

Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Special Nutritionals

ARMS#

12452



2 - LABEL SAMPLE

**000001.**

NV 97-688-870, SUB#1  
7/22/97 RDB

**NUTRITION INFORMATION PER SERVING**

Serving Size 1 Packet/11 grams

VITAMINS	AMOUNT	%RDA
Vitamin A (beta carotene)	1,250iu	25%
Vitamin C (ascorbic acid)	60mg	100%
Vitamin E (DL-alpha tocopheryl acetate)	60iu	200%

**SPECIAL INGREDIENTS**

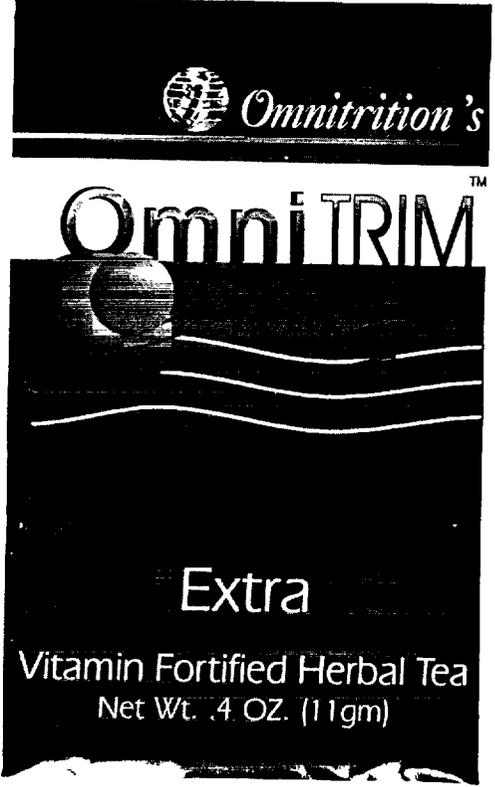
Red Tea Extract	1,000mg
Tyrosine	100mg
Taurine	70mg
Ferulic Acid	10mg

Each packet contains no more than 20 mg of ephedrine  
OmniTRIM™ Extra also contains fructose (fruit sugar), malic acid (provides tartness), and natural fruit flavors

**DIRECTIONS:** Place one packet of OmniTRIM™ Extra in four to eight ounces of water and mix well. Take one serving 30 minutes before meals, three times a day. Begin with one serving a day and gradually increase the level to 3 servings daily over a period of 7 to 10 days. 11 grams of Omni TRIM™ Extra contains no more than 20 mg of ephedrine extracted from the Ephedra Herb.

**CAUTION:** Do not take this product if you are pregnant or lactating. Persons with high blood pressure, cardiovascular disease (especially cardiac arrhythmia), diabetes, prostatic hypertrophy, glaucoma, psychosis, thyroid or Crohn's disease should not take any products containing the ephedra herb except under a physician's supervision. Elderly persons may be more sensitive to the effect of ephedra. If you are taking asthma medications, anorectics (appetite-suppressing drugs), antidepressants, MAO inhibitors, cardiovascular medications, weight loss medications or otherwise under the care of a physician, consult your physician before taking this product. The State of Ohio recommends that the maximum serving of ephedrine for a healthy human is 100 mg in a 24 hour period or the maximum recommended serving or period of use provided in applicable regulations by the United States Food and Drug Administration. This product is safe when used in compliance with the directions and cautions on this label. Avoid the use of antacids containing aluminum with this product. Do not exceed the recommended daily amount. OmniTRIM™ Extra may cause nervousness or insomnia. If such symptoms persist, reduce or discontinue use. Not for use by children under the age of 18. Keep container tightly closed in a cool, dry and dark place.

Packets are not labeled for individual retail sale  
FORMULATED FOR AND BOTTLED BY OMNITRITION INTERNATIONAL, INC.  
CARROLLTON, TEXAS 75006 (972) 417-9200 MADE IN U.S.A.



The image shows the front of a black packet for OmniTRIM™ Extra. At the top, there is a small globe icon followed by the text "OmniTrition's". Below this, the product name "OmniTRIM™" is written in a large, stylized font. Underneath the name, there is a graphic of a globe with wavy lines below it, suggesting water or tea. The word "Extra" is printed in a large, white, serif font. At the bottom of the packet, the text "Vitamin Fortified Herbal Tea" and "Net Wt. 4 OZ. (11gm)" is printed in a smaller white font.

