster metabolism'. It's exciting.

The safe, natural herb in the patch re-sets your metabolism.

### **3 affects from the Svelt-PATCH**

1. **Burn fat.** Your body burns fat rather than storing it. No change is necessary in what you eat or how much you exercise.
2. **More energy.** The extra energy from the patch helps you be more motivated and improves your life.
3. **Less appetite.** Don't struggle anymore to push food away. With the patch you just won't want it.

Transform your body and your life with the gentle, safe sea herb called fucus. Working in your body night and day, the SveltPATCH™ does the work for you.

### **How long does it take?**

We called customers. 94% lost weight. Many lose several pounds in the first week. By the third week over 85% are losing weight steadily.

### **A Major Discovery: Fucus**

For over 100 years a few well-informed European herbalists helped their patients lose weight with this God-send. Then in the 1960s it started to get recognized world wide.

The major affect comes from a gentle amount of iodine which is one of the components of fucus. It continually encourages your body to speed up the metabolism.

Read on. The patch supports weight loss in many ways.

THE SVELT-PATCH is easy and safe for me."



Susan B: A 22 year old administrative assistant from eastern Pennsylvania lost 109 pounds

## How does the Svelt-PATCH™ work?

It is so simple that it is exciting. Anywhere on your skin, just stick on the patch. The natural, concentrated, herb called fucus releases continually into your body. Unlike other products, which work for a few hours — the fucus is constantly feeding your body, gently telling you body to process food with a faster metabolism. So, your body burns fat even while you sleep.

### "The Svelt-PATCH Speeds Up The Body's Metabolism And Burns Up Fat"

—Thomas Angolan for 7 million US readers



Forget working out, counting calories or swallowing food supplements. Consider some of the research that proves you can lose weight easily and with no diet or exercise changes.

#### RESEARCH PROVES IT

Scientific studies and customer surveys in US, Germany, England and country after country show the surprising results again and again.

In one scientific study 100 obese people participated under Dr. Kaplan's direction. He explains, "We tested overweight men and women for 60 days, without having them change their normal lifestyle in any way."

"Every one of these people were unsuccessful with a variety of diet and weight loss plans. Over one half lost more than 20 pounds. Every one of them lost weight after no more than 4 weeks."

# with Patches, without Dieting or Exercise"

— BUNTE Magazine, with 3 Million German readers, ran this headline in a 7 page article featuring six customers and thorough test results

### Scientific Analysis of Fucus

Consider what we learn from advanced instruments that identified what is in the natural sea herb called fucus.

- ✓ Stimulates and balances metabolism.
- ✓ Safely stimulates, even balance the metabolism primarily from iodine. Also from potassium and magnesium.
- ✓ Controls your appetite Potassium, magnesium, Vitamins B and C all help. Your food is absorbed and used better.
- ✓ Stay slim through balance and control of metabolism.
- ✓ Nourishes your muscles while you lose weight from potassium, silicon, sodium, calcium and thiamin.
- ✓ Helps remove toxins with iron.
- ✓ Fights water retention with potassium.
- ✓ Reduces cholesterol with niacin.
- ✓ Cuts fatigue with vitamin C.

### Are there any drawbacks?

Although the Svelt-PATCH™ gives you fast and effective results, it is not for everyone. If you are pregnant, talk to your doctor before using it.

Though many lose significant weight the first week, some take up to three weeks for their body to accept the gentle change and start losing weight.

If you are in good health, it poses no risks. It helps your body to work better.

Obtain long-lasting results with the Svelt-PATCH: without medication or straining exercise.

The average loss for men was 4.7 lbs the first week, 15.7 lbs the first month and 25.1 lbs in two months in one major study.

### Your risk-free home trial — Do not risk 1 cent

Your formal guarantee is right here in the Coupon below. You have it in writing. Call now 800-299-2993 any time 24 hours per day, 7 days a week to order your trial. Even call in the middle of the night!

### Only read this if you do NOT want the Svelt-PATCH™

We love skeptics. Really. Because you are a person who must prove it to yourself. You have tried other weight loss plans that failed.

"I sit around the office all day. Two months ago I had 60 pounds to lose. I decided to try the Patch even though I thought counting calories was the only way. I'm already down to 136 with only 14 more pounds to go."

—Jane C. in rural Kansas

"In 6 weeks my weight dropped from 198 to my target of 183. Five of that came off the first week. Now I keep it off with the Patch."

—Ralph J., in Boston

"I have to look good. I work in the film industry. My weight seems to climb by itself. Now with the Patch it is not a struggle any more."

—Francine S. in the LA area

### — RUSH ORDERS — Call 800-59PATCH

between 9 am and 3 pm Eastern time. Pay an extra \$9.00 by credit card or by using "checks-by-phone." You'll receive it guaranteed in 5 business days.

This one works for 94% of our customers, and you will get an every cent refund if you return it.

We love you for another reason, too. Once you see yourself getting slimmer, you are very likely to sell your friends on the patch.

Just call us any time. Ask questions.

### Order now and get FREE: "Weight Loss Research"

Order by next Thursday and learn how to slim up even faster with the Svelt-PATCH™. You'll get "Weight Loss Research." This booklet (a \$9.95 value) shows you not only the results of Svelt-PATCH research but also research about other weight loss plans.

### Coupon for your 90-day risk-free trial offer, with no obligation to buy.

**YES** Please send me the risk-free at-home trial shipment of the Svelt-PATCH™. If, for any reason, I am not 100% satisfied with the results, I will return the unused portion to you within 90 days. You agree right here in writing that, without asking any questions about why you will send a check to me for the full amount made out in my name. This written, formal guarantee means that I have no obligation to buy the Svelt-PATCH shipment that you send to me. Please send to me (in an unmarked wrapper) the amount that I have selected below.

