

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

ARMS#

12871



2 - LABEL SAMPLE

000001

Food and Drug Administration Office of Regulatory Affairs**Collection Report****For Sample Number: 5316**

Flag		Basis	Sample Type	FIS Smpl Num	
		Compliance	Official	98901323	
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
2421049	27-APR-98	54FCE09	Manufacturer	03R801	5
Related Smpl Num	Position Class	Sampling District			
	INV	SAN-DO			

Product Description

dietary supplement called Diet Fuel

Product Label

See continuation.

Reason for Collection

F/U to complaint number LOS-8119: death

MFG Codes

7A119

Expiration Date**Firm Legal Name**

Twin Labs Inc

Address

2120 Smithtown Ave Ronkonkoma, NY US

Type of Firm

Manufacturer

Size of Lot

1 btl approx. 30 capsules

Est. Value

\$0

Rcpt Type

FDA484

Date Shipped & Doc. Ref.**Description of Sample**

1 btl containing approximately 30 capsules from cousin of deceased.

Method of Collection

Spl consists of half filled btl collected from cousin of deceased.

How Prepared

Btl label ident "5316 4-29-98 KMO", placed in dbl brown paper bag which was FDA sealed.

Collector's Identification on Package and/or Label

"5316 4-29-98 KMO"

Collector's Identification on Seal

"5316 4-29-98 Kenneth M. Okihara"

Sample Delivered To

Federal Express

Dated Delivered

04/30/1998

Orig C/R & Records To

SAN-DO

Lab w/Split Sample

0

Lab

SEA-LAB

Document Number**Document Date**

04/29/1998

Document Type

Affidavit

04/29/1998

Other

Remarks

Spl collected from cousin of deceased, Ms. [REDACTED]
 [REDACTED] FDA 484 was issued to her. She signed an affidavit on 4-29-98 and wrote a one page letter describing how she got them.

Payment Amount**Payment Method**

No Charge

704(d) Sample

No

Collector's Name

Kenneth M Okihara

Name of Signer

Kenneth M Okihara

Date & Time of Signature

05/01/1998

12:15 PM

Meaning

Collector

Kenneth M Okihara

04/30/1998

08:06 PM

Collector

Kenneth M Okihara

04/30/1998

07:52 PM

Collector

000002

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 5316

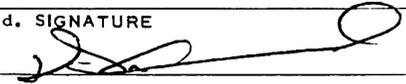
Continuation:

Product Label

Capsules in btl labeled in part "****TWINLAB THERMOGENIC FORMULA DIET FUEL With CITRIMAX & CHROMIUM PICOLINATE 60 CAPSULES***Three capsules provide MaHuang Extract 334 mg***RECOMMENDED USE: As a dietary supplement, take three capsules before breakfast or morning workout***Manufactured by TWIN LABORATORIES INC., Ronkonkoma, NY 11779 USA***". Photocopy of btl label ident & attached.

000003

Proj # 12871

1. PRODUCT Diet Fuel		2. SAMPLE NO. 5316	
3a. SAMPLE CLASSIFICATION <small>(Insert classification code for each PAC No. represented by sample.)</small>		b. LABORATORY CONCLUSIONS	
CODE	PAC NO.	Sample consisted of one (1) previously opened bottle of capsules Analysis for ephedrine alkaloids by 4B 3996 Found: 9.0 mg / 8 = 6.7 mg capsule Ephedrine. A trace of pseudoephedrine was also found (non quantifiable).	
4	03R801		
c. NAME AND TITLE Mikely S. Leonard, Chemist		d. SIGNATURE 	e. DATE 6-12-98
4a. DISTRICT CONCLUSIONS			
b. NAME AND TITLE (District)		c. SIGNATURE	d. DATE

FORM FD 465 (4/78)

PREVIOUS EDITION IS OBSOLETE.

★ U.S. GPO: 1985-461-364/37051

SAMPLE SUMMARY

98 JUN 29 PM 2:25

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-452

000004

ANALYST WORKSHEET		1. PRODUCT Diet Fuel		2. SAMPLE NUMBER 5316	
3. SEALS <input type="checkbox"/> NONE <input checked="" type="checkbox"/> INTACT <input type="checkbox"/> BROKEN		4. DATE REC'D 5/13/98		5. RECEIVED FROM [REDACTED]	
6. DISTRICT OR LABORATORY SEA-DO					

7. DESCRIPTION OF SAMPLE
One brown paper bag, identified "5316 4-29-98 KMO", officially seal "5316 4-29-98 Kenneth M. Okihara", containing one open bottle of product, id'd "5316 4-29-98 KMO" (58 capsules remaining). Received at room temperature.

