

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

ARMS#

13021



2 - LABEL SAMPLE

000001

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 25152

Flag	Flag Remarks				
Complaint Sample					
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Compliance	Investigational	98908964	Completed
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3001075181	18-AUG-98	54FYY09	Manufacturer	04F800	5
Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	INV	NSV-DO			Ambient
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name	
No				Twinlab	

Product Description

Product is Ripped Fuel Metabolic Enhancer capsules contained in a brown glass bottle.

Product Label

See continuation.

Reason for Collection

Collected as a follow up to CFSAN Project No. 13021 (Med Watch Report); and assignment #3-057 dated July 28, 1998. Analyze sample for Ephedrine Alkaloids.

MFG Codes

NO MANUFACTURING CODES ON BTL

Expiration Date

NO EXP DATE

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
Twinlab Corporation	2120 Smithtown Ave Ronkonkoma, NY 117797347 US	Manufacturer	3001075181	

Size of Lot	Est. Value	Rcpt Type	Date Shipped & Doc. Ref.
n/a		FDA484	

Description of Sample

See continuation.

Method of Collection

See continuation.

How Prepared

Sample was placed in a plastic bag. Sample and plastic bag labeled as below; plastic bag officially sealed as below. Sample wrapped in bubble wrap, and placed in cb box. FD-525 attached to smpl. Shipped via Fed Ex to SEA-DO lab.

Collector's Identification on Package and/or Label

"25152 08/18/98 KLC"

Collector's Identification on Seal

"25152 08/21/98 Kimberly L. Cunningham"

Sample Delivered To	Date Delivered	Orig C/R & Records To
via Fed Ex frm NSV-DO	08/24/1998	NSV-DO
	Lab w/Split Sample	Lab
	0	SEA-LAB

Document Number	Document Date	Document Type	Document Remarks
		None	

Remarks

Sample was collected directly from [redacted] on 08/18/98, and held under lock & key in NSV-DO desk from 08/18/98-08/21/98, until off. sealed on 08/21/98. Dealer: [redacted]

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
\$0.00	No Charge	No	No	Kimberly L Cunningham

Name of Signer
Kimberly L Cunningham

Date & Time of Signature
08/24/1998 04:29 PM

Meaning
Collector

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 2515

Continuation:**Product Label**

in part "TWINLAB METABOLIC ENHANCER THERMOGENIC FORMULA RIPPED FUEL 120 CAPSULES"
***Manufactured by: TWIN LABORATORIES INC. Ronkonkoma, NY 11779 USA *** **Two Capsules Provide:
MaHuang...334 mg(standardized for 20 mg ephedra alkaloids) Guarana Extract (standardized for 22% caffeine)...910 mg L-
Carnitine...100 mg Chromium (from Chromic Fuel patented chromium picolinate)...200mcg *No U.S. RDA established.***
***WARNING: Diabetics may use only under a physician's supervision because this product contains chromium picolinate
which may enhance insulin sensitivity. ***"

Description of Sample

Sample consists of 1 bottle of Twinlab Metabolic Enhancer Ripped Fuel containing 120 capsules. Sample is not original product consumed by victim. Complainant disposed of original product, and purchased another bottle of the same product at

Method of Collection

Sample consisting of one glass bottle of Ripped Fuel containing 120 capsules collected directly from complainant at her place of employment on 08/18/98. Did not collect product until CFSAN requested the collection, even though it was not original product taken by victim.

25152
8/27/98
JUBUSSEY



TWINLAB
METABOLIC ENHANCER

HERMOGENIC FORMULA
FUELED



120 Capsules

140% NORMAL SIZE

RECOMMENDED USE: As a dietary supplement, take 2 capsules before morning workout on an empty stomach. Also, take 2 capsules before afternoon and evening meals. Do not exceed 6 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-half 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 the 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

Two Capsules Provide:

- MaHuang Extract 334 mg (standardized for 20 mg ephedra alkaloids)
- Guarana Extract 910 mg (standardized for 22% caffeine)
- L-Carnitine 100 mg
- Chromium (from Chromic Fuel[®] patented chromium picolinate) 200 mcg
- *No U.S. RDA established

