

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

ARMS#

12888



2 - LABEL SAMPLE

000001

Best Quality
FDA

SOURCE NATURAL

DIET-PHENTM

NATURE'S DIET ALTERNATIVE

90 TABLETS

000002



Source Naturals introduces Diet-Phen™, natural diet alternative containing a unique combination of herbal extracts. St. John's Wort can help support a positive mood. Additionally, low levels of ephedra alkaloids may energize the body and heighten cellular metabolism. The amino acid, L-Phenylalanine, is the precursor to a neurotransmitter that helps support an alert state.

WARNING: Contains phenylalanine. Not to be used by phenylketonurics. Do not exceed directed amount. Not to be used if you are pregnant or nursing, have high blood pressure, heart or thyroid disease, diabetes, glaucoma, difficulty in urination due to prostate enlargement, or are taking antidepressant drugs such as MAOI's or SSRI's or any other prescription drug. Reduce or discontinue use if nervousness, tremor, sleeplessness, loss of appetite or nausea occur.

Do not use if either tamper-evident seal is broken or missing.

† **CHROMEMATE**® is a registered trademark of Interhealth Co.

SN996 REV H971

000003

Three tablets contain:	% USRDA
St. John's Wort Extract (<i>Hypericum perforatum</i>)	900 mg
Ma Huang Standardized Extract 8% Yielding 12 mg Ephedra Alkaloids*	150 mg
L-Phenylalanine	500 mg
Acetyl L-Carnitine	50 mg
Niacin (Niacinamide)	25 mg 125%
Vitamin B-6 (Pyridoxine HCl)	25 mg 1250%
Chromium (100 mcg ChromeMate®† Chromium Polynicotinate, 100 mcg Chromium Picolinate)	200 mcg

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SCOTT'S VALLEY, CA 95066

*Each tablet supplies 4 mg ephedrine.

Directions: 1 to 2 tablets in the morning 1/2 hour before breakfast, and one tablet 1/2 hour before lunch, or as recommended by your physician. Do not take before bedtime. Do not exceed 3 tablets daily. For best results, use this product for at least 2 weeks. Not intended for prolonged use or by those under medical supervision. Do not consume alcohol while using this product.

NOT INTENDED FOR USE BY PERSONS UNDER THE AGE OF 18. KEEP OUT OF THE REACH OF CHILDREN.



[REDACTED]
\$26.99

Bottle cap
from [REDACTED]



Diet Phen from

[REDACTED]
the popular herbal alternative to Fen Phen order online or call us at: [REDACTED]

Diet Phen promotes a positive mental attitude while dieting. (See Below). It's main ingredient is the herb St John's Wort.

The best way to lose weight is to modify your diet and exercise regularly! Remember, no pill can replace the benefits of 30 minutes on the exercise bike.

[REDACTED] ships items within one to two business days. Order online or order by phone, fax or mail. Click for order info.

International orders welcome!

other [REDACTED] products on the net:

St John's Wort

DHEA

Melatonin

Ginseng

Essential Oils

Calendula Cream

Herbal Baths

Ear Candles

Herb Teas

Home Page

Product Information

What is Diet Phen

Diet Phen is the popular safe herbal alternative to Fen Phen (the prescription diet pill). Diet Phen is intended to promote a positive mental attitude while dieting and provide a small energy boost. The daily dosage of three tablets contains 900mg of St John's Wort, 12mg of Ephedra, 500mg of L-Phenylalanine, 200mcg of Chromium and a small amount of an amino acid, Niacin and Vitamin B-6.

What is the main ingredient: St John's Wort

St John's Wort is a flowering herb that has long been used to fight anxiety, by promoting relaxation without causing drowsiness. (Newsweek Magazine has called it the natural alternative to Prozac). It's active ingredient is "hypericin." It's use in Diet Phen is intended to reduce the anxiety that often comes from dieting.

Low Dosage Ephedra

Ephedra is an herb used to provide

Price Information

Diet Phen from Source Naturals
\$18.95 90 tablets

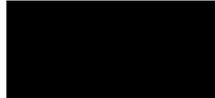
(90 tablets is a month's supply)

Ordering Information

000007



Diet Phen from



the popular herbal
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Internat

000008

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

For Sample Number: 21083

AZMS 12888

Flag	Flag Remarks				
Complaint Sample	This is in f/u to CFSAN Project #12888 in f/u to MEDWATCH #82535				
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Surveillance	Official	98910356	Completed
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
1000102881	09-SEP-98	54FAA99	Manufacturer	09R801	4
Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	INV	LOS-DO			Ambient
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name	
Yes				DIET-PHEN	

Product Description

Dietary Supplement Herbal Tablets.

Product Label

See continuation.

Reason for Collection

Follow up request from Bridgette Wallace for CFSAN Project #12888. Analyze for Ephedrine Alkaloids.

