

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

ARMS#

12888



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

FDA Use Only

Triage unit sequence #	82535
	12888

Page ___ of ___

CFSAN

A. Patient information

1. Patient identifier: [redacted] In confidence

2. Age at time of event: 41 or Date of birth: [redacted]

3. Sex: female male

4. Weight: 147 lbs or ___ kgs

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):
 death (mo/day/yr)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other: _____

3. Date of event (mo/day/yr): 12/25/97

4. Date of this report (mo/day/yr): 4/27/98

5. Describe event or problem:
 This patient has had an extraordinarily complex and serious condition which began Dec 25, 1997, when she presented with her first of 4 separate stroke events.
 1st stroke - Dec 25, 1997 - affecting left side.
 2nd stroke - Jan 5, 1998 - " Right side (4) speech.
 3rd stroke - Feb 5, 1998 - " left side more speech.
 4th stroke - Feb 25, 1998 - leaving her at the time essentially quadriplegic and aphonic due to profound brain stem compromise.
 Once doctors were informed that she had taken the herb Ma Huang, they were certain that it was the primary cause of her strokes.
 Presently she is in out patient re-hab for speech, physical and occupational work.

6. Relevant tests/laboratory data, including dates:
 She has had to date approx. 7 MRA's, 1-Angiogram, Echo Cardiogram, (several) Cat scans. (several) Blood test - continuous to present. Ultra Sounds (TCD's) Continuous to present.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc):
 Borderline high blood pressure - at time that she took Diet pill - it was under control.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known): #1 Diet-Phen "Ma Huang 150mg. Yielding 1mg Alkaloid Ephedra. Source: Naturals, Inc Scotts Valley CA 95066

2. Dose, frequency & route used: #1 1 to 2 tablets morning & 1 tablet before lunch. Not to exceed 3/day

3. Therapy dates (if unknown, give duration) from/to (or best estimate): #1 1 month and 1/2

4. Diagnosis for use (indication): #1 Dietary Supplement. Naturals Diet Alternative.

5. Event abated after use stopped or dose reduced:
 #1 yes no doesn't apply
 #2 yes no doesn't apply

6. Lot # (if known): #1 731712 (?)

7. Exp. date (if known): #1 N/A.

8. Event reappeared after reintroduction:
 #1 yes no doesn't apply
 #2 yes no doesn't apply

9. NDC # (for product problems only): -

10. Concomitant medical products and therapy dates (exclude treatment of event):

D. Suspect medical device

1. Brand name: MEDWATCH

2. Type of device:

3. Manufacturer name & address: REC'D. MAY 16 1998

4. Operator of device:
 health professional
 lay user/patient
 other:

5. Expiration date (mo/day/yr):

6. Model #:

7. If implanted, give date (mo/day/yr):

8. If explanted, give date (mo/day/yr):

9. Device available for evaluation? (Do not send to FDA)
 yes no returned to manufacturer on (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event): RECEIVED MAY 08 1998 000001

E. Reporter (see confidentiality section on back)

1. Name, address & phone #:

2. Health professional? yes no

3. Occupation:

4. Also reported to:
 manufacturer
 user facility
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



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

or FAX to:
 1-800-FDA-0178

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

The public reporting burden for this collection of information has been estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send your comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to

Reports Clearance Officer, PHS
Hubert H. Humphrey Building,
Room 721-B
200 Independence Avenue, S.W.
Washington, DC 20201
ATTN: PRA

and to:
Office of Management and
Budget
Paperwork Reduction Project
(0910-0230)
Washington, DC 20503

Please do NOT
return this form
to either of these
addresses.

FDA Form 3500-back

Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business

Penalty for Private Use \$300



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OR APO/FPO

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MEDWATCH

The FDA Medical Products Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

RECEIVED
CLINICAL RESEARCH & REVIEW/OCS/HFS-452
MAY 12 10:52 AM '98



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Adverse Event Questionnaire

Complaint Number: _____

Investigator: Nianna M. Capalia

Consumer Information	
Date of Report: <u>7/13/98</u> MM/DD/YY	Initial Report Source: <input checked="" 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: [REDACTED]	Gender: <input checked="" type="checkbox"/> F <input type="checkbox"/> M Age: 42 DOB: [REDACTED]
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: <u>12/25/97; 1/5, 2/5, 2/15/98</u>	Give the site of consumption/ingestion (e.g. home, restaurant, office):
Previous Adverse Effects to Product Type: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Last consumption on <u>12/24/97, 1:00pm at 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): (See attachment)	
How long did the symptoms last? Symptoms are still being experienced. Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.). (See attachment)	
List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used <u>at the time</u> of the event: None	
Did event abate after use of suspected product stopped or dose reduced: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown Did symptoms reoccur after reintroduction of suspected product: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input checked="" type="checkbox"/> Not Applicable Did symptoms reoccur after using other products with the same ingredients: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input checked="" type="checkbox"/> 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: (See attachment)	
Occupation of Health Care Provider: <input checked="" type="checkbox"/> MD <input type="checkbox"/> Osteopath <input type="checkbox"/> Naturopath <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other (specify) _____	
What medical tests were performed and what were the results? (See attachment)	
What was the medical diagnosis?	"
What treatment(s) was given (e.g., drugs, other)?	"
Were there any preexisting condition(s)/treatment(s)? See medical records for [REDACTED] (If YES, list them including allergies, and chronic diseases): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	