000002



If your interested in losing weight, making money and feeling great call me  
[REDACTED]



*Omnitrition's*

# OmnitRIM™



OMNITRITION INDEPENDENT DISTRIBUTORS

HFS-636 Project #12452  
KAN-DO #97-0205  
Att. # 2 Page # 9  
7/22/97 RDB

NUTRITION YOU CAN FEEL



Floridian Omnitrition Distributors have achieved great results: (back row, left to right) Suzanne Shepard lost 12 lbs and 2 sizes; Michelle Starr lost 26 lbs and went from a size 14 to a 5/6; Kristin Tucker feels great and has more vitality; Barbara Fathauer lost 20 lbs and 2 jean sizes; Sharie Arbucci lost 20 lbs; (front row) Lisa Nagler lost 15 lbs and has maintained her weight for two years and Tracy Raehn lost 10 lbs and 3 sizes.



## Live the OmniLife™

Nutrition is one of today's most exciting fields of endeavor due to continuing current discoveries and lifestyle changes. Omnitrition International, Inc. is proud to play a part in helping people help themselves nutritiously by making the best decision for their health, mind and body.

Omnitrition has exceptional products to suit the needs of all individuals, from sports enthusiasts and weight loss customers, and from children to adults. Company sales are based on person-to-person marketing with direct home delivery. A good product is the best advertisement that Omnitrition offers. The formulators of Omnitrition's product line believe in using the finest quality ingredients available. Omnitrition has built its high reputation on satisfaction. By making the products the issue, many people come back time after time because of their results.

Many individuals have seen the potential for marketing Omnitrition's growing line of products and like the idea of becoming involved in a home-based business that is easy and inexpensive to start. Becoming an Omnitrition Independent Distributor is simple, with the advantage of a free sign-up.

We hope that you will be as enthusiastic about our products and formulations as the many people who use them everyday. Please read the product label directions carefully and check with your physician before beginning any type of program. Your satisfaction is very important to us. Omnitrition wishes you the best of health and success and hopes to be a continuing part of your future!

### Omnitrition International, Inc.

Main Number (972)417-9200  
 Order Entry Number (800)446-1025  
 Order Entry Fax (972)417-9250  
 Customer Services (972)417-9111  
 Customer Services Fax (972)417-9260

Product Training Line (972)417-9189  
 Testimonial Hotline (972)417-9188  
 TDD Order System (800)972-8482  
 Visit our Web Site at: [www.omnilife.com](http://www.omnilife.com)

ORDER TOLL FREE 1-800-446-1025

HFS-636 Project #12452  
 KAN-DO #97-0205  
 Att. # 2 Page # 10  
 7/22/97 RDB

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**NUTRITION INFORMATION PER SERVING**

Serving Size: 1 Packet/11 grams

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Vitamin A (beta carotene)	1,250iu	25%
Vitamin C (ascorbic acid)	60mg	100%
Vitamin E	60iu	200%

(DL-alpha tocopheryl acetate)

**SPECIAL INGREDIENTS**

Red Tea Extract	1,000mg
Tyrosine	100mg
Taurine	70mg
Ferulic Acid	10mg

Each packet contains no more than 20 mg of ephedrine. OmniTRIM™ Extra also contains fructose (fruit sugar), malic acid (provides tartness), and natural fruit flavors

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CARROLLTON, TEXAS 75006 (972)417-9200 MADE IN U.S.A.

INV 97-688-870, SUB#1  
7/22/97 RDB



OmniTRIM's

OmniTRIM™

Extra

Vitamin Fortified Herbal Tea

Net Wt. .4 OZ. (11gm)

**NUTRITION INFORMATION PER SERVING:**

Serving Size: 1 Packet/11 grams

VITAMINS	AMOUNT	%RDA
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HFS-636 Project #12452

KAN-DO #97-0205

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7/22/97 RDB

000005

## WELL BEING

**OMNITRIM™ REMIND** - Omnitrim™ Remind is a great tasting lemon-lime flavored beverage that contains choline and an abundance of vitamins including C and E. When you need help staying mentally on track, remember "Remind."

**OMNITRIM™ MELATONIN** - Omnitrition's Melatonin is made of the newsworthy melatonin, which research indicates has a remarkable scavenging effect on the most damaging free radical to the human body, the hydroxyl radical. Because melatonin can cross all barriers to enter every cell, it has been called the best free radical scavenger known. You can rest better with Omnitrition's Melatonin in your system.