8. NET CONTENTS <input checked="" type="checkbox"/> NOT APPLICABLE <input type="checkbox"/> NOT DETERMINED <input type="checkbox"/> UNITS EXAMINED		DECLARED/UNIT AMOUNT FOUND _____ % OF DECLARED _____		9. LABELING <input checked="" type="checkbox"/> ORIGINALS SUBMITTED <input type="checkbox"/> COPIES SUBMITTED <input type="checkbox"/> NONE	
---	--	---	--	--	--

10. SUMMARY OF ANALYSIS

container : clear brown glass bottle, 112mm high x 62mm diameter, with black plastic screw-cap, 47mm

labeling : commercially printed paper label glued to bottle

code : "LOT 7A119" stamped on bottle

product : clear, colorless conventionally shaped 2-piece hard gelatin capsules, capsule standard size 0, containing brown herbal powder

Analysis : for ephedrine alkaloids by LIB 3996

Results :	mg/g	mg/capsule
Norephedrine	none det	none det
Ephedrine	9.0	6.7
Pseudoephedrine	trace	trace
Methylephedrine	none det	none det
<u>Methylpseudoephedrine</u>	none det	none det.
Total alkaloid	9.0mg/g	6.7mg/capsule

000005

11. RESERVE SAMPLE In original paper bag, officially sealed "5316 6/11/98 JLBussey", one open bottle of product, 38 capsules remaining, additionally id'd "5/13/98 JLBussey" and one heat-sealed plastic bag of remaining composite id'd "5316 5/13/98 JLBussey". Returned to sample custodian.

12. a. ANALYST SIGNATURE (<input checked="" type="checkbox"/> BROKE SEAL) JLBussey <i>JLBussey</i>		13. WORK SHEET CHECK	a. BY <i>[Signature]</i>
b. <i>[Signature]</i>			b. DATE 6-12-98
c.		14. DATE REPORTED 11 June 98	

Product Labeling
Diet Fuel

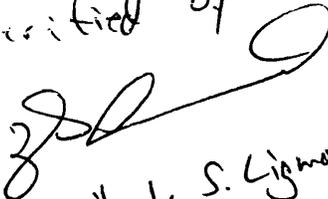
5316
JLBussey

RECOMMENDED USE: As a dietary supplement, take three capsules before breakfast or morning workout. Also, take three capsules before afternoon and evening meals. Do not exceed nine capsules daily. Taking more than the recommended amount will not improve results and may cause adverse reactions listed in the warning below. Begin use with one-third the recommended dose (one capsule three times per day) to assess your tolerance. Improper use may be hazardous to a person's health. For best results, use as part of a low-fat diet and exercise program. The maximum recommended dosage of ephedrine for a healthy adult human is no more than 100 mg in a 24 hour period for not more than 12 weeks. Please note: Guarana extract contains caffeine and should not be taken by those wishing to eliminate caffeine from their diet.

WARNING: Do not use if you are pregnant or nursing or if you are at risk or are being treated for high blood pressure, heart, liver, thyroid or psychiatric disease, diabetes, pernicious anemia, nervousness, anxiety, depression, seizure disorder, stroke or difficulty in urination due to prostate enlargement.

Consult your health care professional before use if you are taking an MAO inhibitor or any other prescription drug. Discontinue use and consult your health care professional if dizziness, sleeplessness, tremors, nervousness, headache, heart palpitations or tingling sensations occur. **NOT INTENDED FOR USE BY PERSONS UNDER THE AGE OF 18.**

[bar code]

Verified by  6-10-88
Michele S. Ligon

TWINLAB
THERMOGENIC FORMULA
DIET
FUEL® 60 CAPSULES
With CITRIMAX™ & CHROMIUM PICOLINATE

- Three capsules provide:
- MaHuang Extract.....334 mg
(standardized for 20mg ephedra alkaloids)
 - Guarana Extract.....909 mg
(standardized for 22% caffeine)
 - CitriMax™ (Garcinia Cambogia-Hydroxycitrate) Extract.....500 mg
 - Chromium (from Chromic Fuel® patented chromium picolinate).....200 mcg
 - L-Carnitine.....100 mg
 - Potassium & Magnesium Phosphate.....100 mg

In a natural thermogenic herbal base containing green tea powder, citrus bioflavonoids (containing naringin), ginger root powder, cayenne powder.

