

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

ARMS#

13405



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CFSAN

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

CFSAN

CFSAN

Form Approved: OMB No. 0910-0291 Expires: 4/30/99
See OMB statement on reverse

FDA Use Only

Trigger unit sequence #	98840
	13405

A. Patient information

1. Patient Identifier	2. Age at time of event: 36 or Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input 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	<input type="checkbox"/> disability
<input checked="" type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other

3. Date of event: 03-05-99
4. Date of this report: 03-05-99

5. Describe event or problem (up to a total of 6400 characters allowed)

36 year old female with past medical history of SVT (SUPRA VENTRICULAR TACHYCARDIA), drank a pepsi cola and took a capsule of Metabolife 356 for breakfast. Within 30 minutes, she had an episode of SVT. She arrived in the Emergency Department in SVT with a heart rate 190 and a blood pressure of 154/116. By the time the physician examined her she has spontaneously converted into a tachycardia of 105, and her blood pressure subsequently became normal. The physician called the poison control center to find out the formulation of the product since the patient did not bring the container to the emergency department. According to poisindex volume 100, it contains among other things: chromium picolinate 75mcg, guarana concentrate, ma huang concentrate, spirulina algae.

6. Relevant tests/laboratory data, including dates (a total of 1000 characters allowed)

EKG showed supraventricular tachycardia

7. Other relevant history, including preexisting medical conditions (up to a total of 500 characters allowed)

past medical history of supra ventricular tachycardia

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)	2. Dose/Frequency/Route used	3. Therapy dates (if unknown, give duration)
#1 Metabolife 356 /multiple ingredients /metabolife international	#1 once / /	#1 From - To (or best estimate)
#2	#2	#2

4. Diagnosis for use (separate indications with commas)

#1 nutritional supplement

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) 7. Exp. date (if known)

#1 #1

#2 #2

8. Event reappeared after reintroduction

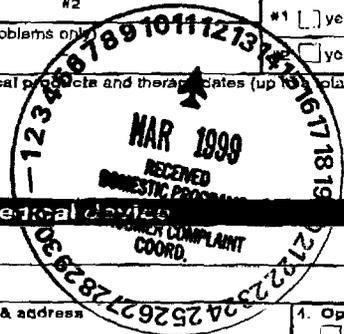
#1 yes no doesn't apply

#2 yes no doesn't apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (up to a total of 1000 characters)

none



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 (mm/dd/yyyy)

6. Model #

7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA)

yes no returned to manufacturer on (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (up to a total of 1000 characters)

E. Reporter (see confidentiality section on back)

1. Name phone #

2. Health professional? yes no

3. Occupation Pharmacist

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.



MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-0787

or FAX to:
1-800-FDA-0178

FDA Form 3500 (WWW)

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

000001

CTU 98840

COMPLAINT / INJURY REPORT

1. COMPLAINT NUMBER
CFSAN #13405 SAN 2056

2. DATE OF COMPLAINT (Month / Day / Year)
3-5-99

3. FORM OF COMPLAINT

- a. TELEPHONE
 LETTER
 VISIT

4. SOURCE OF COMPLAINT

- a. CONSUMER (3) TRADE SOURCE
 GOVERNMENT (4) OTHER
 L S F (Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION

a. NAME AND ADDRESS (Include ZIP Code)

[REDACTED]

b. AREA CODE AND TELEPHONE NUMBER
HOME ([REDACTED])

WORK () N/A

6. COMPLAINT OR INJURY

a. DESCRIPTION OF COMPLAINT / INJURY

See Attached correspondence regarding consumer [REDACTED] and the dietary supplement Metabolife 356. Correspondence dated March 18, 1999 and March 19, 1999.

