

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

ARMS#

13125



0 - FRONT

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Form Approved OMB No. 0910-0291 Expires 12/31/94 See OMB statement on reverse

Page 1 of 3 CFSAN

ARMS # 13125

Trace unit sequence #	89525
	13099

## A. Patient information

1 Patient Identifier [Redacted]	2 Age at time of event: or Date of birth: 20	3 Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4 Weight ____ lbs or ____ kgs
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## B. Adverse event or product problem

1 <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2 Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other
3 Date of event (mo/day/yr) 7-2-98	4 Date of this report (mo/day/yr) 9-9-98

5 Describe event or problem  
my son was taking these products from [Redacted] & a few from the drug store. He sped his body up so much. He lost weight & quite sleeping. Had headaches & became very talkative. was admitted to hospital soon diagnosed as psychotic Schizophrenia. was put on strong med. took 30 day to get my son released. Released as psychotic Schizophrenia, on strong meds. I did not give him meds & he returned to normal. Because of these things he was misdiagnosed. I'm very angry that we as consumers

6 Relevant tests/laboratory data, including dates  
are not made more aware that thing sold in [Redacted] etc & health food stores can be harmful if taken in large doses. I myself was diagnosed with migraine headaches

7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepato/renal dysfunction, etc.)  
This disappear as these thing were stopped  
"son" - 13099 13125  
"myself"/reporter - 13125

## C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)		
#1 See list		
#2		
2 Dose, frequency & route used		3 Therapy dates (if unknown, give duration) from to (or best estimate)
#1 2 1/2 months		#1
#2 2-3 times daily		#2
4 Diagnosis for use (indication)		5 Event abated after use stopped or dose reduced
#1 To Better Health		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2 & make Stronger		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6 Lot # (if known)	7 Exp. date (if known)	
#1	#1	
#2	#2	
9. NDC # (for product problems only)		
10 Concomitant medical products and therapy dates (exclude treatment of event)		

## D. Suspect medical device

1. Brand name		2. Type of device	
3. Manufacturer name & address		4. Operator of device	
5. Expiration date (mo/day/yr)		7. If implanted, give date (mo/day/yr)	
6. Model #		8. If explanted, give date (mo/day/yr)	
9. Device available for evaluation? (Do not send to FDA)		10. Concomitant medical products and therapy dates (exclude treatment of event)	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (mo/day/yr)		000001	

## E. Reporter (see confidentiality section on back)

Name, address & phone # [Redacted]

2. Health professional?	3. Occupation	4. Also reported to
<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	DATE ENTRY operator	<input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input checked="" type="checkbox"/>		



Mail to: MEDWATCH  
5600 Fishers Lane  
Rockville, MD 20852-9787

or FAX to:  
1-800-FDA-0178

1. DHEA: dehydroepiandrosterone 50mg Vitamin C 15mg

2. Hydroxy Cut:  
 Hydroxagen 2000mg  
 (supplying 1000mg of hydroxycitric Acid)  
 MA Huang Extract 334mg  
 (standardized for 6% ephedra)  
 Guarana Extract 916mg  
 (standardized for 22% Caffeine)  
 Willow Bark Extract 100mg  
 (standardized for 15% Salicin)  
 L-Carnitine 100mg  
 Chromium Piccolinate 300mg

3. Mini Two-way Action Mini Thins  
 25mg Ephedrine HCl  
 200mg Guaitensenin

4. PRO RX  
 Vitamin A, C, D, E, Thiamin, Riboflavin, Niacin  
 Vitamin B-6, Folic Acid, B-12  
 Biotin, Pantothenic Acid, Phosphorus,  
 Iodine, Magnesium, Zinc, Copper,  
 Potassium, Sodium, Protein,  
 Phenylalanine