POUNDS I WANT TO LOSE	DURATION & PATCHES	PRODUCT	+ SHIP & HANDLE	SPECIAL PRICE	
				US	CANADA
<input type="checkbox"/> 4 to 8 pounds	2 weeks (15 patches)	US \$23.95	+ \$ 3	US \$26.95	(CAN \$38.90)
<input type="checkbox"/> 8 to 15 pounds	4 weeks (30 patches)	US \$38.95	+ \$ 4	US \$42.95	(CAN \$60.90)
<input type="checkbox"/> 15 to 25 pounds	8 weeks (60 patches)	US \$58.95	+ \$ 6	US \$64.95	(CAN \$92.90)
<input type="checkbox"/> 25 to 35 pounds	12 weeks (90 patches)	US \$78.95	+ \$ 8	US \$86.95	(CAN \$124.90)
<input type="checkbox"/> 45 to 55 pounds	16 weeks (120 patches)	US \$98.95	+ \$10	US \$108.95	(CAN \$156.90)
<input type="checkbox"/> 65 to 75 pounds	20 weeks (150 patches)	US \$118.95	+ \$12	US \$130.95	(CAN \$188.90)

**IMPORTANT:** If you mail your order, on your envelope please use 52 cents postage or 2 stamps. PLEASE PRINT CLEARLY.

- Please include my FREE BONUS. I am completing this order before 11 p.m. next Thursday.  
 My payment is by:  Check (allow 6 weeks)  Money order (4 weeks)  Credit Card (2 weeks)

VISA  MASTER CARD Card No. \_\_\_\_\_ Expires: Month \_\_\_\_\_ Year \_\_\_\_\_

I would like shipment with payment on delivery (C.O.D.). When the product comes to me I will pay an extra \$7.00 for C.O.D. and insurance charges. Available only for shipments to US street (not PO) addresses.

Miss  Mrs.  Ms.  Mr. \_\_\_\_\_ FIRST NAME \_\_\_\_\_ LAST NAME \_\_\_\_\_

STREET ADDRESS \_\_\_\_\_

CITY/TOWN \_\_\_\_\_ STATE \_\_\_\_\_ ZIP CODE \_\_\_\_\_

Call Toll-Free 24 Hours Per Day  
**Svelt-PATCH International, Inc.**  
 5925 Airport Road, Suite 200-W  
 Mississauga, Ontario, Canada L4V 1W1

Try Svelt-PATCH Risk-Free  
**800-299-2993**

**Exhibit B**

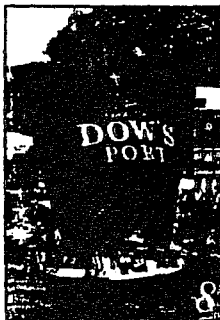
# EUROPEAN ÉLAN

## CONTENTS

- 4 **ÉLAN Diary**  
It's party time *beneath* Paris; top judges come out in favour of Germany's dope smokers; Moscow's child thieves
- 6 **Cinema**  
Richard Mayne reports from the Cannes Film Festival
- 8 **Festivals**  
Hundreds of festivals will be happening across the continent all summer long. We look at some of the less well-known celebrations of European culture
- 10 **Theatre**  
Berlin's annual dramafest shows radical new playwrights
- 11 **Pop**  
Khaled, the Paris-based king of Algerian pop, talks about his controversial plans to work with Sting and Peter Gabriel
- 12 **Music**  
The world's best young opera singers gather in Austria for Plácido Domingo's competition to find his successors
- 13 **Rediscover the Weekend**  
Special offer - take your partner free to stay in a luxury hotel
- 17 **Books**  
Giulio Andreotti, one of the leading figures of postwar Italian politics, reviews Denis Mack Smith's biography of Giuseppe Mazzini, the unsung architect of modern Italy
- 19 **Travel**  
Denmark's castles open their doors to guests
- 20 **Travel**  
Windy City wake call: Chicago is rolling out the red carpet for visitors on the eve of the World Cup football finals
- 22 **Gastronomy**  
The world's greatest collection of rare and historic cookery books has just been catalogued after eight years' research
- 24 **Fashion**  
An exhibition of kimonos in Paris reveals the continuity between traditional and ultra-modern Japanese design
- 25 **Property**  
International jet-setters are flocking to a cleaned-up Marbella
- 27 **Last Word**  
Another Country; Language; Games; Eyewitness



Andreotti on a great Italian patriot



Porto rolls out the barrels



Cannes Film Festival: the good, the bad and the surprising

COVER PAGE PHOTOGRAPHY CREDITS: ET ARCHIVE, (PROGRAM), SCIENCE PHOTO LIBRARY, CAMERA PRESS, TRANSWORLD, MAGNUM, SHUTTER NETWORK

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## COVER STORY

# THE FAT PATCH

FORGET the jaw clamps and lettuce leaves; dieters are now being told that the future lies in a 3cm square patch of sticky plaster. According to the manufacturers, would-be slimmers simply affix the patch to any part of their body, sit back and watch the weight drop off. No exhaustive calorie-counting or gym sessions are required; the only advice for best results is a sensible diet and eight glasses of water a day.

The Svelt Patch, launched in the US, arrived last month in Spain and suppliers are having difficulty in meeting demand. The fact that no European physician has yet approved the treatment, which is available without prescription, shows just how far people are prepared to go to shift stubborn kilos. The promises on the packaging are certainly irresistible to the overweight who have failed with more conventional methods. Those who follow the instructions correctly are supposed to lose up to ten kilos in two months - and it is claimed the weight should stay off so long as a sensible regime is maintained. Moreover, because the patch is worn day and night, you literally lose weight in your sleep.

"Yes, the market is flooded with dubious slimming aids but this is a revolutionary breakthrough," enthused William Neubauer, president of Transdermal Products Inc, a US manufacturer which specialises in homeopathic remedies.

The magic ingredient is contained in *Fucus vesiculosus*, a sea kelp found off the Brittany coast. It can speed up the metabolic rate and break down fatty reserves. Its use in weight-control programmes is not new: sea kelp was recognised as a homeopathic remedy in

Thousands of slimmers are using a new way of losing weight without pain. Isabel Conway tried it too. Additional reporting by Anna Tims

1863 and creams and gels containing the substance have been in use since the 1960s to help break down cellulite externally. However, the patch is a new concept. The dosage is absorbed internally, and at \$30 for a two-week course it is considerably cheaper.

Although the effect it is credited with seems miraculous, the process is apparently simple. The seaweed extract is molecularly bonded to the adhesive in 5mg doses. When stuck to any hair-free part of the body, it releases 0.075 microgrammes of iodine into the bloodstream over a 12 to 16-hour period, stimulating the thyroid gland.

This is where calorie-based diets can come unstuck. No matter how many chocolates you resist, the fat won't shift if your metabolism is not burning the calories you do consume, and many would-be super-waifs are thwarted by an inefficient thyroid gland. The thyroid produces thyroxine, a secretion which, among other things, controls the metabolism by eliminating cholesterol and regularising the body's distribution of fat.

