

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

ARMS#

13167



0 - FRONT

CDER

Individual Safety Report



For VOI by health events

Page

CDER

13167

Expires 12/31/96

9

A. Patient information

1. Patient Identifier: [REDACTED]
 In confidence

2. Age at time of event: 45
 or Date of birth: _____

3. Sex: female male

4. Weight: 200 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) disability
 life-threatening congenital anomaly
 hospitalization required intervention to prevent permanent impairment/damage
 other _____

3. Date of event (mo/day/yr): _____

4. Date of this report 9/11/98 (mo/day/yr)

5. Describe event or problem
 Patient experienced hypertensive crisis (220/120) after taking Metabolife three times a day for five days. Patient was hospitalized and after the medication was discontinued, her blood pressure returned to normal.

6. Relevant tests/laboratory data, including dates
 Blood pressure of 220/120

7. Other relevant history, including pre-existing medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
 Patient has history of hypertension. Patient is Caucasian, non-smoker, no alcohol use, no known allergies.

SEP 11 1998 9:10
 SEP 11 1998
 MEDWATCH CTU

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
 #1 Metabolife, Metabolife Internat'l Incorporated
 #2 _____

2. Dose, frequency & route used
 #1 1 tab T.I.D.
 #2 _____

3. Therapy dates (if unknown, give duration) from to (or best estimate)
 #1 5 days
 #2 _____

4. Diagnosis for use (indication)
 #1 weight loss
 #2 _____

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

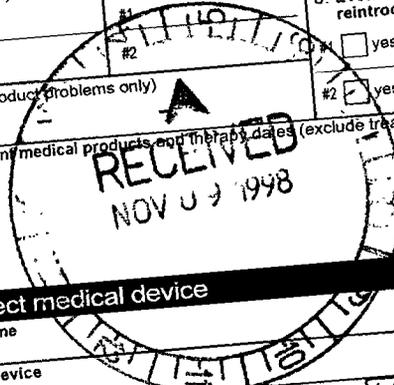
6. Lot # (if known) #1 F858 #2 _____

7. Exp. date (if known) #1 _____ #2 _____

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

9. NDC # (for product problems only) #1 _____ #2 _____

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



D. Suspect medical device

1. Brand name _____

2. Type of Device _____

3. Manufacturer name & address _____

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

5. Expiration Date (mo/day/yr) _____

6. model # _____
 catalog # _____
 serial # _____
 lot # _____
 other # _____

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)

E. Reporter (see confidentiality section on back)

1. Name & Address [REDACTED] phone # [REDACTED]

2. Health professional? yes no

3. Occupation: Physician

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.

FDA

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event

MEDWATCH PRODUCTS REPORTING FORM

Taken By Telephone

000001

CTU 89199

Adverse Event Questionnaire

Complaint Number: _____

Adverse Event Project # 13167

HELEN BESTER

3/26/99 HRB

Consumer Information

Date of Report: 3/25/99
MM/DD/YY

Initial ~~Attachment~~ # 2 Pg 1 of 4

Telephone Correspondence MedWatch
 USP PQRS Poison Control CDC

Name: _____

Gender: F M

Age: 46

Race: 1-White 2-Black 3-Asian/Pacific Islander 4-Native American 5-Hispanic
 8-Other 9-Unknown

Information on Adverse Event

Date of Adverse Event: 9/9/98
Previous Adverse Effects to Product Type:
 Yes No

Give the site of consumption/ingestion (e.g. home, restaurant, office): home

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):

Learned of "Metabolife" product during a pharmacist appointment and was told that it could be purchased at "_____". On my way home I stopped to

How long did the symptoms last?

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

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

estradiol (hormone replacement)

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

symptoms did reoccur but no more products injected.