5. Amino Fuel, L-Carnitine & Branched Chain  
 Amino Acids  
 Protein Amino Acids, <sup>15g</sup> Carbohydrates, 10g  
 L-Alanine - 1200mg L-Arginine 1100, L-Aspartic Acid - 1240mg  
 L-Carnitine - 25mg L-Cystine 919mg, Glycine 3200mg  
 L-Glutamic Acid 2040mg, L-Histidine - 460mg  
 L-Isoleucine 230 L-Leucine 900, L-Lysine, L-methionine  
 Phenylalanine 400mg, Proline 2130, 000002  
 L-Serine 540mg, L-Threonine 480mg  
~~L-Tryptophan~~ 82mg L-Tyrosine 200mg & Valine

The eight essential Amino Acids

The L-tryptophan

B-1, B-2, B-3, B-6 - B-12

Pantothenic Acid, Folic Acid Biotin

PABA Choline Bitartrate

Inositol

6 Diet System

Citrimax (Garcinia) 1500 mg

Kola Nut 550 mg

Guarena Extract 100 mg

Chromium Picolinate 300 mg

Choline Bitartrate 100 mg

Betaine HCl 25 mg

L-Carnitine Complex 300 mg

7 Golden Seal Root

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89525

CFSAN

September 9, 1998

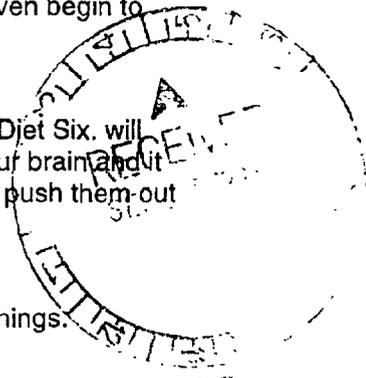
My son had been taking several different drinks from [REDACTED]. Some things were also purchased at the local drug store. He had gotten into the health program real heavy. Wanting to improve myself as well I also was on several of the health improvements. He was drinking some of these drinks 3-4 times a day sometimes more. Thinking that these thing were healthy because the has vitamins and other thing good for the body. As in fact they came from a health food store. More strength more energy and to look good is a plus. So all in all it would make sense that since these thing were good for you and healthy that they are harmless. How far from the truth can this be? Let me tell You. For myself I was diagnosed with migraine headaches. At this point in time I did not contribute it to these drinks and pills. They were good for you. My son keep on until he lost about 20 lbs and was sleeping 2-3 hours a night. Eventually he was not sleeping at all and a lose of appetite. After several day of no sleep no food and talking 90 miles a minute and his thought were getting confused. I took him to a doctor and explained what was going on. He in turn sent us to a hospital. My son ended up in a hospital for 30 day and was put on strong drugs which he had adverse reaction to. I spent 30 days trying to prove his sanity. He was diagnosed as Psychosis Schizophrenia which he is not never has been and hopefully never will be. To get him out of this place I had to promise to keep him on this medication & make an appointment with a Psychiatric doctor who could also prescribe medication. When I got him home I did not give him the medicine because I knew what had happened to him. He had speed his self up on these drinks. I realized also that they were the cause of my little episode. Being off the Halloo, Olanzapine, Verapasmil and cogentin. his doctor can find nothing wrong with him. The thing is if I had not known what had cause my sons reaction I would have kept him on the medication and he would be a nonproductive person today. He was suppose to stay on the medicine for the rest of his life. I feel that the general public needs to be made aware that just because you purchase something in a Health Food Store does not mean it is good for you. The idea of more is better and will make you healthier faster is also a misconcept. My Son and I learned the hard way. Please alert the general public as to what can and will happen with these things. My Son was misdiagnosed and could have been dysfunctional for the rest of his life. If I had not done reasearch on these things and took him off of his medication. I can not even begin to describe the pain, heartache, anxiety. We both lost 30 days of our lives.

From my personal experience mixing ephedrine with Amino Fuel and Djet Six, will make you have severe headaches. It feels as if there is a vise around your brain and it is squeezing it . It will make your eyeballs feel as if something is trying to push them out of your head. You will not be able to tolerate noise.

Something needs to be done to educate the general public about these things.

Thank You  
[REDACTED]

Home: [REDACTED]  
Business: [REDACTED]



REC'D.

