

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

ARMS#

13110



2 - LABEL SAMPLE

**000001**



Medura TEN 13110

# E-Z Trim

90 Tablets

**Directions:**

Take three tablets daily, one tablet approximately 30 minutes before each meal as a dietary supplement.

**Contents:**

Each tablet contains:  
Ma Huang Extract 333 mg  
Guarana Extract 250 mg.

**Caution:**

Keep out of reach of children. Not for use by children, teens, or pregnant or lactating women. Consult with your physician before using this product if you are under a doctor's care for depression or have high blood pressure, diabetes, glaucoma, asthma, prostate enlargement or disease of the heart, kidney or thyroid, or if you are taking an MAO inhibitor or any other prescription drug. Reduce or discontinue use if nervousness, tremor, sleeplessness, or nausea occur. Do not exceed recommended dosage.

This product should not be taken with any other Ma Huang product or anything containing ephedrine or pseudoephedrine.

Store in a cool dry place or refrigerate after opening.

General Merchandise Corporation, Atlanta, GA 30091

EZL995

805024 5/01

000002



medwatch 13110 FW 12/3-14/98 cdc  
Exhibit #4

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Store in a cool dry place or refrigerate after opening.  
General Medicines Corporation, Atlanta, GA 30091

805024 5/01

EZ1985

000003

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

**Collection Report**

**For Sample Number: 1213**

**Flag** 301(k) Sample **Flag Remarks** Complaint is MedWatch 13110.

<b>Episode Number</b>	<b>Origin</b>	<b>Basis</b>	<b>Sample Type</b>	<b>FIS Smpl Num</b>	<b>Status</b>
	Domestic	Compliance	Official	99916294	Completed
<b>FEI</b>	<b>Date Collected</b>	<b>Product Code</b>	<b>Responsible Firm</b>	<b>PAC</b>	<b>Hours</b>
3001452851	15-DEC-98	54FCA09	Manufacturer	03F800	8
<b>Related Smpl Num</b>	<b>Position Class</b>	<b>Sampling District</b>	<b>NDC Number</b>	<b>Permit Number</b>	<b>Storage Rqrmnt.</b>
	INV	MIN-DO			Ambient
<b>Dealer is Consumer</b>	<b>Crx/DEA Schedule</b>	<b>Recall Num</b>	<b>Consumer Compl. Num</b>	<b>Brand Name</b>	
Yes				E-Z Trim	

**Product Description**

Dietary supplement tablets containing 333 mg MaHuang extract and 250 mg Guarana extract.

**Product Label**

See continuation.

**Reason for Collection**

Per CFSAN assignment, MedWatch 13110. User suffered extreme side effects and was hospitalized after use. Analyze for ephedrine alkyls.

**MFG Codes**

805024

**Expiration Date**

5/01

**Firm Legal Name**

Florida Supplement Corp.

**Address**

2815 Evans St Hollywood, FL 33020 US

**Type of Firm**

Manufacturer

**Firm FEI**

3001452851

**FCE**

**Size of Lot**

**Est. Value**

\$0

**Rcpt Type**

None

**Date Shipped & Doc. Ref.**

06/19/1998

**Description of Sample**

See continuation.

**Method of Collection**

See continuation.

**How Prepared**

Vial, carton and bottle all identified as below and placed into brown paper bag. Bag identified similarly and sealed with FDA seal as identified below. Prepared to ship. Broken seals covering sample are attached to info packet..

**Collector's Identification on Package and/or Label**

"1213 12/3/98 CRC" on vial, "1213 12/14/98 CRC" on rest.

**Collector's Identification on Seal**

"1213 12/16/98 Charles R Cote"

**Sample Delivered To**

**Date Delivered**

12/16/1998

**Orig C/R & Records To**

MIN-DO

**Lab w/Split Sample**

0

**Lab**

SEA-LAB

**Document Number**

1

**Document Date**

12/03/1998

**Document Type**

Other

**Document Remarks**

see associated memo

**Remarks**

Sample was open upon collection, had been received via mail by patient, opened and used, then the remaining medication was maintained by cardiologist [redacted] since the incident.