CitriMax™ is a trademark of InterHealth Company.

WARNING: Diabetics may use only under a physician's supervision because this product contains chromium picolinate which may enhance insulin sensitivity.

KEEP OUT OF REACH OF CHILDREN

Manufactured by
TWIN LABORATORIES INC., Ronkonkoma, NY 11779 USA

000006

Photocopy of b11 label

5316 4-29-98 KMO

000007

These capsules provide:

Melting Extract (standardized for 20 mg epiderm alkaloids)	324 mg
Chronic Extract (standardized for 22% caffeine)	907 mg
Chromax™ (Garosin Carboxy- hydroxyethyl) Extract	500 mg
Chromium (from Chromium Tri- potentiated chromium piccolinate)	200 mg
L-Carnitine	100 mg
Potassium 8-Magnesium Phosphate	100 mg

It is a natural thermogenic herbal base containing green tea powder, citrus bioflavonoids (containing mangifl, ginger root powder, cayenne powder).

Chromax™ is a trademark of InterHealth Company.

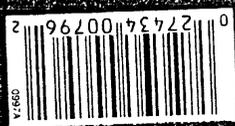
WARNING: Diabetics may use only under a physician's supervision because this product contains chromium piccolinate which may enhance insulin sensitivity.

KEEP OUT OF REACH OF CHILDREN.

Manufactured by
TWIN LABORATORIES INC., Rockhampton, NY 11779, USA.

RECOMMENDED USE: As a dietary supplement, take three capsules before breakfast or evening meals. Do not exceed three capsules before breakfast or evening meals. Do not exceed three capsules daily. Daily use on the recommended amount will not improve health. Begin use with one-third the recommended dose (one capsule three times per day) to assess your tolerance. Improvements may be in accordance with a personal health program. The maximum recommended dosage of epiderm for a healthy adult is 12 mg no more than 100 mg in a 24 hour period. For persons with health problems, please note: Garosin extract contains caffeine from their diet not be taken by those wishing to eliminate caffeine from their diet.

WARNING: Do not use if you are pregnant or nursing or if you are of risk or are being treated for high blood pressure, heart, liver, thyroid or psychiatric disease, diabetes, pernicious anemia, nervousness, nerve difficulty, depression, seizure disorder, stroke or in combination due to produce the following: Consult your health care professional before use if you are taking any MAO inhibitors or any other prescription drugs. Discontinue use and consult your health care professional if you experience: heart palpitations or tingling, weakness, fever. **NOT INTENDED FOR USE BY PERSONS UNDER THE AGE OF 18.**



TWINLAB
THERMOGENIC FORMULA

FEEL
80 CAPSULES

Made with
CITRIMAX™ & CHROMIUM PICCOLINATE

**Food and Drug Administration Office of Regulatory Affairs
Collection Report**

For Sample Number: 5317

Flag	Basis	Sample Type	FIS Smpl Num		
	Compliance	Official	98901455		
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3001608630	01-MAY-98	54BCA01	Manufacturer	03R801	3
Related Smpl Num	Position Class	Sampling District			
5316	INV	SAN-DO			
Product Description					
Mineral supplement tablets					
Product Label					
See continuation.					
Reason for Collection		MFG Codes	Expiration Date		
F/U to LOS 8119: death.		225-618 347			
Firm Legal Name		Address	Type of Firm		
TRACE MINERALS RESEARCH		PO BOX 429 ROY, UT US	Manufacturer		
Size of Lot		Est. Value	Rcpt Type	Date Shipped & Doc. Ref.	
1 btl containing about 20 tabs		\$0	FDA484		
Description of Sample					
Spl consists of previously opened btl containing about 20 tabs collected 4-29-98 fm cousin of deceased.					
Method of Collection					
Spl consists of previously opened btl containing about 20 tablets collected fm cousin of deceased					
How Prepared					
Btl label ident "5317 4-29-98 KMO" then placed in dbl brwon paper bag which was FDA sealed.					
Collector's Identification on Package and/or Label			Collector's Identification on Seal		
"5317 4-29-98 KMO"			"5317 4-29-98 Kenneth M. Okihara"		
Sample Delivered To		Dated Deliverd	Orig C/R & Records To		
Federal Express		05/01/1998	SAN-DO		
		Lab w/Split Sample	Lab		
		0	SEA-LAB		
Document Number		Document Date	Document Type		
		04/29/1998	Affidavit		
		04/29/1998	Other		
Remarks					
Spl collected fm cousin, Ms. [REDACTED]					
Payment Amount	Payment Method	704(d) Sample	Collector's Name		
\$0	No Charge	No	Kenneth M Okihara		
Name of Signer		Date & Time of Signature	Meaning		
Kenneth M Okihara		05/01/1998 01:54 PM	Collector		