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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-benzoic 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):

(See attachment)

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

Check here if ingredients are unknown

St. John's Wort Extract, Ma Huang Standardized Extract, L-Phenylalanine,
Acetyl L-Carnitine, Niacin, Vitamin B-6, and Chromium.

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

Aspartame Color Additive (please specify) _____

Monosodium Glutamate

Sulfite

Other MaHuang

Unknown

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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Adverse Questionnaire (IOM Exhibit 910-D) - Additional Comments

Complaint Number: CFSAN Project #12888

Investigator: Nianna M. Capalia

Date: July 10,1998

*The following comments correspond to questions listed in the Adverse Questionnaire.

Information on Adverse Reaction

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):

The following information is what I learned from Ms. [REDACTED] "victim", and [REDACTED] father. I was at Ms. [REDACTED] home on 7/2/98.

Ms. [REDACTED] took her last pill on Christmas Eve, December 25th, at approximately 1:00pm in the afternoon. She stayed up until 1:00am, then Christmas morning, playing cards with her family. She went to sleep and awoke at 2:30am with beginning of stroke symptoms..

At 2:30am, Ms. [REDACTED] right eye started hurting. Ms. [REDACTED] then walked over to the bathroom to get eye drops. On the way back from the bathroom, Ms. [REDACTED] had trouble walking back to her bed as she said the left side of her body was "not functioning." She then called for her daughter who was sleeping on the floor (as family was over for the holiday and were in other rooms of the home.) The daughter called for Ms. [REDACTED] father in the next room, and the father phoned the paramedics.

Ms. [REDACTED] said she did not feel any pain. She could not walk and could not move her left arm and her left hand; her hand was in a ball/fist position. When the paramedics arrived and she was talking with them. Ms. [REDACTED] said her voice was slurry and she was trying to convince the paramedics that she was not drunk because of her slurred voice.

Ms. [REDACTED] said she had suffered three more strokes since the first one. She said these strokes were on January 5th, February 5th, and February 25th.

Hospitalizations:

Ms. [REDACTED] first hospitalization was from December 25th through January 16th. She was at three facilities during this time; [REDACTED] (12/25-26/98), [REDACTED] until 12/29/98), and [REDACTED] (until 1/15/98).

Ms. [REDACTED] second hospitalization, 2/5/98 at [REDACTED] was immediately after her second stroke. Since the family wanted to get a second opinion for the cause of these strokes, she was transferred to [REDACTED] She and her father said that [REDACTED] linked

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her strokes possibly to the consumption of the dietary supplement she was taking containing Ma Huang. Her health is now monitored under the care of the [REDACTED]

Ms. [REDACTED] and Mr. [REDACTED] provided me a copy of a letter by Dr. [REDACTED] of [REDACTED] that was sent to her health benefits provider. This letter summarizes her past and current health conditions.

(Exhibit #1 - Copy of Letter)

How long did the symptoms last?

If the four strokes were a result of the Diet Phen, Ms. [REDACTED] is still recovering from the symptoms. She has suffered four strokes as a result of the product. After the last stroke, she was left temporarily paraplegic. She is now walking with a cane, though speech is still slurry and some movements are still not back to as they were before the first stroke.

Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.)

[REDACTED] had used a product called DIET-PHEN manufactured by Source Naturals, Inc. of Scott's Valley, CA. She had consumed approximately a bottle and a half for over a month until she experienced her first of four strokes. Each bottle contained 90 capsules and she started taking the product sometime in November. Ms. [REDACTED] does not recall exactly when. She said she took the product as directed three times per day; two in the morning at approximately 6:30am and one in the afternoon between 1:00 and 3:00pm. The purpose of taking this product was to try to lose some weight.

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

No other medications or dietary supplements were taken around the time of this event. On Christmas Eve, Ms. [REDACTED] and her family ate steak that was medium to well done, salad, and noodles.

Medical Information

Give health care provider's name, address, and phone number:

1. [REDACTED]
2. [REDACTED]

(Exhibit #3)

3. [REDACTED]

(Exhibit #4)

4. [REDACTED]

(Exhibit #5 - inpatient records)
(Exhibit #6 - outpatient records)

5. [REDACTED]
(Exhibit #7)

What medical tests were performed and what were the results?

See attached medical records.

Where there any preexisting condition(s)/treatment(s)?