**EASE** - Get relief with Omni Ease! A safe, natural and effective formula designed to temporarily relieve the symptoms of most common aches, pains, and discomfort. Simply spray Omni Ease to relieve: Arthritis, neck ache, back ache, sports related injuries, tired feet, sprains, strains, muscle and finger fatigue, minor sunburn, muscle soreness, minor rashes, bursitis, tendonitis, rheumatism, bruises, morning stiffness, insect bites and sore shoulders.

**CLEARLY TAN** - Sunless Spritz with Vitamins and Antioxidants is developed to enhance your tan. Clearly Tan deepens your tropical tan without extra exposure to the UVA and UVB rays know to cause premature aging and skin damage. This special formula creates a natural-looking tan as individual as your own skin tone because it interacts with the skin's proteins. Clearly Tan works without dyes or fragrances within 24 hours.

**FACIAL 5** - Discover the scientific secret in advanced skin care that could keep skin looking beautiful at every age. Exclusively from the Baroque Collection...Facial 5 Gyoelic Treatment with Oxygen.

EVERY OMNITRITION PRODUCT IS BACKED BY A 30-DAY MONEY BACK SATISFACTION GUARANTEE.

## WEIGHT LOSS

**OMNITRIM™ EXTRA** - Extra is a delicious tea flavored nutritional vitamin fortified drink mix. The popular Omnitrim Extra is flavorful, refreshing, and tastes especially sweet over ice. What does Extra stand for? Extraordinary!

**JAVA TRIM EXTRA** - Java Trim Extra combines the benefits of the ingredients of Omnitrim™ Extra with the taste of delicious coffee and has the added benefit of chromium polynicotinate. Enjoy hot or cold.

**OMNITRIM™ CHARGE** - Charge ahead and be on top of your day with Omnitrim Charge. The orange-cranberry nutritional beverage mix contains tyrosine and phenylalanine as well as an array of vitamins. Let "Charge" help you add lift to your life!

**OMNITRIM™ VICTORY** - A chromium supplement-a blend of chromium, fibers and oriental botanical extracts.

**ENZYME** - EnZyme is especially formulated to replace the important enzymes lost in the cooking and processing of food. These enzymes help to convert foods to their simpler form to permit assimilation of maximum nutrition.

**OMNITRITION™ VICTORY PLUS** - A special compliment to our weight loss products, Omnitrim™ Victory Plus contains the nutrient that has everyone talking-coenzyme Q10.

**OMNI IV** - Omni IV™, Omnitrition's original product, is a deliciously mixable liquid dietary supplement containing 147 vitamins, minerals, and herbs. Readily available for absorption by your body. A great way to drink your vitamins!

## PHYSICAL FITNESS

**OMNITRIM™ EXCEL** - Includes an excellent combination of the best ingredients to help you add "Excel" to your workouts! This grapefully delicious flavored drink is a favorite of world class athletes and body builders. Excel for Excellence!

**OMNITRIM™ CHARGE** - Charge ahead and be on top of your day with Omnitrim Charge. The orange-cranberry nutritional beverage mix contains tyrosine and phenylalanine as well as an array of vitamins. Let "Charge" help you add a lift to your life!

**OMNI IV** - Omni IV™, Omnitrition's original product, is a deliciously mixable liquid dietary supplement containing 147 vitamins, minerals and herbs. Readily available for absorption by your body. A great way to drink your vitamins!

**OMNISHIELD ANTIOXIDANT** - Our state of-the-art antioxidant provides a balanced, comprehensive nutritional base. Just take a look at the label's ingredient list and you'll see it all!

**PHYTO NUTRIENTS** - Designed to support your diet with a broad spectrum of popular standardized phytochemicals and includes Siberian and Korean Ginseng.

**GINSENG** - An herb with possible benefits of helping the body withstand stress, reduce cholesterol, improve mental alertness and aid in overall health. Only one serving per day and you're on your way to a healthier you.

WE HAVE MANY OTHER PRODUCTS AVAILABLE IN OUR FULL CATALOG. GET YOURS TODAY!!!

A# #6 INV 97-688-870 P.1  
7/22/97 RDB

000006

**OMNITRITION**  
INDEPENDENT MARKETING ASSOCIATE

WELCOME

Current discoveries and lifestyle changes make nutrition one of today's most exciting fields of endeavor. Omnitrition International is proud to be part of helping people help themselves nutritiously by making the best decision for their health, body and mind. Omnitrition has products to suit the needs of individual lifestyles, sports enthusiasts, weight loss customers, business people and housewives, just to name a few. We base our sales on person to person marketing with direct to home delivery. A good product is the best advertisement that Omnitrition offers. By making the products the issue, many people come back time after time due to their results. The formulators of these products believe in using the finest quality ingredients that money can buy. We are so sure that you will be completely satisfied, a 30-day money back guarantee is offered with each retail purchase.