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.
RanchoKoma, NY 11779 USA



000005

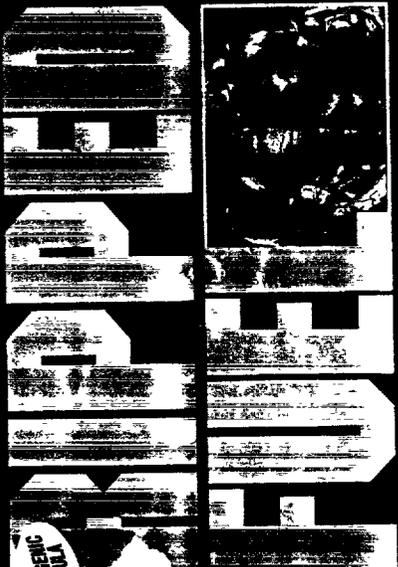


RECOMMENDED USE: As a dietary supplement take 2 capsules before morning workout on an empty stomach. Also, take 2 capsules before afternoon and evening meals. Do not exceed 6 capsules daily. Taking more than the recommended amount will not improve results and may cause adverse reactions listed in the warning below. Begin use with one-half the recommended dose (one capsule three times per day) to assess your 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 taking 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

TWINLAB
METABOLIC ENHANCER



120 Capsules

Two Capsules Provide

Maitrang Extract (standardized for 20 mg ephedra alkaloids)	334 mg	U.S. RDA
Guarana Extract (standardized for 22% caffeine)	910 mg	
L-Carnitine	100 mg	
Chromium (from Chromic Fuel [®] patented chromium picolinate)	200 mcg	

*No U.S. RDA established

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.
Ranikona, NY 11779 USA



000006

Proj 13021

ANALYST WORKSHEET		1. PRODUCT Ripped Fuel		2. SAMPLE NUMBER 25152	
3. SEALS <input type="checkbox"/> NONE <input checked="" type="checkbox"/> INTACT <input type="checkbox"/> BROKEN		4. DATE REC'D 8/26/98		5. RECEIVED FROM R. A. Synstad	
7. DESCRIPTION OF SAMPLE One plastic bag, officially sealed "25152 08/21/98 Kimberly L. Cunningham", containing one open bottle (labeling removed, 120 capsules present) and one label, bottle id'd "25152 08/18/98 KLC". Received at room temperature.					
8. NET CONTENTS <input type="checkbox"/> NOT APPLICABLE <input type="checkbox"/> NOT DETERMINED <input checked="" type="checkbox"/> UNITS EXAMINED		DECLARED/UNIT AMOUNT FOUND 120 CAPS 120 % OF DECLARED 100%		9. LABELING <input checked="" type="checkbox"/> ORIGINALS SUBMITTED <input checked="" type="checkbox"/> COPIES SUBMITTED <input type="checkbox"/> NONE	

10. SUMMARY OF ANALYSIS

container : clear brown glass bottle, 129mm high x 68mm diameter, with black plastic screw cap, 55mm diameter

labeling : commercially printed paper, removed by investigator

code : "LOT82383" stamped on bottle

product : clear, colorless conventionally shaped 2-piece hard gelatin capsule, capsule standard size 00, containing brown herbal powder

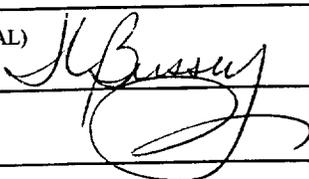
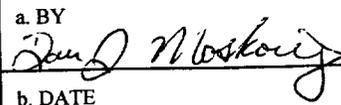
Analysis : For ephedra alkaloids by LIB 3996

Results :	mg/g	mg/tab
ephedrine	10.5	8.3
pseudoephedrine	3.0	2.4
<u>methyl ephedrine</u>	<u>trace</u>	<u>trace</u>
total alkaloid	13.5	10.6

98 SEP -2 MD 74

RECEIVED
CLINICAL RESEARCH
& REVIEW/DSM: JFC: 452

11. RESERVE SAMPLE In original plastic bag, officially sealed "25152 8/27/98 JLBussey", one open bottle additionally id'd "8/26/98 JLBussey", 100 capsules remaining, one heat sealed plastic bag of remaining composite id'd "25152 8/26/98 JLBussey", original label and original seal. Returned to sample custodian.

12. a. ANALYST SIGNATURE (<input checked="" type="checkbox"/> BROKE SEAL) JLBussey 		13. WORK SHEET CHECK	a. BY 
b.			b. DATE 8/28/98
c.		14. DATE REPORTED 27 Aug 98	

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