SEP 1 8 1998

MEDWATCH CTU

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89525



*FROM THE DESK OF*  
Gerald Mierle, Investigator  
Food and Drug Administration

**MEMORANDUM**

Date: 8 March 1999

From: Gerald Mierle

Subj: MedWatch # 13125 Documents

To: Bridgette M. Wallace, ARMS Monitor, HFS-636

Attached are the Investigational Records of MedWatch # 13125 as requested. The investigation included WedWatch # 13099 also with its records sent under separate cover. The mother of the patient in MedWatch # 13099 submitted MedWatch # 13125 and # 13099.

All of the records for MedWatch #13125 were collected from the patient or her doctor's office. Ms. [REDACTED] stated in an interview at her place of employment on 5 May 1999 that she had taken some of her son's ephedra containing products and also she had given him some of her prescription Ephedrine. The clinical records reviewed on Ms. [REDACTED] cover a single visit to an allergist because of a possible sinus infection. He did not prescribe any ephedrine containing products.

**ATTACHMENTS:**

1. Assignment dtd November 10, 1998
2. Authorization For Medical Records Disclosure dtd 5 March 1999
3. Adverse Event Questionnaire dtd 5 March 1999

**EXHIBITS:**

1. Unpurged Medical Records on patient identified in MedWatch # 13125

Gerald Mierle, CSO  
[REDACTED]

**Distribution:**

ORIG: Wallace, HFS-636  
CC: Kevin Morrow, BLT-DO, R&E  
BLT-DO, [REDACTED]  
Wallace, HFS-636 (Additional Copy)

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ARMS #13125

FROM THE DESK OF  
Gerald Mierle, Investigator  
Food and Drug Administration

MEMORANDUM

Date: 8 March 1999

From: Gerald Mierle

Subj: MedWatch # 13099 Documents

To: Bridgette M. Wallace, ARMS Monitor, HFS-636

Attached are the Investigational Records of MedWatch # 13099 as requested. The investigation included WedWatch # 13125 also with its records sent under separate cover. The mother of the patient in MedWatch # 13099 submitted MedWatch # 13125 and # 13099.

All of the records for MedWatch #13099 were collected from the patient's Lawyer [REDACTED] She is a partner with the firm of:

[REDACTED]

[REDACTED]

Ms. [REDACTED] has control of the medical records, Nutritional Supplements, and empty containers. She had interviewed the patient in MedWatch # 13099. When I contacted the mother she had referred me to the lawyer's office. Ms. [REDACTED] was informative and copied all of the pertinent medical records in this investigation for the FDA. She also copied the labeling of the "Hydroxycut" and the "Mini Two Way Action" Tablets, both of which contain ephedrine. She also gave 20 tablets of the "Mini Two Way Action" as a sample. Receipt for sample was issued for the sample and documents. Ms. [REDACTED] signed an "Authorization For Medical Records Disclosure" for the patient. The Sample is being held at the Richmond R.P. under Lock and Key awaiting determination as to where it should be sent for analysis.

The sample was marketed by: BDI Pharmaceuticals, a division of Body Dynamics, INC A check of the national OEI lists the mfr type for Body Dynamics, Inc. as "D 53" & "L 60", CFN as 1831179, last EI date as 4/28/93 with Inspection conclusion as "A C" with reschedule date of "08/94" Priority "1".

ATTACHMENTS:

1. Assignment dtd November 10, 1998
2. Authorization For Medical Records Disclosure dtd 4 March 1999
3. Adverse Event Questionnaire dtd 4 March 1999

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4. FDA 484 Receipt for Sample dtd 4 March 1999
5. OEI Print Screen for Body Dynamics, Inc.