One way of activating lazy thyroids is the pure protein diet, but it takes a brave soul to face a future of egg whites and ultra-lean steak. What the diet patch is said to do in

a more painless way is to step up the production of thyroxine and so ensure a more effective burning up of fatty tissue.

But can this tiny sticking plaster really work the miracles which the manufacturers credit it with?

As a life-long member of the blame-it-on-the-metabolism school of failed dieters, I decided to give it a go. Most people, apparently, begin with the patch on their wrist as a reminder of their resolve, then move it to a less conspicuous place as they grow used to it.

Full of scepticism I fixed it to my thigh and, armed with a supply of chocolate bars for moral support, awaited results. As a gesture of goodwill I gave up alcohol for the first two weeks, but filled the void with sweets and puddings. I drank the recommended eight glasses of water a day but otherwise my haphazard eating and exercise habits did not change.

Too my astonishment, my bathroom scales began to register a slow but unmistakable progress. After two months I had shed 9kg and there was visibly less flesh in my thighs and upper arms where it is usually most stubborn. As with any weight reduction method the loss rate varied from a peak of 2kg in the first week to just 0.5kg in week seven.

Such a simple remedy after so many years of research and experiment sounds too good to be true, so what are the catches?

Although the patch has been slowly percolating through Europe in the last six months, no medical research has been done this side of the Atlantic.

"There was no need," said Paul Bone of Promades, the distributors in Belgium where over 80,000

## Overweight? Not if you



The Three Graces: the Rubenesque ideal of beauty has today become a synonym for fitness

SOME two-thirds of Europeans have tried to lose weight in the past two years but many are not in fact too fat, writes Tessa Thomas. The latest survey by the European Centre of Research and Information on Obesity shows that while 52 per cent of Europeans are of normal weight, only 27 per cent of us are happy with our size.

So where does plumpness end and overweight begin? Diet gurus may suggest low "normal weights" to win more disciples. Insurance companies base their averages on middle-income white men to the exclusion of everyone else.

But a study by British psychologists shows that the issue is complicated by cultural factors. They compared the body images and attitudes of women from London and Barcelona and found that while middle-aged Spanish women were heavier than their British counterparts, they perceived themselves as lighter.

"People's perception of their weight is tied to cultural norms

# FROM STOUT TO SLIM WITHOUT DIETING

## CAN IT REALLY BE THAT SIMPLE?

patches have been sold in six months. *Fucus* is registered as a food additive and a category III ingredient for weight control products by the US Food and Drug Administration (FDA), and that for me is as good as the Bible.

The only claimed proof that the drug has any effect comes from its manufacturer. Transdermal Products points to trials it organised in the US, during which 100 overweight men and women tried out the patch over 60 days without any radical alteration to their lifestyle. All had spent years on fruitless weight-loss programmes and all admitted that it was lack of willpower that had let them down.

"A quarter had no faith in the patch, but most emerged from the trial on average 10kg lighter," said Neubauer. "Since then we began selling them in tens of thousands."

But those halcyon days are over. When some retail companies supplied by Transdermal Products made claims about its efficacy, the FDA investigated. It ruled that if the *Fucus vesiculosus* extract is used in patch form, which means it enters the bloodstream directly, it must be re-registered as a "new drug". This is an official category for existing drugs presented in new form of dosage.

"Before a new drug can be approved it has to undergo clinical tests to prove that it's safe and that it works," said Ken Shelin of the FDA. "We withdrew the patch from the market a couple of years ago and since then the manufacturer has not come back to us to offer the necessary data" - a technicality, insists Neubauer, not an indictment of his creation.

The Belgian distributor, Pomades, admits that it is unaware of

this development but says it will not stop plans to target dieters across Europe and in the Far East.

Weight-watching organisations have greeted the Svelt Patch with suspicion and medical experts worldwide have questioned the safety of the method.

"I'd like to see whether the active ingredients can be absorbed through the skin without being altered or deactivated and what level of increases of thyroxin it causes," said Dr John Stevenson, consultant endocrinologist at London's Wynn Institute for Metabolic Research. "Your thyroid produces the amount of thyroxin that is right for your body. Too much is dangerous and can cause an increased heartbeat or angina."

Neubauer insists that there is no danger of this: "The absorption of the iodine remains constant however many patches you wear. I have 16 on my arm this very minute to test the adhesive."

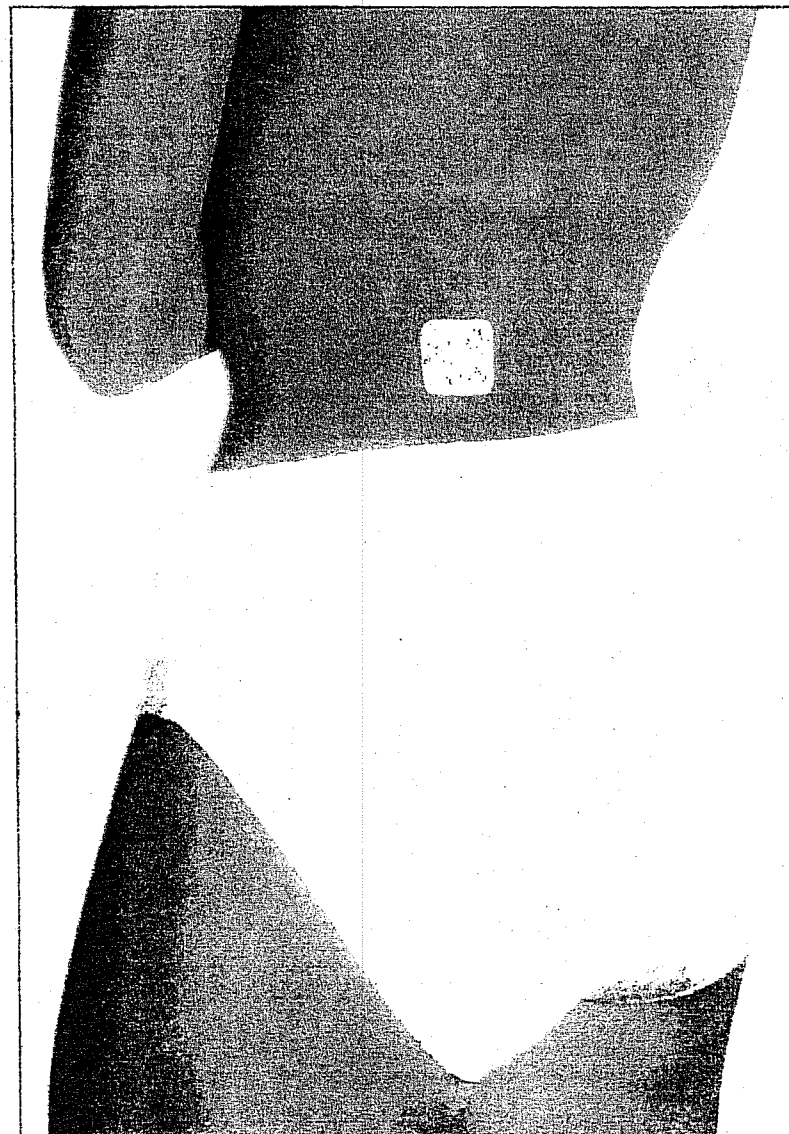
Expert hostility is, Paul Bone says, only to be expected. "The medical world is notoriously hostile towards slimming products. Its understandably conservative view is that the only way to lose weight is by eating less, period."

