

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

ARMS#

12978



0 - FRONT

# MEDWATCH

For VOLUNTARY report by health professionals of events and product problems

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page \_\_\_ of \_\_\_

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### A. Patient information

1. Patient Identifier [Redacted]	2. Age at time of event: 4/15/96 or Date of birth: [Redacted]	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.  Adverse event and/or  Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

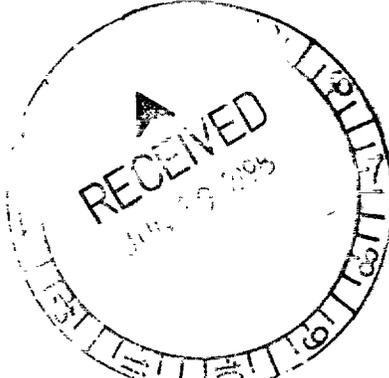
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

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

4. Date of this report (mo/day/yr) 5/18/96

5. Describe event or problem

Severe Hypertension  
Infarction of tips of toes



6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

HTN.  
Smoking  
Obesity

### C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Metabolife 1889 356 Diet

#2

2. Dose, frequency & route used

#1 1 PO QID

#2

3. Therapy dates (if unknown, give duration from to (or best estimate))

#1 Several weeks

#2

4. Diagnosis for use (indication)

#1 obesity

#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 ~~2808~~

#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)

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

Needed to add ASA & Procardia to ↓ BP & stop spasm of distal arteries

### 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 #

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)

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

1. Name & address 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.

PLEASE TYPE OR USE BLACK INK



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

or FAX to:  
1-800-FDA-0178

85031

Adverse Reaction Questionnaire

Complaint Number: CFSAN Project # 12978

Investigator: Jean T. Briones

Consumer Information	
Date of Report: <u>05/18/98</u> MM/DB/YY	Initial Report Source: <input type="checkbox"/> ORA Consumer Injury <input type="checkbox"/> Telephone <input type="checkbox"/> Correspondence <input type="checkbox"/> MedWatch <input type="checkbox"/> USP <input type="checkbox"/> PQRS <input type="checkbox"/> Poison Control <input type="checkbox"/> CDC
Name: [REDACTED]	Gender: <input type="checkbox"/> F <input checked="" type="checkbox"/> M Age: <u>56</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 Reaction	
Date of Adverse Reaction: <u>04/15/98</u>	Give the site of consumption/ingestion (e.g. home, restaurant, office): <u>Home</u>
Previous Reaction to Product Type: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
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): <u>Noticed a loss of circulation in both his legs about the same time he began taking the product.</u>	
How long did the symptoms last? <u>6 weeks.</u>	
Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.): <u>After 6 weeks, saw doctor about his legs; stopped taking product; symptoms subsided after two weeks. Had been taking 6 pills a day for 6 wks.</u>	
List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: <u>Back medications: vicatin, soma, has used these on and off for back pain without problems.</u>	
Did event abate after use of suspected product stopped or dose reduced: <input checked="" type="checkbox"/> Yes <input 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: [REDACTED]	
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? <u>see records.</u>	
What was the medical diagnosis? What treatment(s) was given (e.g., drugs, other)?	
Were there any preexisting condition(s)/treatment(s)? (If YES, list them including allergies, and chronic diseases): <u>Back pain &amp; medications indicated above.</u>	

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Product Category

Adverse reaction to:

Medical Food (under medical supervision)  Infant Formula

Dietary Supplement (a vitamin; an essential mineral; a protein; a herb or similar nutritional substance 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, gamma-aminobutyric 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 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 label.*

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

Check here if ingredients are unknown

*See label.*

If a particular ingredient is suspected of contributing to the reaction, 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 reaction result in a congenital anomaly:  Yes  No

RECEIVED  
CLINICAL RESEARCH  
& REVIEW/OSN HFS-452

000003

[REDACTED]

September 11, 1998

Attention: Joan Briones  
Department of Health and Human Services  
FDA Sacramento Resident Post  
801 I Street, Room 443  
Sacramento, CA 95814

Dear Ms. Briones:

Included with this letter are copies of chart notes regarding the two patients with adverse outcome secondary to MetaboLife. They have both agreed to be contacted.

The first patient is [REDACTED] whose phone number is [REDACTED]. The second patient is [REDACTED], and she can be reached at [REDACTED]

I hope the FDA can be of some help in getting this product off the market. It is very heavily advertised in our area and since my complaints to the FDA, I have seen several other patients with tachycardia secondary to this product. If you have any questions please call me at [REDACTED] Thank you for your help.

Sincerely,  
[REDACTED]

CFSAN PROJECT #s 12978,  
12979  
SAN TRAIL3 # 98-1432  
JTB  
Exhibit 1, 1 of 1

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