

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

ARMS#

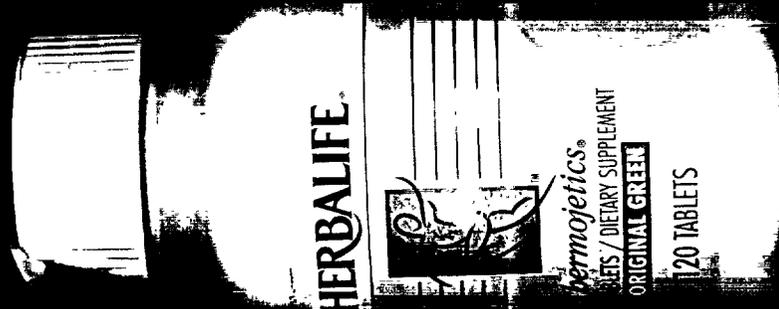
13009



2 - LABEL SAMPLE

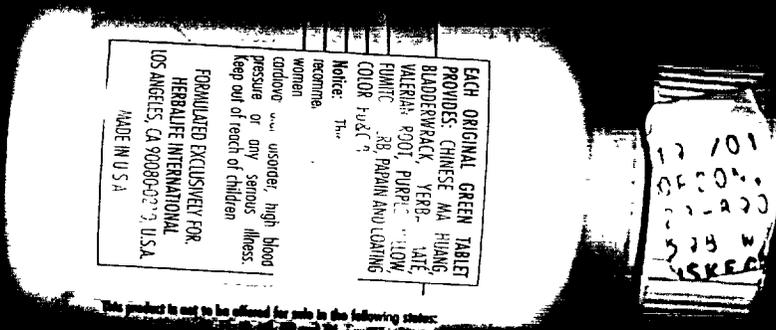
**000001**

#13009 A  
pg 204



000002

#13009 A  
pg 30F4



EACH ORIGINAL GREEN TABLET  
PROVIDES: CHINESE MA HUANG,  
BLADESWRACK, YERB.,  
VALERIAN, ROOT, PURPLE, LATE,  
FUMIC, 88, PAIN AND COATING  
COLOR PACT 9

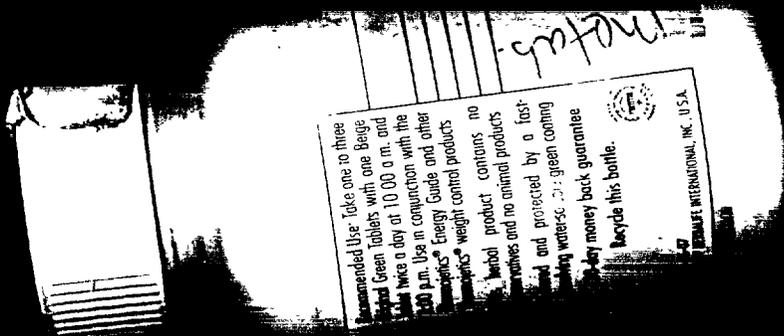
Notice: This  
recomen  
women  
cardio us, usorder, high blood  
pressure or any serious illness.  
Keep out of reach of children

FORMULATED EXCLUSIVELY FOR  
HERBALIFE INTERNATIONAL  
LOS ANGELES, CA 90080-0222 U.S.A.  
MADE IN U.S.A.

This product is not to be allowed for sale in the following states:

000003

#13009 A  
pg 4054



000004

Herbalife, Original Green, label contents:

PROTECT # 13009  
EXHA PG 1 OF 4

Herbalife  
Thermojetics  
Herbal Tablets/Dietary Supplement  
Original Green  
120 Tablets

Each Original Green Tablet Provides: Chinese Ma Huang,  
Bladderwrack, Yerba Maté, Valerian Root, Purple willow,  
Fumitory herb, Papain and Coating Color: FD&C

-Part of label has been rubbed off, can not read some words-

Notice: (can't read) women (can't read) disorder, high blood  
pressure or any serious illness. Keep out of reach of  
children.

Formulated exclusively for: Herbalife International Los  
Angeles, CA 90080-0210, U.S.A. Made in U.S.A.

This product is not to be offered for sale in the following  
states: AR, FL, ID, NE, OR and TN.

Lot 057230

Recommended Use: Take one to three Original Green Tablets  
with on Beige Tablet twice a day at 10:00 a.m. and 3:00 p.m.  
Use in conjunction with the Thermojetics Energy Guide and  
other Thermojetics weight control products.

This herbal product contains no preservatives and no animal  
products.

Colored and protected by a fast-dissolving water-soluble  
green coating.