Patches as a way of supplying remedies are transforming medical treatment. As the drug is absorbed directly into the blood, doses can be smaller than in pills where up to 35 per cent of the substance is absorbed by the digestive system.

At the moment the jury is out. While the more stringent Americans are shying away from the unknown, portly Europeans seem less concerned about possible medical risks. After all, a sticky plaster is infinitely easier than a regular work-out in the gym.



Doctors say the only way to lose weight is to eat less, but this ignores psychological factors



Svelt Patch: It releases a seaweed ingredient into the bloodstream to speed the metabolism

## think you aren't

and values, and these change from one country to another even within Europe," says epidemiologist Jakob Seidell who is writing a book on Europeans and their weight.

The further south and east you go, says Seidell, the higher the average weight, so the overweight people are the less self-conscious. The fervent dieters are found in northern Europe, with the Germans in the lead. More than 70 per cent of German women have recently dieted, compared with 58 per cent of Italians.

National eating habits obviously play a part, says Seidell, with the high carbohydrate Mediterranean diet favouring a slimmer silhouette than the fat-rich northern diet. But the very tendency to put on weight often leads to unnatural eating and more extreme dieting habits, which may explain why the British psychologists found that Spanish girls ate more regular meals and rarely resorted to

special diets, while their heavier British counterparts snacked and starved by turns.

It is not only the need and desire to shed kilos, however, that changes across borders. In the absence of scientific proof, people pick and choose different methods.

More than three-quarters of French slimmers put their faith in mineral water. The British, more than any other nationality, favour meal substitutes. The Italians are the least attracted to this method, and Danes and the Dutch do not even get the opportunity: such methods are available only on a doctor's prescription.

Whatever the awareness or technique, the sad truth is that most dieters will not achieve their goal. According to Seidell, this is because most weight-loss methods do not include a psychological element to prevent relapse.

Additional research by Sara Rhodes

CINEMA

SURPRISES IN  
THE FIRST WEEK  
AT CANNES

PAGE 6

EUROPEAN

20 - 26 MAY 1984 No 210

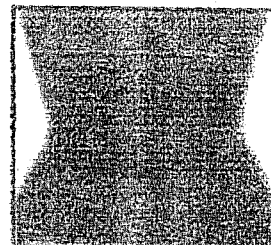
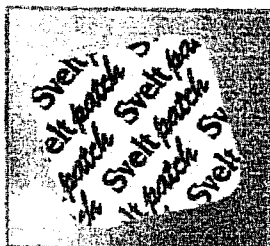
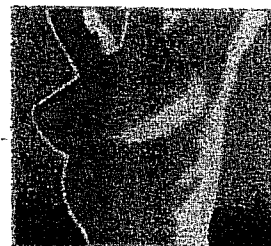
# ÉLAN

FESTIVALS

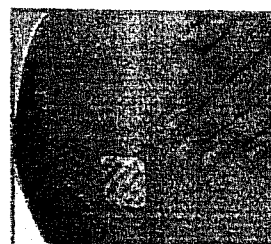
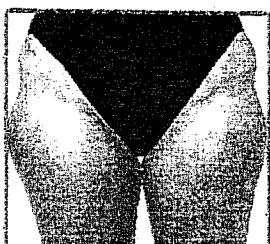
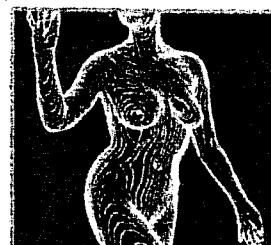
THE SUMMER'S  
OUTBURST OF  
CULTURE

PAGE 8

WOMEN OF THE YEAR



And now  
**THE FAT  
PATCH...**



... miracle  
diet or just  
too good to  
be true?

GRILL, TANGERS, PROCKERS, BIRDS, MEXICAN, 1984, GREAT BRITAIN, ORIGINAL, NY

**Exhibit C**





# TRANSDERMAL PRODUCTS INTERNATIONAL MARKETING CORP.

**Home**

## Company Profile

Products

Feedback

Advertisements

Transdermal Products International Marketing Corporation is an experienced manufacturer and marketer of transdermal patches utilizing all-natural, non-prescription, over-the-counter ingredients.

In over 30 countries our distributors are selling profitable all-natural health products. Transdermal Products International Marketing Corporation's products are typically very different from what consumers can get elsewhere. Users experience visible, significant and pleasing results.

Potential distributors have an opportunity for a highly successful and profitable product line. Support from Transdermal Products International Marketing Corporation with custom manufacturing and marketing can often help a new distributor become profitable.

All of Transdermal Products International Marketing Corporation's products are over-the-counter and are geared to aid weight loss, control smoking and aid male potency. The term "Drug" is used by the United States to describe an active ingredient whether prescription or non-prescription. We are careful to refrain from using the word drug in connection with our all-natural active ingredients.

Transdermal Products International Marketing Corporation is

registered with the Department of Health and Human Services, the Public Health Service and the Food and Drug Administration as a manufacturer of products that are all-natural and that contain no prescription drugs as active ingredients.