Was a health care provider seen?: Yes No

Give health care provider's name, address and telephone number: SEE Exhibits 1, 2 & 4

Occupation of Health Care Provider: MD Osteopath Naturopath Nurse Pharmacist
 Other (specify)

What medical tests were performed and what were the results? SEE Exhibits 1, 2 & 4

What was the medical diagnosis? SEE Exhibits 1, 2 & 4

What treatment(s) was given (e.g., drugs, other)? SEE Exhibits 1, 2 & 4

Were there any preexisting condition(s)/treatment(s)? SEE Exhibits 1, 2 & 4
(If YES, list them including allergies, and chronic diseases): Yes No

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Make my initial purchase. The product was sold out of the back of the shop. I was told to make my check payable to _____ in the amount of \$42.95. I took 3 pills that day about 2:00 pm. The next day I took 2 pills in the morning and 2 more that night. I did the same on 9/6/98 and on 9/7/98. When I went to work at 11:00 pm on 9/7/98 I complained to the Pharmacist of a severe headache and feeling over treated. He suggested that I take my blood pressure and it was higher than normal and in the 397

3/26/99 HRB

ATTACHMENT # 2 Pg 2 of 4

high range according to him. I ~~took~~ cut my pills back to 1 pill in the morning and 1 at night on 9/8/98. That night I had another headache which was even more severe than the previous night. Again we checked my blood pressure and it was even higher than the night before.

After the completion of my 11 p.m. to 7:00 a.m. shift of 9/8/99, I went home still suffering from the severe headache and went straight to bed.

Upon waking up that afternoon I had a headache so severe that I began to panic. I placed a call to my sister who is married to a doctor to ask for advice. When she answered the phone I was crying to the point that she could neither recognize who I was nor what the problem was.

Once I was able to communicate with her she asked me what my blood pressure was. I told her and she told me to go straight to the hospital immediately and asked me if there was anyone available to drive me. There wasn't, so I drove myself. Upon my arrival at the hospital I told them of the events and they immediately started me on an IV and admitted me to the intensive care unit overnight. Dr. [REDACTED] was the admitting doctor.

Later I was seen by Dr. [REDACTED] and Dr. [REDACTED]. Dr. [REDACTED] discussed in detail my family history and I was sent for a chest xray, ~~and~~ CT Scan, EKG, and drew blood. ~~At~~ At some point I was told

000003

3/26/99 HRB

of records # 2 Pg 3 of 4

told that my blood pressure was high enough that if I had waited longer to come in that either a heart attack or stroke was imminent^{op?} The next morning Dr. [REDACTED] came back and told me that he was placing me on Norvasc to control my blood pressure and that they had discovered that I had a hypoactive thyroid. He prescribed Levoth for this condition. I was then discharged and told to schedule a follow up visit with either Dr. [REDACTED] or Dr. [REDACTED]. I chose Dr. [REDACTED]. I was given some samples of medicine.

On Friday, Sept. 11, 1998, I went to [REDACTED] to have my prescriptions filled, pick up my check and turn in my insurance claim. While there I began suffering with another severe headache and flushed with heat. Again we checked my blood pressure and it was extremely high. I called Dr. [REDACTED] office again and was instructed to come directly to his office.

Upon my arrival they began monitoring my blood pressure. I was given medication to reduce the pressure. He gave me a oral morphine tablet and told me to take it as soon as I got home. He also told me to not to return to work for another 3 days.

I continued seeing Dr. [REDACTED] for blood pressure monitoring and medication refills through the end of 1998.

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Due to an insurance plan modification to a PPO plan I switch my general practitioner to Dr. [REDACTED]. On Sunday, March 14, 1999 I suffered with severe vertigo.

3/26/99 HRB

ATTACHMENT # 2 Pg 4 of 4

pain. I saw Dr. [REDACTED] on Monday March 15, 1999 and was given an EKG. He sent me directly to [REDACTED]

[REDACTED] I was given a stress test and was released on the afternoon of March 17, 1999.

I was also diagnosed with Hypercalcemia at a level of 11.2 and have been referred to Endocrinologist, [REDACTED]

[REDACTED] I will see her on April 19, 1999. I will follow up with Dr. [REDACTED] (Cardiologist. [REDACTED])

[REDACTED] on April 14, 1999.

I was given a complete physical in Dr. [REDACTED] office on Wednesday, March 24, 1999.

I am suffering with severe fatigue. My test results are expected on Tuesday, March 30, 1999.

Note: Product was returned and I was given a full cash refund.

[REDACTED]
3/25/99

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): *Metabolife*

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):

The product was not available for review. The consumer returned the product for a full refund.

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 *Ephedra sinense L (ma huang)*
- 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) *Medical records attached to the report.*

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

Adverse Event Project # 13167

3/26/99 HRB

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