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) NO (2) YES
(If "Yes" Explain in Remarks)

7. INJURY OR ILLNESS RESULTED

a. EIB (HFC - 161) NOTIFIED
(1) NO
(2) YES

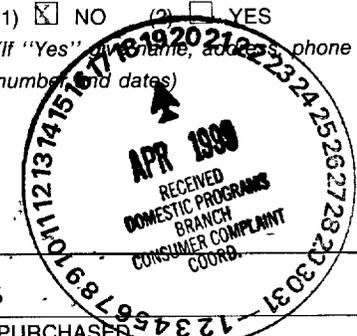
b. TYPE SYMPTOMS ONSET (HR.)
(1) VOMITING
(2) NAUSEA
(3) DIARRHEA
(4) FEVER
(5) SKIN/EYE IRR.
(6) HEADACHE
(7) OTHER

c. ATTENDING HEALTH PROFESSIONAL?
(1) NO (2) YES
(If "Yes" give name, address, and phone number)

d. HOSPITALIZATION REQUIRED?
(1) NO (2) YES
(If "Yes" give name, address, phone number, and dates)

DATE: Not known

anxiety attack



8. PRODUCT AND LABELING

a. BRAND NAME
Natural Herbs

b. PRODUCT NAME
Metabolife 356

c. SIZE AND PACKAGE TYPE
90 caplets/ plastic btle

d. NAME AND LOCATION OF STORE WHERE PURCHASED
Purchase through the internet

e. PACKAGE CODE / SERIAL NUMBER / ETC.
"K83711/01"

f. DATE PURCHASED
2-10-99

g. PRODUCT USED (1) NO (2) YES
(If "Yes" enter date) Date: 3rd week of Feb.

h. AMT. REMAINING
See Remarks

9. MANUFACTURER / DISTRIBUTOR OF PRODUCT

a. HOME DISTRICT
LOS-DO
b. C.F. NO. FBI No.
3002622506

c. NAME AND LOCATION OF FIRM (Include ZIP Code)
Metabolife International Inc.
5070 Santa Fe Street
San Diego, CA 92109

d. IMPORT PRODUCT
(1) NO
(2) YES

10. EVALUATION AND DISPOSITION

a. PROBLEM KEY WORD
(1) CODE RX (2) DESCRIPTION ILLNESS
b. EVALUATION
(1) NOT AN FDA OBLIGATION
(2) OBLIGATION, NO VIOLATION
(3) FDA ACTION INDICATED
(4) INSUFFICIENT INFORMATION UNABLE TO EVALUATE

b. DISPOSITION
(1) IMMEDIATE FOLLOW-UP
(2) F / U NEXT EI
(3) CLOSED WITHOUT FURTHER INVESTIGATION
(4) REFERRED TO OTHER FEDERAL AGENCY (Closes File)
(5) REFERRED TO STATE / LOCAL AGENCY (Closes File)
(6) REFERRED TO OTHER FDA CFSAN DISTRICT
(7) REFERRED TO OCI

11. PRODUCT CODE
54FCY99

12. INFORMATION COPIES TO:
 HFM-660 HFZ-343
 HFD-730 HFC-161
 HFV-210 HFS-635
 OTHER CFSAN LOS-D

13. REMARKS

5. Consumer [REDACTED] did not file a complaint. The ER physician at [REDACTED] filed the complaint via Medwatch form. Complaint Assignment: CFSAN Project 13405.
3h. One open bottle of dietary supplement with less than 50 caplets, plus one unopen bottle of dietary supplement that the consumer is sending back to the firm for monetary credit.