Transdermal Products International Marketing Corporation conforms to all requirements of good practice of manufacturing and quality control (GMP) of products to be sold or distributed for export. Transdermal Products International Marketing Corporation's manufacturing plant in which the products are produced, is subject to governmental inspections at suitable intervals and are in accordance with applicable provisions of the health and Safety Code of the State of Pennsylvania, and the Food and Drug Administration in the United States of America.

## **History**

The incorporators recognized the need for a safe and effective remedy to help people lose weight and stop smoking. Prior to the incorporation, company principles began the research and development phase of operations in November 1988. We contracted with Marvin Kaplan Ph.D., a well known, published biochemist, nutritionist and homeopathic specialist and practitioner. Dr. Kaplan developed a proprietary formula designed specifically for transdermal application. Dr. Kaplan's formula needed to be molecularly bonded to an adhesive in order to release the ingredients in time release sequence directly proportional to the surface of the patch. This was accomplished by Dr. Kaplan utilizing independent research & development facilities.

Initial prototypes and tests showed very effective results. Not only was it safe and effective, the ingredients were all-natural and the product provided an almost effortless aid for weight loss and assisting smokers kick their habit. With successful prototypes, Transdermal Products International Marketing Corporation was incorporated and a marketing program was

established. Management objectives were to provide products that are highly profitable for distributors and that could generate substantial revenue. By giving the distributors the option for private label or to leverage their association with Transdermal Products International Marketing Corporation, distributors have strong control over their business and their margins.

Transdermal Products International Marketing Corporation private labeled and began by selling to established, successful companies engaged in direct marketing throughout the world. The company maintains its corporate offices in Bristol, Pennsylvania, a suburb of Philadelphia, Pennsylvania, U.S.A.

In 1989 the company recorded gross sales far in excess of it's business plan with its weight control patch and continued to grow each year. In 1991, Transdermal Products International Marketing Corporation introduced the anti-smoking patches which proceeded the nicotine patch. In 1996 the "Male Potency Patch" was introduced.

Since incorporation, in over 30 countries our distributors are selling profitable all-natural transdermal patch products from Transdermal Products International Marketing Corporation.

### A List Of Our Products

---

## Contact Information

### **Telephone**

215-785-5480

### **FAX**

215-788-2800

### **Postal address**

200 Rittenhouse Circle, 2 East Building, Bristol, PA  
19007

### **Electronic mail**

General Information:

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[gsnyder@transdermalproducts.com](mailto:gsnyder@transdermalproducts.com)

[bnewbauer@transdermalproducts.com](mailto:bnewbauer@transdermalproducts.com)

[wmgood@transdermalproducts.com](mailto:wmgood@transdermalproducts.com)

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# TRANSDERMAL PRODUCTS INTERNATIONAL MARKETING CORP.



## Products

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## Products

### Weight Control Patch

	<p>This pioneer weight loss patch contains 100% <i>fucus vesiculosus</i> as its active ingredient, "which has long been recognized as a remedy for obesity." Per maximum results the patch should be used in conjunction with a sensible, daily exercise program, water intake (at least eight glass every day) and a balanced nutritional diet. By following this program the user is virtually guaranteed success in his or her weight loss objectives. The weight control patch practically eliminates hunger pangs and other symptoms generally associated with weight reduction. One patch per day, with all-natural ingredient, is a completely safe and effective way for controlling weight. The patch is painless and harmless. The patch goes to work automatically while the user lives a normal life.</p>
--	---

### Anti-Smoking Patch

The anti-smoking patch was created specifically to help smokers quit smoking. Our patch contains *Lobelia Inflata*, a natural herb.

Our anti-smoking patch is not habit forming, contains no nicotine, and will have positively no effect on the taste of anything the user eats or drinks. It is Absolutely harmless in relation to the heart rate, blood pressure or gastrointestinal

**Exhibit F**

**Fucus Vesiculosus Transdermal Patch Protocol 9109**

**EFFICACY STUDY PROTOCOL 9109**

**TITLE** An Evaluation of Fucus Vesiculosus (5 mg) in the Treatment for Obesity

**INVESTIGATOR** Marvin Kaplan PhD.

**STUDY SITE** 160 Rittenhouse Circle  
Bristol, Pennsylvania 19007

**STUDY DATES** September 1991 - January 1992

**REPORT ORIGIN** Transdermal Products, Inc.  
160 Rittenhouse Circle  
Bristol, Pennsylvania 19007

**STUDY OBJECTIVE** To evaluate the effectiveness in weight reduction of a Fucus Vesiculosus in a sustained controlled release patch formula, in subjects having exogenous obesity.

**STUDY MEDICATION AND DOSAGE** Active Ingredient: Fucus Vesiculosus  
Formulation: 5 mg's sustained release patch  
Dosage: One patch daily  
Route: Transdermal  
Lot No. 910823-0  
Manufacturer: Transdermal Products, Inc.  
160 Rittenhouse Circle  
Bristol, PA 19007

**STUDY DESIGN** To determine the average amount of body weight loss over a sixty day period for both men and women who were highly motivated and agreeing to follow a well balanced diet while wearing one Fucus V. 5 mg. patch per day. The subjects were evaluated for effectiveness at one week intervals for the first thirty days and then ten day intervals for the next thirty days.

**SELECTION CRITERIA** 100 male and female subjects between the ages of 19 - 67 years of age, whose body weight was between 17 - 163 pounds in excess of normal as determined from the Metropolitan Life Insurance Co. body weight charts, were admitted to the study.

**STUDY  
VARIABLES**

**Effectiveness:**

Primary - body weight was recorded by the investigator and evaluated the first and last "weigh in" for each participant in the program.

Secondary - Each participant recorded their own progress on the instruction sheets that accompanied the proposed balanced diet.

**STATISTICAL  
METHODS**

Demographic and background variables were compared to obtain participants representing all occupational groups; labor, blue collar, white collar, executives, plus homemakers (working and non-working mothers)

**Participants:**

73% White	62 Women
20% African American	38 Men
<u>6% Hispanic</u>	
100%	<u>100 People</u>

All participants had attested to trying many and varied diets and weight loss programs over a period of one or more years. Approximately 25% expressed skepticism about the effectiveness of a "patch" to lose weight.