MFG Codes

Not seen.

Expiration Date

Firm Legal Name

Source Naturals, Inc.

Address

23 Janis Way Scotts Valley, CA 95066 US

Type of Firm

Manufacturer

Firm FEI

1000102881

Size of Lot

One previously opened bottle. Took sample from 35 original tablets.

Est. Value

\$26.99

Rcpt Type

FDA484

Date Shipped & Doc. Ref.

98 OCT 20 PM 1:29

Description of Sample

See continuation.

Method of Collection

See continuation.

How Prepared

Sample placed in clear plastic bag and identified as "21083 9/9/98 NMC". It was then placed in a brown paper bag and then sealed as "21083 9/9/98 Nianna M. Capalia".

Collector's Identification on Package and/or Label

"21083 9/9/98 NMC"

Collector's Identification on Seal

"21083 9/9/98 Nianna M. Capalia"

Sample Delivered To

SEA-DO Sample Custodian via Fed-Ex #4172-3753-4814

Date Delivered

09/09/1998

Orig C/R & Records To

LOS-DO

Lab w/Split Sample

0

Lab

SEA-LAB

Document Number

Document Date

09/09/1998

Document Type

Affidavit

Document Remarks

Signed by attorney providing sample.

Remarks

Sample was obtained from complainant's attorney per CFSAN instruction. Attorney would like results mailed to him at c/o

Payment Amount

\$0.00

Payment Method

No Charge

704(d) Sample

No

702(b) Portion

No

Collector's Name

Nianna M Capalia

Name of Signer

Nianna M Capalia

Date & Time of Signature

09/10/1998 11:45 AM

Meaning

Collector

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSR/HFS-452

Continuation:

Product Label

Photo copy of product label provided by attorney as original bottle of tablets was not provided for this sample. Label photocopied reads in part: "****DIET-PHEN***NATURE'S DIET ALTERNATIVE***SOURCE NATURALS, INC.***SCOTT'S VALLEY***CA***0001303 9***\$26.99***"

Description of Sample

Sample consists of 20 brownish oblong tablets approximately 3/4" in length each in a clear whirlpack plastic bag. (Product bottle was not provided by attorney.)

Method of Collection

Sample consists of tablets from one previously opened bottle of DIET-PHEN. Client's attorney provided 20 of the 35 remaining tablets. Tablets were placed in a clear plastic whirl pack bag.

ANALYST WORKSHEET	1. PROJECT <p style="text-align: center;">Diet-Phen</p>	2. SAMPLE NUMBER 21083															
3. SEALS <input type="checkbox"/> NONE <input checked="" type="checkbox"/> INTACT <input type="checkbox"/> BROKEN	4. DATE REC'D 10/2/98	5. RECEIVED FROM [REDACTED]															
6. DISTRICT OR LABORATORY SEA-DO																	
7. DESCRIPTION OF SAMPLE One brown paper bag, officially sealed "21083 9/9/98 Nianna M. Capalia", containing one plastic bag id'd "21083 9/9/98 NMC" with 20 tablets. 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 found code : none found product : mottled brown oblong biconvex tablets Analysis : for ephedrine alkaloids by LIB 3996 Results : <table style="margin-left: 20px;"> <thead> <tr> <th></th> <th>mg/g</th> <th>mg/tab</th> </tr> </thead> <tbody> <tr> <td>ephedrine</td> <td>4.9</td> <td>4.5</td> </tr> <tr> <td>pseudoephedrine</td> <td>trace</td> <td>trace</td> </tr> <tr> <td>methyl pseudoephedrine</td> <td>trace</td> <td>trace</td> </tr> <tr> <td>total alkaloid</td> <td>4.9</td> <td>4.5</td> </tr> </tbody> </table> <p style="margin-left: 100px;">trace trace DO NONE FOUND.</p>				mg/g	mg/tab	ephedrine	4.9	4.5	pseudoephedrine	trace	trace	methyl pseudoephedrine	trace	trace	total alkaloid	4.9	4.5
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RECEIVED
 CLINICAL RESF ARCH
 & REVIEW/OSN HFS-452
 .98 OCT 20 P 1 :29

11. RESERVE SAMPLE In original paper bag, officially sealed "21083 10/6/98 JLBussey", one plastic bag (10 tablets remaining) additionally id'd "10/2/98 JLBussey" and one heat sealed plastic bag of remaining composite id'd "21083 10/2/98 JLBussey". Returned to sample custodian.	
12. a. ANALYST SIGNATURE (<input checked="" type="checkbox"/> BROKE SEAL) JLBussey	13. WORK SHEET CHECK a. BY <i>Janet L. Burke</i> b. DATE <i>10/9/98</i>
c.	14. DATE REPORTED 6 Oct 98