000008

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 5317

Continuation:

Product Label

Mineral supplement tablets in btls labeled in part "****TRACE MINERALS RESEARCH PowerHouse SPORTS RECOVERY Bone, Joint and Ligament Nutritional Support System***180 TABLETS***TRACE MINERALS RESEARCH P.O. BOX 429 Rou, Utah, 84067****". Photocopy of label submitted with documents.

000009

Photocopy of btl label



(Continued from other column)

chloride and <0.000003% isopropanol. HERBS & ENZYMES: 1700 mg. of the following herbs: Yucca, Devils Claw, Burdock Root, Mexican Sarsaparilla Root, Capsicum, Hydrangea, 120 GDU units of Bromelain concentrate (equivalent to 800 mg. of standardized Bromelain). The following natural source food enzymes: Amylase, Protease, Lipase, Cellulase. In a base of 100 mg. Alfalfa leaf. All natural. No sugar, starch, yeast. No dicalcium phosphate, preservatives, fillers, animal products, or synthetics. Nothing artificial. Coated with vegetable cellulose, natural mint and chlorophyll. Concentrace is a trade name for concentrated sea minerals from the Great Salt Lake.

Feel the difference on your money back!

OUR GUARANTEE

... 100% MONEY BACK ...

5317
4-29-98
KMO



7 86601 22501 0

TRACE MINERALS



K E S E A R C H

PowerHouse SPORTS RECOVERY

Bone, Joint and Ligament Nutritional Support System

A powerhouse of herbs, minerals and nutrients uniquely synergized with Concentrace, Trace Minerals.

PowerHouse is a dietary supplement made from the highest quality sea minerals from Concentrace, calcium, herbs, and nutrients. Designed to give nutritional support for the bones and joints of the body. You may expect a wide spectrum of nutritional benefits.

Suggested Use: 3 tablets twice daily. When desired, use 2-4 tablets daily for maintenance or use one of our other quality nutritional supplements.

6 tablets provide the following:

MINERALS: (Source)	%USFDA*
Calcium (from Ammono Acid Chelate & Alfalfa)	275 mg. 27%
Magnesium (from Concentrace & Alfalfa)	351 mg. 25%
Chloride	1020 mg. **
Sulfur (as sulfates, from Concentrace)	37 mg. **
Potassium	73 mg. **
Sodium	2.25 mg. **
Lithium	2 mg. **
Boron (from Concentrace & Boron Proteinolate)	2 mg. **

* USFDA (U.S. Recommended daily allowance for adults and children over 12)

** USFDA not established.

Plus the following in naturally occurring, varying trace amounts from Concentrace: Carboxate, Bromide, Fluoride, Iodine, Phosphorus, Selenium, Phosphoric, Nickel, Manganese, Chromium, Strontium, Cobalt, Zinc, Tin, Calcium, Cadmium, Cerium, Barium, Copper, Iron, Silicon, Titanium, Molybdenum, Vanadium, Gallium, Gold, Silver, Cesium, Beryllium, Strontium, Vanadium, Dysprosium, Holmium, Terbium, Praseodymium, Lutetium, Gadolinium, Samarium, Barium, Yttrium, Erbium, Neodymium. Plus the other minerals found in sea water. Also contains 0.0000014% dimethylsiloxane/ethylammonium

(Continued next column)