**RESULTS**

	<u>Women</u>	<u>Men</u>
7 Days	3.04%	2.35%
14 Days	4.87%	4.18%
21 Days	6.35%	5.92%
30 Days	7.92%	7.79%
40 Days	9.66%	8.95%
50 Days	11.71%	11.54%
60 Days	13.59%	12.46%
Age Range ( In Years)	19 to 64	22 to 67
Average Age	37	35
OverWeight Range in Pounds	17 to 163	21 to 148
Average OverWeight	54 Lbs.	52 Lbs.



**Effectiveness:**

At the first postbaseline evaluation (after 7 days of wearing the patch) the overall mean weight loss for the participants was 2.69% of baseline. Each subsequent postbaseline evaluation reported by the participants produced a constant decrease in their baseline weight. At the end of 30 days the mean postbaseline weight loss for the participants was 7.85% body weight. At the conclusion of the 60 day period the investigator reports a mean weight loss of all participants of 13.02% of baseline average weight.

**Safety:**

Side effects experienced by only 2 persons consisted of mild skin irritation when wearing the patch on the inside of the upper arm. The same subjects did not repeat this side effect after alternating the placement of the patch. No other side effects were reported.

**CONCLUSIONS**

The efficacy of the Fucus Vesiculosus Weight Control Patch was 100%. All participants lost weight while wearing the patch for the full 60 days. Those with the least amount of body weight to lose, continued to wear the patch to maintain their desired body weight. The most significant weight loss was 71 pounds by one highly motivated individual who followed the "letter of the plan", ate properly, consumed 8, 8-ounce glasses of water per day, walked daily and participated in a structured and supervised exercise program.

Efficacy Study Body Weight Loss 9109

Subject	Sex (M/F)	Race	Body Frame	Begin Weight (Pounds)	End Weight (Pounds)	Total Weight Loss	% of Body Wt. Loss
1	Female	White	Medium	197	168	29	0.147
2	Female	White	Small	141	124	17	0.124
3	Male	White	Small	178	163	15	0.0833
4	Female	Black	Large	225	181	44	0.197
5	Female	White	Large	151	129	22	0.1466
6	Female	White	Medium	171	140	31	0.1822
7	Male	White	Large	217	181	36	0.1659
8	Female	Black	Medium	162	137	25	0.155
9	Male	White	Small	213	191	22	0.1033
10	Female	White	Large	160	133	27	0.171
11	Female	Hispanic	Medium	136	113	23	0.166
12	Male	White	Large	249	213	36	0.1459
13	Male	White	Medium	212	197	15	0.0693
14	Male	White	Large	335	275	60	0.1799
15	Female	Black	Large	331	260	71	0.214
16	Female	White	Small	122	113	9	0.0748
17	Female	White	Medium	150	128	22	0.1466
18	Male	Black	Medium	212	195	17	0.0791
19	Female	White	Large	171	133	38	0.225
20	Female	White	Small	141	128	13	0.0896
21	Female	White	Medium	161	141	20	0.1252
22	Male	White	Large	221	183	38	0.1701
23	Female	Black	Large	160	140	20	0.1252
24	Male	White	Large	252	229	23	0.0907
25	Male	White	Small	199	167	32	0.1585
26	Female	White	Medium	175	143	32	0.1822
27	Male	White	Medium	162	145	17	0.1037
28	Female	White	Small	124	118	6	0.0468
29	Female	Black	Large	164	145	19	0.1168
30	Male	Hispanic	Medium	223	191	32	0.1455
31	Female	White	Medium	144	127	17	0.1168
32	Male	Black	Large	190	171	19	0.0989
33	Female	White	Small	146	133	13	0.0896
34	Male	White	Large	242	206	36	0.1503
35	Female	White	Small	116	104	12	0.1008
36	Male	White	Medium	190	174	16	0.0833
37	Male	White	Large	294	245	49	0.1659
38	Female	Black	Large	232	186	46	0.197
39	Male	White	Medium	170	152	18	0.1033
40	Female	Black	Small	174	147	27	0.155
41	Female	White	Small	147	136	11	0.0748
42	Male	White	Large	211	180	31	0.1459
43	Male	Black	Small	138	128	10	0.0693
44	Female	Hispanic	Small	111	99	12	0.1058
45	Female	White	Medium	171	144	27	0.1579
46	Female	White	Large	191	151	40	0.211
47	Male	Black	Large	185	152	33	0.1799
48	Female	White	Medium	147	124	23	0.1579
49	Male	White	Medium	141	130	11	0.0791
50	Female	White	Small	180	159	21	0.1139

Subject	Sex (M/F)	Race	Body Frame	Begin Weight (Pounds)	End Weight (Pounds)	Total Weight Loss	% of Body Wt. Loss
51	Female	Black	Large	225	178	47	0.211
52	Male	White	Large	223	185	38	0.1701
53	Male	White	Medium	173	157	16	0.0907
54	Female	Black	Small	119	113	6	0.0468
55	Female	White	Large	191	148	43	0.225
56	Female	White	Medium	149	124	25	0.166
57	Male	White	Large	186	157	29	0.1585
58	Female	Hispanic	Small	178	159	19	0.1058
59	Female	White	Small	135	127	8	0.0608
60	Female	White	Large	176	141	35	0.197
61	Male	White	Medium	192	172	20	0.1037
62	Female	Black	Medium	144	133	11	0.0748
63	Female	White	Large	139	115	24	0.171
64	Female	White	Small	138	124	14	0.1008
65	Female	White	Large	160	124	36	0.225
66	Male	White	Medium	175	150	25	0.1455
67	Female	White	Small	114	109	5	0.0468
68	Female	White	Large	143	121	22	0.155
69	Female	Black	Medium	153	136	17	0.1139
70	Female	Black	Large	136	120	16	0.1168
71	Male	Hispanic	Small	149	139	10	0.0693
72	Female	White	Medium	144	121	23	0.1579
73	Male	White	Large	194	159	35	0.1799
74	Female	White	Medium	149	132	17	0.1139
75	Female	White	Medium	149	124	25	0.171
76	Female	Black	Large	171	146	25	0.147
77	Male	White	Small	154	153	1	0.0082
78	Female	White	Large	142	124	18	0.1248
79	Female	White	Large	160	137	23	0.1466
80	Male	White	Large	274	208	66	0.241
81	Female	White	Small	139	122	17	0.1252
82	Male	White	Small	138	124	14	0.0989
83	Female	White	Large	164	147	17	0.1008
84	Female	Black	Large	202	175	27	0.1322
85	Male	White	Large	191	162	29	0.1503
86	Female	White	Small	147	138	9	0.0608
87	Female	White	Large	191	170	21	0.11
88	Female	White	Small	133	125	8	0.0608
89	Male	Black	Medium	183	168	15	0.0833
90	Female	White	Large	145	138	7	0.047
91	Male	White	Large	247	223	24	0.0959
92	Male	Hispanic	Large	200	179	21	0.1033
93	Female	White	Large	164	144	20	0.1248
94	Male	White	Large	215	190	25	0.1159
95	Female	White	Large	169	153	16	0.097
96	Female	White	Small	123	116	7	0.0608
97	Male	Black	Medium	140	130	10	0.0691
98	Female	White	Medium	175	168	7	0.04
99	Female	White	Large	232	206	26	0.111
100	Male	White	Medium	183	171	12	0.063