Ms. [REDACTED] said there were none. Previous medical records to the 12/25/97 incident from [REDACTED] are attached.
(Exhibit #8)

Information on Suspected/Alleged Product

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

Attached is a copy of the label, other product information, and forwarding letter to Ms. [REDACTED] second attorney. This was all obtained form the first lawyer with whom Ms. [REDACTED] consulted, [REDACTED]. While I was at Mr. [REDACTED] office, Mr. [REDACTED] informed me the case has been forwarded to attorney [REDACTED].
(Exhibit #9)

[REDACTED]

The label reads in part:

“***SOURCE NATURALE***DIET-PHEN***NATURE’S DIET ALTERNATIVE***90 TABLETS***Source Naturals Introduces Diet-Phen, nature’s 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.

Directions: 1 to 2 tablets in the morning ½ hour before breakfast, and one tablet ½ 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.

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.

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

Other: Ma Huang Extract.

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12888

[REDACTED]

[REDACTED]

[REDACTED]

June 5, 1998

[REDACTED]

[REDACTED]

RE: [REDACTED]

Dear [REDACTED]:

Enclosed please find copies of the bottle labels from the Diet Phen product which Ms. [REDACTED] was taking prior to her four (4) strokes. I am also enclosing copies of various articles which were taken from the Internet regarding the "MaHuang" ingredient (ephedra).

As we discussed, Ms. [REDACTED] began taking the Diet Phen product in November and consumed three (3) pills a day (totalling approximately 130 tablets) until December 25, 1997 when she suffered the first of four strokes.

Please give me a call once you have had an opportunity to look into this matter.

Very truly yours,

[REDACTED]

[REDACTED]

By: [REDACTED]

[REDACTED]

Enclosures

000009

Department of Health and Human Services
U.S. Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612
Los Angeles District

Rec'd by (DOEP)
7/17/98

MEMORANDUM

Date: July 15, 1998
From: Nianna Capalia
cc: Linda Hartley
To: Bridgette M. Wallace
Subject: CFSAN Project #12888

Per your request, attached is follow-up to the "Diet-Phen Ma Huang" assignment. Enclosed are copies of medical records and labeling, and the filled Adverse Event Questionnaire.

The consumer listed on the assignment, [REDACTED] is the sister of the person who used the Diet-Phen product. Ms. [REDACTED] home is in [REDACTED] and is currently there now. At the time of reporting to Med-Watch about this incident, she had been staying with her sister, Ms. [REDACTED] who was slowly recovering from her four strokes.

Ms. [REDACTED] resides at [REDACTED]. At the time of my visit, 7/2/98, Ms. [REDACTED] father, [REDACTED] was at the residence. These two people gave me information for the Adverse Reaction Questionnaire, the addresses of the five hospitals from which medical records were to be collected, and the lawyer's address to collect copies of labeling.

On 7/2/98, Ms. [REDACTED] said that she would be leaving on 7/10/98 for approximately a month and a half to visit her sister in [REDACTED]. During this time, Mr. [REDACTED] will go back to his home in [REDACTED].

Attached is 1) Copy of CFSAN project # 12888, 2) Filled Adverse Event Questionnaire with attached Additional Comments sheet, and 3) Exhibits.

Please do not hesitate to contact me should you have any further questions. My phone number is 949.798-7743.

Nianna M. Capalia
Nianna M. Capalia

98 JUL 16 P 2:55

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-452

000010

To: lal@nicks, mlj@ni... k6c@nicks
From: Bridgette Wallace@...P@FDA.CFSAN
Certify: Y
Subject: Fwd: Death - f/u MaHuang Diet Phen Assignment
Date: Wednesday, December 2, 1998 at 1:35:49 pm EST
Attached: None

Comments:
Please let me know. thx.

----- Original Message -----
To: Bridgette Wallace@OFP@FDA.CFSAN
Cc: Vincent Iacono@LOS@FDAORAPAR
From: Nianna M. Capalia@LOS@FDAORAPAR
Date: Tuesday, December 1, 1998 at 1:50:20 pm PST
Attached: None

I have just received a phone call in follow up to your CFSAN assignment (Diet-Phen Ma Huang assignment, project #12888, completed 7/15/98.)

The caller was [REDACTED] father of [REDACTED] had suffered four strokes in late 1997/early 1998 after ingesting a product called "Diet Phen" for over a month, as directed.

Mr. [REDACTED] phoned to say that his daughter, Ms. [REDACTED] passed away October 17. She supposedly suffered an aneurism due to a main blood vessel in the brain bursting. Ms. [REDACTED] was still recouping from her recent strokes and staying in [REDACTED] with her sister since 7/10/98. Ms. [REDACTED] is survived by a 12 year old daughter.

Mr. [REDACTED] lives in [REDACTED] and will be visiting [REDACTED] in three weeks. He said he could gather the medical records from his surviving daughter in [REDACTED] and bring them to give to us when he is in [REDACTED]. Please let me know if and how you would like to me to follow up.

Nianna Capalia
LOS-DO
949.798-7743

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