

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

ARMS#

12948



2 - LABEL SAMPLE

000001

"ESCALATION"

By ENZYMATIC Therapy®

800 783 2256

NO. 821 P.S.E. Lg 120 capsules

"The Original All-NATURAL energizing dietary Supplement with thermogenic properties"

1 capsule 1 to 3 times daily before meals NOT more often than every 3 to 4 hours. DO NOT give to persons under 18 years of age.

code (BAR) 7 6 3948 20464 9 (side) 34 91+3 (5,6) ET1 R1

(ON BOTTOM) C93P04 G G 3A Lot #

Each capsule contains:

Cola Nut 250 mg = 35 mg Caffeine

Green Tea 250 mg = 15 mg Caffeine

MA HUANG 250 mg = 15 mg. Ephedrine

MNF. - ENZYMATIC Therapy®, Green Bay, Wisconsin, 54311

WARNING: Keep out of reach of children. Seek the advice of a physician prior to use if you are pregnant or nursing, or if you have high blood pressure, heart or thyroid disease, diabetes, difficulty in urination due to prostate enlargement or if taking monoamine oxidase (MAO) inhibitors or any other prescription drug. Reduce or discontinue use if nervousness, tremor, irritability, rapid heart beat, sleeplessness, loss of appetite or nausea occur. NOT intended for use by persons under 18 years old.

000002

Label from Escalation

Proj # 12948

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 43425

RT 1303

Flag **Flag Remarks**

Complaint Sample

Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Compliance	Investigational	99917555	Completed
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
2128693	21-JAN-99	54FGE09	Manufacturer	56R801	8
Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	INV	DAL-DO			Ambient
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name	
Yes			DAL89126	ESCALATION	

Product Description
hard gelatin capsules

Product Label
See continuation.

Reason for Collection	MFG Codes	Expiration Date
Sample collected as a follow up on Consumer Complaint DAL 8-9126. Analyze for ephedra alkaloids.	"093PO4QG3A" stamped on bottom of plastic bottle.	N/A

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
Enzymatic Therapy, Inc	825 Challenger Dr-Bx22310 Green Bay, WI 54305-2310 US	Manufacturer	2128693	

Size of Lot	Est. Value	Rcpt Type	Date Shipped & Doc. Ref.
1 X 120 capsule bottle	\$0	FDA484	

Description of Sample
1-zip lock plastic bag containing 15 capsules of non-rx dietary supplement product collected from bottle labeled "ESCALATION".

Method of Collection
Collected 15 capsules from consumer sample in her home.

How Prepared
Zip lock bag containing capsules identified "43425 MU 1/21/99, placed in clear plastic bag sealed "43425 1/21/99 Margarito J. Uribe"

Collector's Identification on Package and/or Label	Collector's Identification on Seal
'43425 MU 1/21/99"	"43425 1/21/99 Margarito J. Uribe"

Sample Delivered To	Date Delivered	Orig C/R & Records To
FED EX 801017390960	01/22/1999	DAL-DO
	Lab w/Split Sample	Lab
	0	SEA-LAB

Document Number	Document Date	Document Type	Document Remarks
		None	

Remarks
Product collected from consumers home from a previously opened plastic bottle labeled "ESCALATION" which was approx. 1/2 full of capsules.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
\$0.00	No Charge	No	No	Margarito J Uribe

000003

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

For Sample Number: 43425

Name of Signer
Margarito J Uribe

Date & Time of Signature
01/22/1999 02:14 PM

Meaning
Collector

99 JUN 16 P 3:22

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-43425

000004

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

For Sample Number: 43425

Continuation:

Product Label

Plastic bottle labeled in part "ESCALATION The original all natural energizing dietary supplement with thermogenic properties *** NO. 821 P.S.E. LG *** 120 capsules *** Each capsule contains: COLA NUT EXTRACT (COLA NITIDA) *** 250 mg *** contains 35 mg caffeine *** GREEN TEA EXTRACT (CAMELLIA SENESIS) ***250 mg *** contains 15 mg caffeine *** MA HUANG EXTRACT (EPHEDRA SINENSIC) *** 250 mg *** contains 15 mg of Ephedrine *** MANUFACTURED EXCLUSIVELY BY ENZYMATIC THERAPY, GREEN BAY, WISCONSIN, 54311 *** Directions: Adults 18 years of age and older: One capsule one to three times daily before meals not more often than every three or four hours. Do not give to person under 18 years of age. *** "

000005

ANALYST WORKSHEET		1. PRODUCT white capsules (Escalation)		2. SAMPLE NUMBER 43425	
3. SEALS <input type="checkbox"/> NONE <input checked="" type="checkbox"/> INTACT <input type="checkbox"/> BROKEN		4. DATE REC'D 2/5/99		5. RECEIVED FROM [REDACTED]	
7. DESCRIPTION OF SAMPLE One plastic bag, officially sealed "43425 1/21/99 [REDACTED]" containing one plastic bag with 15 capsules id'd "43425 [REDACTED] 1/21/99". 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 type="checkbox"/> ORIGINALS SUBMITTED <input type="checkbox"/> COPIES SUBMITTED <input checked="" type="checkbox"/> NONE	

10. SUMMARY OF ANALYSIS

container : investigator's plastic bag

labeling : none

code : none

product : opaque white conventionally shaped hard gelatin capsules containing tan powder, capsule standard size 0

Analysis : for ephedra alkaloids by LIB 3996

results :	mg/g	mg/capsule
ephedrine	15.6	11.7
pseudoephedrine	2.0	1.5
<u>methylpseudoephedrine</u>	<u>trace</u>	<u>trace</u>
total alkaloid	17.6	13.2

RECEIVED
 CLINICAL RESEARCH
 & REVIEW/OSHHS-43
 '99 JUN 16 P 3:23

11. RESERVE SAMPLE In original bag, officially sealed "43425 2/11/99 JLBussey", one plastic bag with 8 remaining capsules and one plastic heat sealed bag of remaining composite id'd "43425 2/8/99 JLBussey". Returned to sample custodian.

12. a. ANALYST SIGNATURE (IF BROKE SEAL) JLBussey <i>JLBussey</i>		13. WORK SHEET CHECK	a. BY <i>Janet S. Burke</i>
b.			b. DATE 2/11/99
c.		14. DATE REPORTED 11 Feb 99 000006	