WEIGHT RANGE BY WEIGHT AND FRAME (POUNDS)

MEN

DESIRABLE WEIGHT			HEIGHT Inches	15%-45% OVERWEIGHT					
Small Frame	Medium Frame	Large Frame		Small Frame		Medium Frame		Large Frame	
				15%	45%	15%	45%	15%	45%
114	121	132	61	131	165	140	175	151	181
117	125	134	62	135	170	144	181	155	184
120	128	138	63	138	174	147	186	159	200
123	131	142	64	141	178	151	190	163	206
125	134	144	65	144	181	154	194	166	209
130	138	148	66	149	189	158	200	171	215
134	142	154	67	154	194	163	206	177	223
138	146	158	68	158	200	168	212	181	229
142	150	162	69	163	206	173	218	186	235
145	154	165	70	167	210	177	223	190	239
147	158	170	71	171	213	182	229	196	247
153	162	174	72	176	222	187	235	201	252
158	167	180	73	181	229	192	242	206	261
162	172	184	74	186	235	198	249	212	267
166	177	189	75	190	241	204	257	217	274

WOMEN

DESIRABLE WEIGHT			HEIGHT Inches	15%-45% OVERWEIGHT					
Small Frame	Medium Frame	Large Frame		Small Frame		Medium Frame		Large Frame	
				15%	45%	15%	45%	15%	45%
94	100	110	56	108	133	116	145	127	160
96	103	113	57	111	139	118	149	130	164
99	106	116	58	114	144	122	154	133	168
101	108	118	59	116	146	124	157	136	171
104	111	121	60	120	151	128	161	139	175
107	114	124	61	123	155	131	165	143	180
110	118	128	62	126	160	135	171	147	186
113	121	132	63	130	164	139	175	151	191
116	125	135	64	133	168	144	181	155	196
120	129	139	65	138	174	148	187	160	202
124	133	143	66	143	180	153	193	164	207
125	137	147	67	147	186	158	199	169	213
132	141	152	68	152	191	162	204	174	220
136	145	156	69	157	197	167	210	179	226
140	149	160	70	162	203	171	216	185	232

## GENERAL GUIDELINES

1. For a lower fat intake, omit 1 pat margarine.
2. Coffee and tea should be served without added sugar. (Sugar substitutes may be used in moderation.) Other noncaloric beverages include tap water, seltzer, club soda, mineral water and diet soda.
3. Extra vegetables, raw or cooked, may be added to the diet. These make good between-meal snacks since they are filling, high in fiber and very low in calories.
4. Fish, poultry or lean meat should be broiled, roasted or otherwise prepared without added fat.
5. Whole fruits are preferable to fruit juices. Fruit may be omitted from lunch and/or dinner and eaten as a snack between meals. Use no more than 3 to 4 servings of fruit each day.

## VEGETABLE LIST

All vegetables should be fresh, frozen canned without added sugar. Each can be substituted, cup for cup, for any other vegetable on this list.

---

Asparagus	Chicory	Onions
Bean Sprouts	Collards	Radishes
Beets	Cucumbers	Spinach
Broccoli	Eggplant	String Beans
Brussels Sprouts	Escarole	Tomatoes
Cabbage	Green Peppers	Turnips
Carrots	Kale	Turnip Greens
Cauliflower	Lettuce	Zucchini (Summer Squash)
Celery	Mushrooms	

## FRUIT LIST

All fruit should be fresh, frozen or canned without sugar. The amount specified for each fruit constitutes one serving.

---

Apple.....1 small	Grapes.....12
Apple Juice.....1.3 cup	Honeydew Melon.....1/8 medium
Applesauce, unsweetened...1/2 cup	Mango.....1/2 small
Apricots.....2 medium	Orange.....1 small
Banana.....1/2 small	Orange Juice.....1/2 cup
Raspberries.....1/2 cup	Papaya.....3/4 cup
Blueberries.....1/2 cup	Peach.....1 medium
Strawberries.....3/4 cup	Pear.....1 small
Cantaloupe.....1/4 small	Pineapple Chunks...1/2 cup
Cherries.....10 small	Plums.....2 medium
Figs, fresh.....1	Prunes, dried.....2 medium
Grapefruit.....1/2	Tangerine.....1 medium
Grapefruit Juice.....1/2 cup	Watermelon.....1 cup diced or 1/2 small slice

WHOLE GRAIN LIST

Bread, whole grain - 1 slice  
Cereals, whole grain (wheat, oat or rye) - 1/2 cup  
Crackers, whole grain (wheat, rye, oat, rice) - 3-4 squares  
White potato, baked or boiled - 1 small  
Rice, brown or long grain - 1/2 cup cooked  
Vegetables:  
    Corn - 1/3 cup  
    Peas - 1/2 cup

High Fiber Diet - Approximately 1200. Calories

Daily Diet Pattern

Breakfast

Citrus fruit - 1 serving  
Whole grain- - - 2 slices bread or 1 cup whole grain cereal  
Skim milk- - - - 1 cup (8 oz.)  
Decaf coffee or weak tea

Lunch

Legumes, cooked - - - - 1/2 cup, or low-fat cottage cheese - 4 oz (1/2 cup)  
Fish <sup>or</sup> chicken - - - - 2 oz.  
\*Leafy vegetable salad - 1 to 2 cups  
Oil-free salad dressing (optional)  
Whole grain - - - - - 1 slice bread or 3-4 crackers  
Soft margarine- - - - - 1 tsp. or 1 pat  
\*Fresh or water-pack fruit- 1 serving  
Decaf coffee, weak tea, or other noncaloric beverage