**OMNITRITION**  
INDEPENDENT MARKETING ASSOCIATE

OMNITRITION'S PRODUCTS ARE  
PRODUCED USING ONLY THE FINEST  
INGREDIENTS AVAILABLE!

YOU DON'T KNOW HOW GOOD  
YOU CAN FEEL 'TILL YOU DO!!

For More Information and a  
Free Sample Call



**Omnitrition**  
INDEPENDENT MARKETING ASSOCIATE

**Independent Distributor**

*Feel Great, Lose Weight*

*Without Drastic Dieting or Strenuous Exercise*



Att. # 6, P. 2

INV 97-688-870

Omnitrition has tens of thousands of individuals who are satisfied customers. Many people who start out as retail customers have gone on to become Distributors (with the advantage of a free sign-up). They have seen the potential for marketing Omnitrition's growing line of products and like the idea of becoming involved in a home-based business that is easy and inexpensive to start.

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**OMNITRITION**  
INDEPENDENT MARKETING ASSOCIATE

WOULD YOU LIKE  
TO  
LOSE WEIGHT  
WITHOUT  
STRENUOUS  
DIETING?

ARE YOU TIRED  
OF  
FEELING TIRED?

WOULD YOU LIKE  
TO GET MORE OUT  
OF YOUR  
WORKOUTS?

IF YOU ANSWERED YES  
TO ANY OF THESE  
QUESTIONS, LOOK  
INSIDE FOR MORE  
INFORMATION

# Well Being



**Omnitrim Remind** - Omnitrim Remind is a great tasting lemon-lime flavored beverage that contains choline and an abundance of vitamins including C and E, When you need helps staying mentally on track, remember "REMIND."



**Omnitrim Melatonin** - Omnitrim Melatonin is made of the newsworthy Melatonin. which research indicates has a remarkable scavenging effect on the most damaging free radical to the human body, the hydroxyl radical. Because melatonin can cross all barriers to enter every cell, it has been called the best free radical scavenger known.

You can rest better with Omnitrim Melatonin in your system.



**Omnitrim Ease** - Get relief with Omnitrim Ease! A safe, natural and effective formula designed to temporarily relieve the symptoms of most common aches, pains, and discomfort. Simply spray Omnitrim Ease to relieve: Arthritis, neck ache, back ache, sports related injuries, tired feet, sprains, strains, muscle and finger fatigue, minor sunburn, muscle soreness, minor rashes, bursitis, tendonitis, rheumatism, bruises, morning stiffness, insect bites and sore shoulders.



**Facial 5** - Discover the scientific secret in advanced skin care that could keep skin looking beautiful at every age. Exclusively from the Baroge Collection...Facial 5 Glycolic Treatment With Oxygen.

**Omnitrim Victory** - A chromium supplement - a blend of chromium, fibers, and oriental botanical extracts.

**You Don't Know How Good You Can Feel, 'till You Do!**



Before

# Weight Loss

After



**Omnitrim Extra** - Omnitrim Extra is a delicious tea flavored nutritional vitamin fortified drink mix, The popular Omnitrim Extra is flavorful, refreshing, and tastes especially sweet over ice. What does Omnitrim Extra stand for? EXTRAORDINARY!



**Omnitrim Java Trim Extra** - Java Trim Extra combines the benefits of the ingredients of Omnitrim Extra with the taste of delicious coffee and has the added benefit of chromium polynicotinate. Enjoy it hot or cold.

**Omnitrim Charge Plus** - Do you want a lift plus more of your dietary supplement? Try Charge Plus containing Garcinia Cambogia Extract, a novel ingredient for dietary management. This ingredient comes from a fruit that has received great interest recently due to its benefits. Feel and look great with the popular addition to our weight management line!

**Enzyme** - Enzyme is especially formulated to replace the important enzyme lost in the cooking and processing of food. These enzymes help to convert foods to their simpler form to permit assimilation of maximum nutrition.