30-day money back guarantee

Recycle this bottle

1553-US-07 C 1997

000005

#13009  
EXH B  
pg 20fb



000006



#13009  
EXH B  
pg 4 of 6

0233  
0783

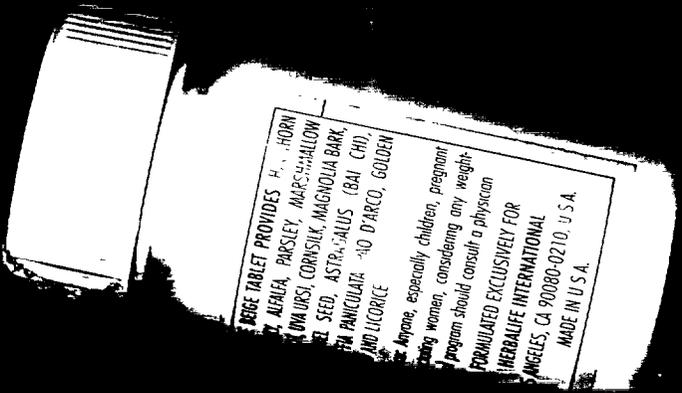
ONE REIGE TABLET PROVIDES: HAWTHORN BERRY, ALFAIFA, PARSLEY, MARSHMALLOW ROOT, VIVA URSI, CORIANDER, MAGNOLIA BARK, FENNEL SEED, ASTRAGALUS (BAI CHU), PRALINA, TILICULATA, PIVO D'ARCO, GINSENG ROOT, CORIACE

Notice: Anyone, especially children, pregnant or lactating women, considering any medical program should consult a physician.

FORMULATED EXCLUSIVELY FOR:  
HERBALIFE INTERNATIONAL  
LOS ANGELES, CA 90080-0210, U.S.A.  
MADE IN U.S.A.

800008

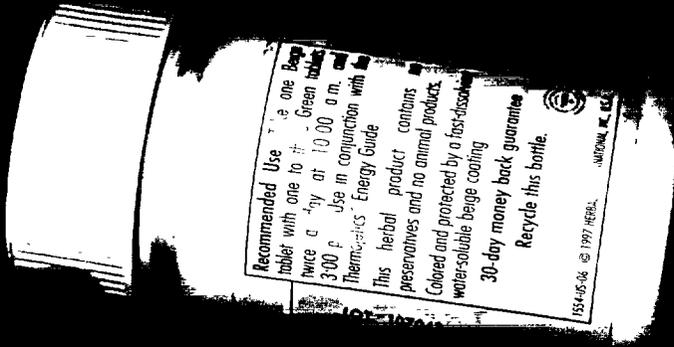
#13009  
EXH B  
pg 5 of 6



... TABLET PROVIDES ... HORI  
... ALFAFA, PARSLEY, MARCHALLOW  
... URSI, CORNSILK, MAGNOLIA BARK,  
... SEED, ASTER, CALUS (BAIL CHD),  
... PANICOLATA, NO D'ARCO, GOLDEN  
... AND LICORICE  
... women, especially children, pregnant  
... women, considering any weight-  
... program should consult a physician  
... FORMULATED EXCLUSIVELY FOR  
... HERBALIFE INTERNATIONAL  
... ANGELES, CA 90080-0210, U.S.A.  
... MADE IN U.S.A.

000009

13009 ENMB  
pg 6 of 4



000010

#13009  
EXH B  
pg 10F6

Herbalife, Beige, label contents:

Herbalife  
Thermojetics  
Herbal Tablets/Dietary Supplement  
Beige  
60 Tablets

One Beige Tablet Provides: Hawthorn, Berry, Alfalfa,  
Parsley, Marshmallow Root, Uva Ursi, Cornsilk, Magnolia  
Bark, Fennel Seed, Astragalus (Bai Chi), Pfaffia Paniculata,  
Pao D'Arco, Golden Rod, and Licorice.

Notice: Anyone, especially children, pregnant or lactating  
women, considering any weight control program should consult  
a physician.

Formulated exclusively for: Herbalife International Los  
Angeles, CA 90080-0210, U.S.A. Made in U.S.A.

Lot 107043

Recommended Use: Take one Beige tablet with one to three  
Green Tablets twice a day at 10:00 a.m. and 3:00 p.m. Use  
in conjunction with the Thermojetics Energy Guide.

This herbal product contains no preservatives and no animal  
products.

Colored and protected by a fast-dissolving water-soluble  
beige coating.

30-day money back guarantee

Recycle this bottle

1554-US-06 C 1997 Herbalife International, Inc., U.S.A.