Dinner

Fish, poultry, or lean meat - 4 oz.  
\*Vegetables - - - - - 2 cups  
Whole grain - - - - - 1 slice bread, or baked or boiled potato - 1 small  
\*Fruit - - - - - 1 to 2 servings  
Decaf coffee, weak tea, or other noncaloric beverage

Snack

Whole grain - - - 1 slice bread, 2 rice cakes, 3-4 crackers, or 1 small pita bread  
Soft margarine- - 1 tsp. or 1 pat  
Skim milk or low fat yogurt

\* Consult vegetable and fruit lists for many ideas and suggestions

Notes:

- 1- For a lower fat intake, omit 1 pat margarine.
- 2- Coffee and tea should be served without added sugar. (Sugar substitutes may be used in moderation.) Other noncaloric beverages include tap water, seltzer, club soda, mineral water, and diet soda.
- 3- Extra vegetables, raw or cooked, may be added to the diet. These make good between-meal snacks since they are filling, high in fiber, and very low in calories.
- 4- Fish, poultry or lean meat should be broiled, roasted, or otherwise prepared without added fat.
- 5- Whole fruits are preferable to fruit juices. Fruit may be omitted from lunch and/or dinner and eaten as a snack between meals. Use no more than 3-4 servings of fruit each day.

### VEGETABLE LIST

All vegetables should be fresh, frozen, or canned without added sugar. Each can be substituted, cup for cup, for any other vegetable on this list.

-----

Asparagus  
Bean Sprouts  
Beets  
Broccoli  
Brussels Sprouts  
Cabbage  
Carrots  
Cauliflower  
Celery

Chicory  
Collards  
Cucumbers  
Eggplant  
Escarole  
Green peppers  
Kale  
Lettuce  
Mushrooms

Onions  
Radishes  
Spinach  
String Beans  
Tomatoes  
Turnips  
Turnip Greens  
Zucchini (Summer squash)

### FRUIT LIST

All fruit should be fresh, frozen or canned without sugar. The amount specified for each fruit constitutes one serving.

-----

Apples..... 1 small  
Apple juice..... 1/3 cup  
Applesauce, unsweetened... 1/2 cup  
Apricots..... 2 medium  
Banana..... 1/2 small  
Raspberries..... 1/2 cup  
Blueberries..... 1/2 cup  
Strawberries..... 3/4 cup  
Cantaloupe..... 1/4 small  
Cherries..... 10 small  
Figs, fresh..... 1  
Grapefruit..... 1/2  
Grapefruit juice..... 1/2 cup

Grapes..... 12  
Honeydew melon.... 1/8 medium  
Mango..... 1/2 small  
Orange..... 1 small  
Orange juice..... 1/2 cup  
Papaya..... 3/4 cup  
Peach..... 1 medium  
Pear..... 1 small  
Pineapple chunks.. 1/2 cup  
Plums..... 2 medium  
Prunes, dried..... 2 medium  
Tangerine..... 1 medium  
Watermelon..... 1 cup diced or  
1/2 small slice



Sample: Day 1

Breakfast

Orange - 1 small  
Oatmeal - 1 cup  
Skim milk - 1 cup  
Coffee

Lunch

Chick peas - 1/2 cup  
Tossed green salad - 1 cup  
Diet (oil-free) dressing - 2 tbsp  
Whole rye crackers - 4  
Margarine - 1 pat  
Unsweetened baked apple - 1 small  
Noncaloric beverage

Dinner

Broiled halibut - 4 oz  
Steamed broccoli - 1 cup  
Stewed tomatoes - 1 cup  
Baked potato - 1 small  
Banana - 1 small  
Noncaloric beverage

Snack

Rice cakes - 2  
Margarine - 1 pat  
Skim milk - 1 cup

Sample: Day 2

Breakfast

Grapefruit sections - 1/2 cup  
Wheatena or oat bran - 1 cup  
Skim milk - 1 cup  
Coffee

Lunch

Water-pack tuna - 2 oz  
Tossed salad - 2 cups  
Diet (oil-free) dressing - 2 tbsp  
Rice cakes - 2  
Margarine - 1 pat  
Tangerine - 1 medium  
Noncaloric beverage

Dinner

Veal chop - 4 oz.  
Brussels sprouts - 1 cup  
Mixed vegetables - 1 cup  
Whole wheat bread - 1 slice  
Unsweetened sliced peaches - 1/2 cup  
Noncaloric beverage

Snack

Pita round - 1 small  
Margarine - 1 pat  
Skim milk - 1 cup

Sample: Day 3

Breakfast

Orange - 1 small  
Whole grain flakes - 1 cup  
(e.g. Nutrigrain)  
Skim milk - 1 cup  
Coffee

Lunch

Lentil soup - 1 cup  
Mixed salad - 1 cup  
(lettuce, tomatoes, green pepper, cucumber, celery)  
Diet (oil-free) dressing - 2 tbsp  
Whole wheat bread - 1 slice  
Margarine - 1 pat  
Pear - 1 small  
Noncaloric beverage

Dinner

Lean beef patty - 4 oz  
Steamed mushrooms and onions - 1 cup  
String beans - 1 cup  
Parsleyed potato - 1 small  
Applesauce, unsweetened - 1/2 cup  
Noncaloric beverage

Snack

Rye bread - 1 slice  
Margarine - 1 pat  
Skim milk - 1 cup

Sample Day 4

Breakfast

Grapefruit sections - 1/2 cup  
Wheatena - - - - - 1 cup  
Skim milk - - - - - 1 cup  
Coffee

Lunch

Water-pack tuna - - - - - 2 oz.  
Tossed salad - - - - - 2 cups  
Diet (oil-free) dressing - 2 Tbsp.  
Rice cakes - - - - - 2  
Margarine - - - - - 1 pat  
Tangerins - - - - - 1 medium  
Noncaloric beverage

Dinner

Veal chop - - - - - 4 oz.  
Brussels sprouts - - - - - 1 cup  
Mixed vegetables - - - - - 1 cup  
Whole wheat bread - - - - - 1 slice  
Unsweetened sliced peaches - 1/2 cup  
Noncaloric beverage

Snack

Pita round - - 1 small  
Margarine - - 1 pat  
Skim milk - - 1 cup