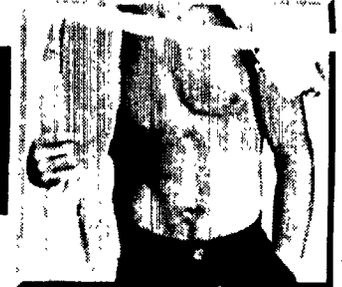
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**We have Many Other Products Available In Our Full Catalog! GET YOURS TODAY!!!**

# Physical Fitness



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**Omnitrim Charge** - Charge ahead and be on top of your day with Omnitrim Charge. The orange-cranberry nutritional beverage mix contains tyrosine and phenylalanine as well as an array of vitamins. Let Omnitrim Charge help you add a lift to your life!

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**Omnishield Antioxidant** - Our state-of-the-art antioxidant provides a balanced, comprehensive nutritional base. Just take a look at the label's ingredient list and you'll see it all!



**Phyto Nutrients** - Designed to supplement your diet with a broad spectrum of popular standardized phytochemicals and includes Siberian and Korean Ginseng.



**Ginseng** - An herb with possible benefits of helping the body withstand stress, reduce cholesterol, improve mental alertness and aid in overall health, Only one serving per day and you're on your way to a healthier you.

A.H. # C, P.S. 2008 000008

# WELCOME!

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If You're Interested In Losing Weight,  
Making Money And Feeling Great,  
Call [REDACTED]

*Omnitrition's Products Are  
Produced Using The Finest  
Ingredients Available!*

Omnitrition has tens of thousands of individuals who are satisfied customers. Many people who start out as retail customers have gone on to become Distributors (with the advantage of a free sign-up). They have seen the potential for marketing Omnitrition's growing line of products and like the idea of becoming involved in a home-based business that is easy and inexpensive to start.

For More Information And A  
FREE Sample Call:

*Omnitrition*  
Independent Marketing Associate

Contact:

If You're Interested In Losing Weight,  
Making Money And Feeling Great,  
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INV 97-698-810  
7/22/97  
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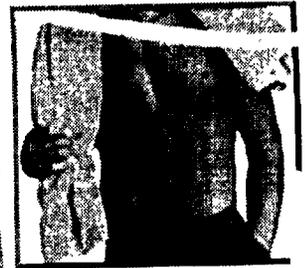


*Omnitrition*

**Would You Like To  
LOSE WEIGHT  
Without Strenuous  
Dieting?**



**Would You Like  
To Get MORE  
Out Of Your  
Workout?**



**Are You  
TIRED Of  
Feeling TIRED?**

*If You Answered YES To Any Of  
These Questions, Look Inside  
For More Information...*