000011

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

**Collection Report**

**For Sample Number: 2528**

<b>Flag</b>	<b>Flag Remarks</b>				
<b>Episode Number</b>	<b>Origin</b>	<b>Basis</b>	<b>Sample Type</b>	<b>FIS Smpl Num</b>	<b>Status</b>
	Domestic	Surveillance	Investigational	98907884	Completed
<b>FEI</b>	<b>Date Collected</b>	<b>Product Code</b>	<b>Responsible Firm</b>	<b>PAC</b>	<b>Hours</b>
3000835908	04-AUG-98	54FCA99	Manufacturer	03F800	5
<b>Related Smpl Num</b>	<b>Position Class</b>	<b>Sampling District</b>	<b>NDC Number</b>	<b>Permit Number</b>	<b>Storage Rqrmt.</b>
	INV	DET-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>	
No				Herbalife	

**Product Description**  
tablets, green-like in color, diet supplement, herbal

**Product Label**  
See continuation.

<b>Reason for Collection</b>	<b>MFG Codes</b>	<b>Expiration Date</b>
Request for F/U from DOEP, CFSAN Project #13009, analyze for ephedrine alkaloids	057230	

<b>Firm Legal Name</b>	<b>Address</b>	<b>Type of Firm</b>	<b>Firm FEI</b>	<b>FCE</b>
Herbalife International Inc	930 E 233rd St Carson, CA 907456203 US	Manufacturer	3000835908	

<b>Size of Lot</b>	<b>Est. Value</b>	<b>Rcpt Type</b>	<b>Date Shipped &amp; Doc. Ref.</b>
114	\$0	FDA484	

**Description of Sample**  
50 tablets collected at random from consumer's bottle

**Method of Collection**  
collected at random from consumer's portion

**How Prepared**  
sample placed in whirl-pak bag, ID and sealed as stated below, prepared for shipment, maintained in locked office until shipment

<b>Collector's Identification on Package and/or Label</b>	<b>Collector's Identification on Seal</b>
"INV2528CAF08/04/98"	"INV2528Cheryl A. Fuhs08/04/98"

<b>Sample Delivered To</b>	<b>Date Delivered</b>	<b>Orig C/R &amp; Records To</b>
[REDACTED]	08/06/1998	DET-DO
	<b>Lab w/Split Sample</b>	<b>Lab</b>
	0	SEA-LAB

<b>Document Number</b>	<b>Document Date</b>	<b>Document Type</b>	<b>Document Remarks</b>
		None	

**Remarks**  
collected from consumer [REDACTED]

<b>Payment Amount</b>	<b>Payment Method</b>	<b>704(d) Sample</b>	<b>702(b) Portion</b>	<b>Collector's Name</b>
\$0.00	No Charge	No	No	Cheryl A Fuhs
<b>Name of Signer</b>	<b>Date &amp; Time of Signature</b>		<b>Meaning</b>	
Cheryl A Fuhs	08/06/1998 01:31 PM		Collector	

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

**For Sample Number: 2528**

**Continuation:**

**Product Label**

tablets collected from consumer's bottle labelled, in part, as follows: "Herbalife\*\*\*Thermojetics Herbal Tablets/Dietary Supplement Original Green 120 tablets\*\*\*Each original green tablet provides. Chinese Ma Huang, Bladderwrack\*\*\*Formulated exclusively for Herbalife International Los Angeles, CA"

FLAG

Pro # 13009

ANALYST WORKSHEET		1. PRODUCT Green tablets		2. SAMPLE NUMBER 2528	
3. SEALS <input type="checkbox"/> NONE		<input checked="" type="checkbox"/> INTACT <input type="checkbox"/> BROKEN		4. DATE REC'D 8/19/98	
		5. RECEIVED FROM		6. DISTRICT OR LABORATORY SEA-DO	
7. DESCRIPTION OF SAMPLE One plastic bag officially sealed "INV2528 08/04/98 Cheryl A. Fuhs", containing 50 tablets. Received at room temperature.					
8. NET CONTENTS		<input checked="" type="checkbox"/> NOT APPLICABLE <input type="checkbox"/> NOT DETERMINED <input type="checkbox"/> UNITS EXAMINED		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 found

code : none found

product : oblong, biconvex green coated tablets with brown herbal interior, 20mm long x 10mm wide x 6mm thick

Analysis : for ephedrine alkaloids by LIB 3996

Results :	mg/g	mg/tab
ephedrine	4.6	4.5
pseudoephedrine	2.0	1.9
<u>methyl pseudoephedrine</u>	<u>trace</u>	<u>trace</u>
total alkaloid	6.5	6.4

RECEIVED  
CLINICAL RESEARCH  
& REVIEW/OSN HFS-452

'98 SEP -2 110:24

'98 AUG 33 110:22

RECEIVED  
CLINICAL RESEARCH  
& REVIEW/OSN HFS-452

11. RESERVE SAMPLE		In original plastic bag, officially sealed "2528 8/24/98 JLBussey", 30 remaining tablets and one heat sealed plastic bag of remaining composite id'd "2528 8/20/98 JLBussey". Returned to sample custodian.	
12. a. ANALYST SIGNATURE ( <input checked="" type="checkbox"/> BROKE SEAL) JLBussey		13. WORK SHEET CHECK	a. BY <i>Dan J. Moskowitz</i>
b.			b. DATE 8/28/98
c.		14. DATE REPORTED 24 Aug 98	