TRACE MINERALS RESEARCH, P.O. Box 429 • Roy, Utah 84601

180 TABLETS

300CC006

000010

Food and Drug Administration Office of Regulatory Affairs**Collection Report****For Sample Number: 5318**

Flag		Basis	Sample Type	FIS Smpl Num	
		Compliance	Official	98901460	
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3001351519	01-MAY-98	54BCE01	Dealer	03R801	3
Related Smpl Num	Position Class	Sampling District			
5316	INV	SAN-DO			
Product Description					
Dietary supplement capsules					
Product Label					
See continuation.					
Reason for Collection			MFG Codes	Expiration Date	
F/U to LOS-8119: death.			7A86		
Firm Legal Name		Address	Type of Firm		
Eas Inc		555 Corporate Cir Golden, CO US	Dealer		
Size of Lot		Est. Value	Rcpt Type	Date Shipped & Doc. Ref.	
1 btl, approx. full w/360 capsules		\$0	FDA484		
Description of Sample					
1 btl, almost full, containing approx. 360 capsules.					
Method of Collection					
Spl consists of 1 btl containing approx. 360 capsules collected from [REDACTED] cousin of deceased.					
How Prepared					
Btl label ident "5318 4-29-98 KMO", then placed in dbl brown paper bag which was FDA sealed.					
Collector's Identification on Package and/or Label			Collector's Identification on Seal		
"5318 4-29-98 KMO"			"5318 4-29-98 Kenneth M. Okihara"		
Sample Delivered To			Dated Deliverd	Orig C/R & Records To	
Federal Express			05/01/1998	SAN-DO	
			Lab w/Split Sample	Lab	
			0	SEA-LAB	
Document Number			Document Date	Document Type	
			04/29/1998	Affidavit	
			04/29/1998	Other	
Remarks					
Spl collected fm cousin of deceased, [REDACTED] 4-29-98.					
Payment Amount	Payment Method	704(d) Sample	Collector's Name		
\$0	No Charge	No	Kenneth M Okihara		
Name of Signer		Date & Time of Signature		Meaning	
Kenneth M Okihara		05/01/1998 02:44 PM		Collector	

000011

**Food and Drug Administration Office of Regulatory Affairs
Collection Report**

For Sample Number: 5318

Continuation:

Product Label

Dietary supplement capsules in btls labeled in part "EAS EXPERIMENTAL AND APPLIED SCIENCES University Tested HMB Protein Breakdown Suppressor Dietary Supplement 360 CAPSULES" Recommended Use: As a dietary supplement, take 4 capsules, 3 times per day with meals Each capsule supplies: 250 mg of Calcium B-Hydroxy B-Methylbutyrate Monohydrate (HMB) 50 mg of Potassium Phosphate EXPERIMENTAL AND APPLIED SCIENCES, INC. Building Better Bodies Through Science! 555 Corporate Circle, Golden, CO 80401. Photocopy of btl label ident & submitted w/records.

000012

Photocopy of b11 label

000013

The branched chain amino acid (BCAA) metabolite β -Hydroxy β -Methylbutyrate Monohydrate (HMB) has been shown to support the body's ability to minimize protein breakdown and damage to muscle cells which can occur subsequent to intense resistance exercise."

S. Nissen, et al. "Effect of HMB Supplementation on Strength and Body Composition of Trained and Untrained Males Undergoing Intense Resistance Training." *FASEB J* 10: A287

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Nutritional uses of HMB are licensed to Experimental and Applied Sciences, Inc. under U.S. Patent #5,348,979.



EAS
EXPERIMENTAL AND APPLIED SCIENCES

University Tested

5318
4-29-98
KMU

HMBTM
Protein Breakdown SuppressorSM

PATENTED

Dietary Supplement
360 CAPSULES

Recommended Use:

As a dietary supplement, take 4 capsules, 3 times per day with meals. Do not exceed recommended dose. Consult with a physician prior to use if you have any medical conditions. Do not use if pregnant or lactating.