14. NAME AND TITLE OF DISPOSITION OFFICIAL

Janice Wai, CSO

15. DATE

3-5-99

COMPLAINT / INJURY FOLLOW-UP				1. COMPLAINT NUMBER CFSAN #13405	
2.a. ACTION REQUESTED (1) <input checked="" type="checkbox"/> INVESTIGATION (2) <input checked="" type="checkbox"/> COLLECT SAMPLE (3) <input type="checkbox"/> INSPECTION (4) <input type="checkbox"/> OTHER:		2.b. REMARKS (Additional details) Obtain affidavit, medical disclosure record, and the Adverse Event Questionnaire from the consumer			
2.c. REQUESTING OFFICIAL'S NAME AND TITLE Charlotte Carey, Consumer Complaint Coordinator			2.d. DATE REQUESTED 3-25-99		2.e. PRODUCT NAME Metabolife 356
3.a. ASSIGNED TO: J. Wai		3.b. DUE BY: April 5, 1999		4.a. ACTION TAKEN (1) <input checked="" type="checkbox"/> INVESTIGATION (2) <input checked="" type="checkbox"/> SAMPLE COLLECTED (3) <input type="checkbox"/> INSPECTION (4) <input type="checkbox"/> NONE	
4.b. SAMPLE NUMBER(s) 23373					
4.c. DESCRIPTION OF ACTION TAKEN On 4-1-99, I visited the consumer [redacted] and I collected one bottle of dietary supplement. The bottle contained less than the 90 caplets. Forms FDA-484, Receipt for Sample, and FDA-461, Authorization for Medical Records Disclosure, were issued to Ms. [redacted] and they were signed by her. A questionnaire form on Adverse Event was filled out with the consumer. An affidavit was signed by Ms. [redacted]. During the interview with Ms. [redacted] there were two bottles of the dietary supplement Metabolife 356. The consumer released the open bottle to me for FDA analysis. The other unopen bottle was packaged for mailing. The consumer was returning the unopen bottle for monetary credit. The cost per bottle was \$40.00. The package containing the dietary supplement was addressed [redacted]. The consumer purchased the dietary supplement through the internet. I then drove to [redacted]. The hospital is actually located in [redacted] and not in [redacted]. The hospital address is [redacted]. I presented the Medical Disclosure Record form with the signature of [redacted] to the hospital's medical records department. FDA credentials were shown. I was told that the medical records would take 8 to 10 working days. Since I was from the FDA, the hospital placed a "rush" order for the medical records.					
4.d. ACTION OFFICIAL'S NAME AND TITLE <i>Rhonda Dean, Consumer Safety Officer</i>			4.e. ACTION DISTRICT SAN		4.f. DATE COMPLETED 4-5-99
5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE			6. PROGRAM DATA		
5.a. HOME DIST. LOS-DO	5.c. NAME AND ADDRESS Metabolife International Inc. 5070 Santa Fe Street San Diego, CA 92109		5.a. OPERATION 13	5.b. PAC 03R801	5.c. PRODUCT CODE 54FCY99
5.b. CF NO. -FEI 3002622506			5.d. EMP. HOME DIST. G	5.e. EMP. NO. 754	5.f. POS CL. 2
				5.g. HOURS 20	
7. EVALUATION (0) <input checked="" type="checkbox"/> PENDING (1) <input type="checkbox"/> NO ACTION INDICATED (NAI) (2) <input type="checkbox"/> VOLUNTARY ACTION INDICATED (VAI) (3) <input type="checkbox"/> OFFICIAL ACTION INDICATED (OAI) (4) <input type="checkbox"/> NOT AN FDA OBLIGATION (5) <input type="checkbox"/> REFERRED TO HOME DISTRICT (6) <input type="checkbox"/> INSUFFICIENT INFO. UNABLE TO EVAL. (7) <input type="checkbox"/> REFERRED TO OCI			8. FINAL DISPOSITION (1) <input type="checkbox"/> FOLLOW-UP NEXT E1 (2) <input type="checkbox"/> WARNING LETTER (3) <input type="checkbox"/> CITATION (4) <input type="checkbox"/> SEIZURE (5) <input type="checkbox"/> INJUNCTION / PROSECUTION (6) <input type="checkbox"/> REFERRED TO OTHER AGENCY (7) <input type="checkbox"/> RECALL (8) <input type="checkbox"/> NO ACTION To: CFSAN for disposition (Indicate Agency in Remarks)		
9. INFO. COPIES TO: <input type="checkbox"/> HFB-100 <input type="checkbox"/> HFD-730 <input type="checkbox"/> HFV-236 <input type="checkbox"/> HFZ-343 <input checked="" type="checkbox"/> HFC-161 <input type="checkbox"/> HFS-635 <input checked="" type="checkbox"/> LOS-DC <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____					
REMARKS <p style="text-align: right;">000003</p>					
NAME AND TITLE OF DISPOSITION OFFICIAL			DISPOSITION		DISPOSITION DATE