EXHIBITS:

1. Unpurged Medical Records on patient identified in MedWatch # 13099
2. Labeling for "Hydroxycut" lot # 36921 10/99
3. Labeling for "Mini Two Way Action" lot # 98F0396 6/00
4. Confidentiality Statement for [REDACTED] to Law Firm

Gerald Mierle, CSO  
[REDACTED]

Distribution:

ORIG: Wallace, HFS-636  
CC: Kevin Morrow, BLT-DO, R&E  
BLT-DO, [REDACTED]  
Wallace, HFS-636 (Additional Copy)

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## Adverse Event Questionnaire

Complaint Number: 13125

Investigator: Gerald Meale

Consumer Information		
Date of Report: <u>3/5/99</u> MM/DD/YY	Initial Report Source: <input type="checkbox"/> ORA Consumer Injury	
<input type="checkbox"/> Telephone <input type="checkbox"/> Correspondence <input checked="" type="checkbox"/> MedWatch <input type="checkbox"/> USP <input type="checkbox"/> PQRS <input type="checkbox"/> Poison Control <input type="checkbox"/> CDC		
Name: <span style="background-color: black; color: black;">[REDACTED]</span>	Gender: <input checked="" type="checkbox"/> F <input type="checkbox"/> M	Age: <u>43</u>
Race: <input checked="" type="checkbox"/> 1-White <input type="checkbox"/> 2-Black <input type="checkbox"/> 3-Asian/Pacific Islander <input type="checkbox"/> 4-Native American <input type="checkbox"/> 5-Hispanic <input type="checkbox"/> 8-Other <input type="checkbox"/> 9-Unknown		

Information on Adverse Event	
Date of Adverse Event: Previous Adverse Effects to Product Type: <input type="checkbox"/> Yes <input type="checkbox"/> No	Give the site of consumption/ingestion (e.g. home, restaurant, office): <u>Home</u>

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):  
*Extreme Headache with eye pain (both felt as if there was extreme pressure inside). About 1 week after starting to take a pill that she believes contained Ma Huang and prescription Ephedrine.*

How long did the symptoms last?  
*etc.). Took 2 Tabs BID of prescription med Ephedrine.*

Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.):  
*Took 2-3 Tabs Q 3-4H of the OTC product from [REDACTED] (Exercise Section)*

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:

Did event abate after use of suspected product stopped or dose reduced: Yes No Unknown  
 Did symptoms reoccur after reintroduction of suspected product: Yes No Unknown Not Applicable  
 Did symptoms reoccur after using other products with the same ingredients: Yes No Unknown Not Applicable

Medical Information
Was a health care provider seen?: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Give health care provider's name, address and telephone number: <u>Dr. [REDACTED] MD Allergist</u>
Occupation of Health Care Provider: <input type="checkbox"/> MD <input type="checkbox"/> Osteopath <input type="checkbox"/> Naturopath <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input checked="" type="checkbox"/> Other (specify) <u>Allergist</u>
What medical tests were performed and what were the results? <u>None</u>
What was the medical diagnosis? <u>Migraine</u> What treatment(s) was given (e.g., drugs, other)? <u>Ephedrine</u>
Were there any preexisting condition(s)/treatment(s)? <u>Want to See M.D. do to Headaches</u> (If YES, list them including allergies, and chronic diseases): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

*Thought they were allergies.*

**Product Category**

1. Adverse event attributed to:

Medical Food (under medical supervision)  Infant Formula

Dietary Supplement (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzolic acid, and rutin; and mixtures of these ingredients.)

Other (traditional food) \_\_\_\_\_

**Other Product Problems**

2.  Foreign Object  
(specify): \_\_\_\_\_

3.  Other (specify): \_\_\_\_\_

**Information on Suspected/Alleged Product**

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label): Unknown -

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):

Check here if ingredients are unknown

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

Aspartame

Monosodium Glutamate

Sulfite

Other \_\_\_\_\_

Unknown

Color Additive (please specify) \_\_\_\_\_

Is the product label available, if yes submit a quality copy along with this questionnaire:  Yes  No  Unknown  
Product Sample Available:  Yes  No  Unknown

**Outcome Attributed to Adverse Event:**

(if yes, include pertinent medical records)

Death:  Yes  No

Life-Threatening:  Yes  No

Hospitalization:  Yes  No (if YES, indicate if initial or prolonged) \_\_\_\_\_

Required intervention to prevent permanent impairment/damage:  Yes  No

Did the adverse event result in a congenital anomaly:  Yes  No

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