Each capsule supplies:

- 250 mg of Calcium β -Hydroxy β -Methylbutyrate Monohydrate (HMB)
- 50 mg of Potassium Phosphate



7A86

Distributed by
EXPERIMENTAL AND APPLIED SCIENCES, INC.
Building Better Bodies Through ScienceSM
555 Corporate Circle Golden, CO 80401
Questions or comments? Call 1-800-297-9776 (Dept. 4312)



Food and Drug Administration Office of Regulatory Affairs**Collection Report****For Sample Number: 5319**

Flag	Basis	Sample Type	FIS Smpl Num		
	Compliance	Official	98901483		
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
1000117125	01-MAY-98	54CBR99	Manufacturer	03R801	3

Related Smpl Num	Position Class	Sampling District
5316	INV	SAN-DO

Product Description

Creatine monohydrate dietary supplement powder

Product Label

See continuation.

Reason for Collection
F/U to LOS-8119: death.**MFG Codes**
801082**Expiration Date****Firm Legal Name**
Weider Nutrition International**Address**
2002 South 5070 West Salt Lake City, UT US**Type of Firm**
Manufacturer**Size of Lot**
1 btl approx. 1/5 full of powder**Est. Value**
\$0**Rcpt Type**
FDA484**Date Shipped & Doc. Ref.****Description of Sample**

Spl consists of 1 btl approx. 1/5 full (3-oz.) of powder collected from cousin of deceased on 4-29-98.

Method of Collection

Spl consists of 1 btl approx. 1/5 full of powder collected from [REDACTED] cousin of deceased, in [REDACTED] 4-29-98.

How Prepared

Btl label ident "5319 4-29-98 KMO", btl placed in dbl brown paper bag which was FDA sealed.

Collector's Identification on Package and/or Label
"5319 4-29-98 KMO"**Collector's Identification on Seal**
"5319 4-29-98 Kenneth M. Okihara"**Sample Delivered To**
Federal Express**Dated Deliverd**
05/01/1998**Orig C/R & Records To**
SAN-DO**Lab w/Split Sample**
0**Lab**
SEA-LAB**Document Number****Document Date**
04/29/1998
04/29/1998**Document Type**
Affidavit
Other**Remarks**

Spl collected fm [REDACTED] cousin of deceased, at [REDACTED] on 4-29-98.

Payment Amount
\$0**Payment Method**
No Charge**704(d) Sample**
No**Collector's Name**
Kenneth M Okihara**Name of Signer**
Kenneth M Okihara**Date & Time of Signature**
05/01/1998 03:53 PM**Meaning**
Collector**000014**

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 5319

Continuation:

Product Label

Dietary supplement powder in btl labeled in part "****WEIDER CREATINE MONOHYDRATE Dietary Supplement SUPPORTS SYTHESIS OF ATP CELL VOLUMIZER PROMOTES STRENGTH NET WT 1.1 LB(500G)***DIRECTIONS: For best resyktsm taje 20 grams of creatine monohydrate for 5 consecutive days spread out over the day in 4 servings of 5 grams***INGREDIENTS: PURE CREATINE MONOHYDRATE Researched and manufactured by, Weider Nutrition International Salt Lake City, UT, USA 84014****". Photocopy of btl label ident & submitted w/records.

000015

Photocopy of b11 Label

000016

CREATINE

Creatine is a precursor to the bioenergetic fuel, Creatine Phosphate (CP). In muscle, CP replenishes cellular ATP levels during maximum intensity contractions. Supplementation with creatine, as directed, contributes to increased muscle CP levels, more work output, more muscular power, better recovery and increased muscle hydration. Scientific studies show that when muscles are hydrated, muscle catabolism is minimized.

PRODUCT	MUSCLE PROTEIN	MUSCLE DEFINITION	WEIGHT GAIN	STRENGTH	ENDURANCE	RECOVERY	TESTOSTERONE ENHANCEMENT	TOTAL NUTRITION
ULTRA WHITE POW	•	•	•	•	•	•	•	•
CREATINE 200	•	•	•	•	•	•	•	•
TRIGLYCERIN	•	•	•	•	•	•	•	•
AMPHOSTERIN	•	•	•	•	•	•	•	•
PREVIALE	•	•	•	•	•	•	•	•
LEAN POW	•	•	•	•	•	•	•	•
COMPLETE RX	•	•	•	•	•	•	•	•

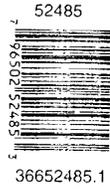
KEEP OUT OF REACH OF CHILDREN

As with all supplements, if you are under a physician's care or taking medication consult your physician before using.