Adverse Event Questionnaire

Complaint Number: 13405

Investigator: JANICE WAI

Consumer Information	
Date of Report: <u>04/01/99</u> MM/DD/YY	Initial Report Source: <input type="checkbox"/> ORA Consumer Injury ----- <input type="checkbox"/> Telephone <input checked="" 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:
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>MARCH 5th</u> 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>AT HOME</u>
<p>The following information relates to the consumers' use of the product.</p> <p>Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): <u>feeling of Anxiety, numbness, increase heart rate, lack of oxygen to the brain, and increase energy.</u></p> <p>How long did the symptoms last? <u>off and on</u></p> <p>Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). <u>two caplets with water.</u></p> <p>List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: <u>Dietary Supplement: Natural Herbs Metabolic 356.</u></p> <p>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</p> <p>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</p> <p>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</p>	
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) _____	
<p>What medical tests were performed and what were the results? <u>Doctor got the patient to relax to lower the heart rate.</u></p> <p>What was the medical diagnosis? What treatment(s) was given (e.g., drugs, other)? } <u>see medical records.</u></p>	
<p>Were there any preexisting condition(s)/treatment(s)? <u>2 episodes of Tachycardia prior to this incident.</u> (If YES, list them including allergies, and chronic diseases): <input checked="" type="checkbox"/>Yes <input type="checkbox"/>No</p>	

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-benzic acid, and rutin; and mixtures of these ingredients.)

Other (traditional food) N/A

Other Product Problems

2. Foreign Object (specify): N/A

3. Other (specify): N/A

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):

Product Name: Natural Herbs MetaboLife Dietary Supplement 356
xxx Diet xxx 90 Caplets xxx MetaboLife International,
Inc. 5070 Santa Fe Street, San Diego, CA 92109 (619) 490-5222 xxx

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

Check here if ingredients are unknown

Guarana Concentrate (seed), Ma Huang Concentrate, Bee Pollens, Ginseng,
Ginger, Lecithin, Bovine Complex, Damiana, Sarasparilla, Golden
Seal, Nettles, Gotu Kola, Spirulina Algae, Royal Jelly

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

- Aspartame
- Monosodium Glutamate
- Sulfite
- Other Ma Huang Concentrate
- 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

Consumer is currently taking Oxazepam, 10mg, for anxiety. Drug medication from ER physician at [redacted]

TO: Lori Love, M.D., Ph.D.

FROM: Constance J. Hardy *CJH*

DATE: March 18, 1999

SUBJECT: ARMS 13405

I spoke to Ms. [REDACTED] the consumer who took Metabolife 356. She stated she had a medical history of tachycardia. She began taking the product about 2 weeks before the noted event. Initially she took 2 tablets before breakfast and supper (she normally did not eat lunch), but she found that she felt very jittery and could not tolerate the feeling. She subsequently switched (within the first few days) to 1 tablet before breakfast and occasionally one before supper. On the day of the event she had a Pepsi with the Metabolife; she stated she had never consumed the two products together in the past. About 1-2 hours later when she went to pick up her child, she began to experience SVT [note the MEDWATCH form says within 30 minutes].

She also noted that during her use of Metabolife 356 she had felt she was having episodes of SVT but she never associated it with the use of the product but felt these episodes were consistent with her medical condition.

000006

TO: Lori Love, M.D., Ph.D
FROM: Constance J. Hardy *CJH*
DATE: 6/9/99
SUBJECT: ARMS 13405—additional consultation with the patient

I talked to [REDACTED] on June 8, 1999 and she mentioned she had experienced another "tachycardia" attack while she was at work, approximately one month after the 3/5/99 event. She explained that a cardiologist was called in to the emergency room and she was told at that time that she has supraventricular tachycardia. At that time and currently she is on Verapamil. She also asked me about a product called "Fat Eliminator" and whether or not we had any adverse events reported on it. I told her I did not know.

I talked to [REDACTED] again on June 9, 1999, and she clarified the following. About 2 years prior to taking Metabolife she had experienced "tachycardia" episodes which occurred about every 8 months, but then the attacks became more frequent, about every two months. She also described the 3/5/99 event as "I felt like I had a racing heart"; she also clarified that the way she felt was not like the experiences she had had with previous tachycardia events. During her stay in the emergency room on 3/5/99 she stated she was only told to eliminate the diet pills from her diet; no other directions as far as restrictions to be taken, were given to her. She verified that she was not taking "Fat Eliminator" but had asked me about it because she had ordered it sometime ago; she also emphasized that since being placed on Verapamil she intended to discuss the product "Fat Eliminator" with her doctor to see if it was "OK" to take.

File name:c:\connie\ephedrafu\fu13405a-arms.doc

000007