**Payment Amount**

**Payment Method**

**704(d) Sample**

No

**702(b) Portion**

No

**Collector's Name**

Charles R Cote

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

**Collection Report**

**For Sample Number: 1213**

**Continuation:**

**Product Label**

"E-Z Trim 90 Tablets \*\*\*Directions: Take three tablets daily, one tablet approximately 30 minutes before each meal as a dietary supplement. Contents: Each tablet contains: Ma Huang Extract 333 mg. Guarana Extract 250 mg. \*\*\* Distributed by: General Merchandising Corporation, Atlanta, GA 30091\*\*\* "

**Description of Sample**

Sample consists of product and container/label as well as shipping carton. Product is dietary supplement tablets in white HDPE bottle with white screw off lid bearing stick on label as below. Each contains 90 tablets. In addition, a single tablet, originally taken from the bottle for distribution to me (by the physician) is included in its amber vial.

**Method of Collection**

Sample was collected from physician who was holding remaining medication. Sample is a single tablet in an amber vial, issued to me on 12/3/98 by the physician and the remaining bottle, carton and contents issued to me on 12/14/98 after written permission from patient was finally obtained. This represents all of remaining stock received by patient. Note..patient returned one full bottle to distributor for refund.

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

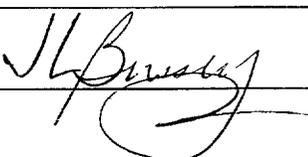
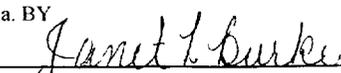
**Collection Report**

**For Sample Number: 1213**

**Name of Signer**  
Charles R Cote

**Date & Time of Signature**  
12/16/1998 02:14 PM

**Meaning**  
Collector

1. WORKSHEET		2. PRODUCT E-Z Trim		3. SAMPLE NUMBER 1213																			
4. SEALING <input checked="" type="checkbox"/> INTACT <input type="checkbox"/> BROKEN		5. DATE REC'D 2/5/99		6. RECEIVED FROM [REDACTED]																			
7. DESCRIPTION OF SAMPLE One paper bag wrapped box, officially sealed "1213 12/16/98 Charles R. Cote", containing one open bottle of product (55 tablets remaining) id'd "1213 12/14/98 CRC and one prescription bottle (one tablet remaining) id'd same. 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 checked="" type="checkbox"/> COPIES SUBMITTED <input type="checkbox"/> NONE																			
10. SUMMARY OF ANALYSIS																							
<p>container : opaque white plastic bottle, 111mm tall x 61mm diameter, with white plastic child-safety screw cap, 51mm diameter</p> <p>labeling : commercially printed on paper label glued to bottle</p> <p>code : "805024 5/01" stamped on bottle label</p> <p>product : mottled dark brown oblong biconvex tablets, 22mm long x 9mm wide x 7.5mm thick</p> <p>Analysis : for ephedra alkaloids by LIB 3996</p> <table border="0"> <tr> <td>results :</td> <td>mg/g</td> <td>mg/tablet</td> </tr> <tr> <td>norephedrine</td> <td>trace</td> <td>trace</td> </tr> <tr> <td>ephedrine</td> <td>5.0</td> <td>7.9</td> </tr> <tr> <td>pseudoephedrine</td> <td>2.4</td> <td>3.7</td> </tr> <tr> <td>methylephedrine</td> <td>trace</td> <td>trace</td> </tr> <tr> <td>total alkaloid</td> <td>7.4</td> <td>11.6</td> </tr> </table>						results :	mg/g	mg/tablet	norephedrine	trace	trace	ephedrine	5.0	7.9	pseudoephedrine	2.4	3.7	methylephedrine	trace	trace	total alkaloid	7.4	11.6
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<p>RECEIVED CLINICAL RESEARCH &amp; REVIEW/OSN/HFS-452</p> <p>99 JUN 14 10:32</p>																							
11. RESERVE SAMPLE In original box, officially sealed "1213 2/11/99 JLBussey", one open bottle additionally id'd "2/8/99 JLBussey" (35 tablets remaining), one prescription bottle as described above (one tablet remaining), and one plastic heat sealed bag of remaining composite id'd "1213 2/8/99 JLBussey". Returned to sample custodian.																							
12. a. ANALYST SIGNATURE (if BROKE SEAL) JLBussey 				13. WORK SHEET CHECK																			
b.				a. BY 																			
c.				b. DATE 2/11/99																			
				14. DATE REPORTED 11 Feb 99																			
				000007																			