NOTE: If you are pregnant, lactating, or on prescribed medication, consult with your physician before using.

STORE IN A COOL, DRY PLACE WITH LID TIGHTLY CLOSED.

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.



5319
4-29-98
KMO

W E I D E R

CREATINE MONOHYDRATE

Dietary Supplement



**SUPPORTS SYNTHESIS OF ATP
CELL VOLUMIZER
PROMOTES STRENGTH**

DIRECTIONS: For best results, take 20 grams of creatine monohydrate for 5 consecutive days spread out over the day in 4 servings of 5 grams (approximately one rounded scoop). Following the loading phase, 3 to 4 grams per day (approximately one level scoop) are necessary to maintain the health benefits of creatine monohydrate. Best if taken immediately after exercise and between meals.

MIXING INSTRUCTIONS: Mix one rounded scoop of creatine monohydrate with 3 to 4 ounces of any, high-glycemic (high-sugar), low-acidic juice or beverage (grape juice, apple juice, etc.) Avoid hot beverages, acidic beverages (orange juice, etc.) and caffeine (coffee) when taking creatine monohydrate, as they may interfere with the efficacy of the compound.

Supplement Facts

Serving Size: 1 scoop (5 g)	Amount Per Serving	% Daily Value*
Servings Per Container: approximately 100	Creatine Monohydrate	5g
		*Daily Value not established.

INGREDIENTS: PURE CREATINE MONOHYDRATE

Researched and manufactured by Weider Nutrition, International, Salt Lake City, UT, USA 84014
Weider® 1-800-FLEX-IT OR 1-800-435-3948

Food and Drug Administration Office of Regulatory Affairs**Collection Report****For Sample Number: 5320**

Flag	Basis	Sample Type	FIS Smpl Num		
	Compliance	Official	98901488		
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
1000117125	01-MAY-98	54FCA99	Manufacturer	03R801	3
Related Smpl Num	Position Class	Sampling District			
5316	INV	SAN-DO			
Product Description					
Chromium Picolinate					
Product Label					
See continuation.					
Reason for Collection			MFG Codes	Expiration Date	
F/U to LOS-8119: death.			AH3657B	12/99	
Firm Legal Name		Address	Type of Firm		
Weider Nutrition International		2002 South 5070 West Salt Lake City, UT US	Manufacturer		
Size of Lot		Est. Value	Rcpt Type	Date Shipped & Doc. Ref.	
1 btl containing approx. 50 tabs.		\$0	FDA484		
Description of Sample					
Spl consists of 1 btl containing approx. 50 tabs collected from cousin of deceased on 4-29-98.					
Method of Collection					
Spl consists of 1 btl containing approx. 50 tabs collected from [REDACTED], cousin of deceased.					
How Prepared					
Btl label ident "5320 4-29-98 KMO" then placed in dbl brown paper bag which was FDA sealed.					
Collector's Identification on Package and/or Label			Collector's Identification on Seal		
"5320 4-29-98 KMO"			"5320 4-29-98 Kenneth M. Okihara"		
Sample Delivered To		Dated Delivered	Orig C/R & Records To		
Federal Express		05/01/1998	SAN-DO		
		Lab w/Split Sample	Lab		
		0	SEA-LAB		
Document Number		Document Date	Document Type		
		04/29/1998	Affidavit		
		04/29/1998	Other		
Remarks					
Spl collected from [REDACTED] cousin of deceased, at [REDACTED]					
Payment Amount	Payment Method	704(d) Sample	Collector's Name		
\$0	No Charge	No	Kenneth M Okihara		
Name of Signer		Date & Time of Signature		Meaning	
Kenneth M Okihara		05/01/1998 04:47 PM		Collector	

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Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 5320

Continuation:

Product Label

Chromium picolinate tablets in btl labeled in part "***JOE WEIDER CHROMIUM PICOLINATE DIETARY SUPPLEMENT HIGH POTENCY 200 mcg***500 TABLETS***DIRECTIONS: Take one (1) tablet daily at meal time.***OTHER INGREDIENTS: Cellulose and magnesium stearate***Distributed by: Great American Nutrition Salt Lake City, UT USA 84104 Another brand of WEIDER NUTRITION***". Photocopy of btl label ident & submitted w/records.

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