# 12450

1 FLAG SURVEILLANCE <input type="checkbox"/> COMPL <input checked="" type="checkbox"/> CE <input checked="" type="checkbox"/>				2 TYPE SA INV		3 SAMPLE NUMBER 97 - 688-870		
4 CF NO nocfn		5. DATE COLLECTED 7/22/97		6. PRODUCT CODE 31PDG99		7. RESP FIRM M	8. PROGRAM ASSIGN CODE 1. 21R801	9. HOURS 1 8
10. RELATED SPL		11. PC 2	12. COLL NO. 299	13. SPLING DIST KAN		14. COLL DIST KAN		2 3
15. PRODUCT NAME AND IDENTIFICATION (Quote pertinent labeling including firm name and address) Sample consists of 4 X .4 OZ. packets of Vitamin Fortified Herbal Tea and promotional literature. The product is labeled in part as follows: "*** Omnitrition's <b>OmniTRIM</b> ***Extra***Vitamin Fortified Herbal Tea***Net Wt. .4 OZ. (11gm)*** <b>SPECIAL INGREDIENTS</b> ***Red Tea Extract***Tyrosine***Taurine***Each packet contains no more than 20mg of ephedrine.*** <b>CAUTION:</b> Do not take this product if you are pregnant or lactating. Persons with high blood pressure, cardiovascular disease (especially cardiac arrhythmia)*** <b>FORMULATED FOR AND DISTRIBUTED BY: OMNITRITION INTERNATIONAL, INC. CARROLLTON, TEXAS 75006 (972)417-9200 MADE IN U.S.A.***"</b>								
16. REASON FOR COLLECTION (Indicate analysis needed & document assignment. Include CP No. and/or Assignment No. if applicable.) Assign.# 97-0205 received from HFS-636 PAC 21R801						17. MFG CODES (Labels, pkg, shipping containers) V7142 64541		
18 MANUFACTURER (Name, address & ZIP) Formulated & Dist. By: OMNITRITION INTERNATIONAL CARROLLTON, TEXAS 75006 (972) 417-9200			19. SHIPPER (Name, address & ZIP) [REDACTED]			20. DEALER (Name, address, ZIP & telephone) [REDACTED]		
21. SIZE OF LOT FROM WHICH SAMPLED 20 packets (Mrs. [REDACTED] wanted to keep 16 in her possession)				22. EST VALUE approx. \$20		23. RECEIPT ISSUED FDA472 FDA484 NONE x		24. DATE SHIPPED & DOC REF 6/5/97 6/07/97 USPS ship label
25. DESCRIPTION OF SAMPLE AND METHOD OF COLLECTION (Number and size of units, etc.) Sample consists of 4 packets of Omnitrition's OmniTRIM herbal tea and promotional literature provided by Mrs. [REDACTED] at her residence 7/22/97.								
26. HOW PREPARED Product identified as in #27, officially sealed in plastic bag, promotional literature also id. & attached, FD-525 attached.								
27. COLL IDENT ON PKG AND/OR LABEL "INV97-688-870 7/22/97"				28. COLLECTOR'S IDENTIFICATION ON SEAL RDB "INV97-688-870 7/22/97 Randy D. Baxter"				
29. SAMPLE DELIVERED TO [REDACTED] FedEx				30. DATE DELIVERED 7/23/97		31. LAB Seattle		
32. LAB W/SPLIT SAMPLE n/a				33. ORIG C/R & RECORDS TO HFS-636 CFSAN/OSN				
34. RCDS OBTAINED	a. INVOICE NO. AND DATE 6/5/97 (Retail Sales Order Form)				b. SHIPPING RECORD (B/L, F/B, Waybill, Affidavit, etc.) NO. AND DATE Copy of orig. shipping carton/attached.			
	c. OTHER DOCUMENTS (Affidavits from dealers, etc.) SIGNER'S NAME AND DATE Two page affidavit signed by [REDACTED] 7/22/97.							
	35. REMARKS (If additional space is needed, attach Form FDA 464a, C/R Continuation Sheet) See continuation sheet for list of promotional literature collected along with the physical sample.							
36. CONSUMER COMPLAINT NO. OR RECALL NO. STL 4058		37. AMT. \$ no charge CRED CD. C V <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		38. 704(d) SPL YES NO <input type="checkbox"/> <input checked="" type="checkbox"/>		39. COLLECTOR (Typed name and signature) Randy D. Baxter, CSO		



1. COLLECTOR (Print of type name and Signature) Randy D. Baxter <i>[Signature]</i>	2. DISTRICT [REDACTED]	3. C/R NO. INV97-688-870	4. DATE COLLECTED 7/22/97
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5. REMARKS  
The following attachments cover the shipping and receipt of the OmniTRIM product and promotional literature ~~sever~~ collected from Mrs. [REDACTED] her residence 7/22/97. *203*

ATTACHMENTS:

1. STL 4058 Complaint/Injury Report dated 7/03/97.
2. STL 4058 2516a Complaint/Injury Follow-Up dtd. 7/23/97.
3. IOM Exhibit 910-D (Adverse Reaction Questionnaire, 2 pages.
4. Omnitrition Retail Sales Order Form dtd. 6/5 showing sale of 1 case Tea Packets to [REDACTED] Sold by [REDACTED] Independent Distributor. [REDACTED] business card is attached to the order form.
5. Photocopy of shipping carton's label postmarked by USPS 6/07/97 in [REDACTED]
6. Promotional brochures which identify Omnitrition's products and their intended uses, 4 pages.
7. Omnitrition International Inc. full color booklet, 33 pages.
8. Omnitrition International, Inc. RULES AND REGULATIONS HANDBOOK, 29 pages.

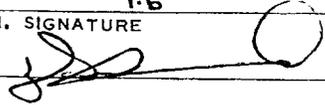
**000011**

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Page 3 of 7 Pages



plot 2

1. PRODUCT <b>Omni Trim Herbal Tea</b>		2. SAMPLE NO. <b>97-688-870</b>																								
3a. SAMPLE CLASSIFICATION <small>(Insert classification code for each PAC No. represented by sample.)</small>		b. LABORATORY CONCLUSIONS																								
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FORM FD 465 (4/78)

PREVIOUS EDITION IS OBSOLETE.

★ U.S. GPO: 1985-461-364/37051

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SAMPLE SUMMARY

000013