

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

ARMS#

1 3335



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MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

CFSAN

Page 1 of 1

FDA Use Only	
Triage unit sequence #	96476
	13335

A. Patient information

1. Patient Identifier	2. Age at time of event: or Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 350 lbs or kgs
In confidence	38 y/6		

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 (m/day/yr)	<input type="checkbox"/> disability
<input 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 (m/day/yr)	4. Date of this report (m/day/yr)
12/30/98	1/6/99

5. Describe event or problem

acute onset A-fib (Atrial fibrillation) - a fast ventricular response of around 200. p started Metabolife for wt loss. admitted to hosp & treated.

TX w/ vancomycin / co-trimoxazole / cardiac drip & conversion.

6. Relevant tests/laboratory data, including dates

CBC / SMA 12 / TSH / thyroid panel / were all NI.

2 echoes unremarkable (unremarkable)

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

non-smoker
Ø ETH
Ø Obesity / HTN / silent
and glaucoma.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	365 pm (over)	
#1	Metabolife	
#2		
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1 as directed on package	#1 12/30/98	
#2	#2	
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced	
#1 Obesity	#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2	#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 K-84511-01	#1	
#2	#2	
9. NDC # (for product problems only)	8. Event reappeared after reintroduction	
	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	

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

See #7

D. Suspect medical device

1. Brand name	RECEIVED FEB 08 1999
2. Type of device	3
3. Manufacturer name & address	4. Operator of device
	<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other
5. Expiration date (m/day/yr)	6. model #
	JAN 23 1999
7. If implanted, give date (m/day/yr)	8. If explanted, give date (m/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 (m/day/yr)	000001

E. Reporter (see confidentiality section on back)

1. Name & address	phone
[Redacted]	
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation Physician
4. Also reported to	
<input checked="" 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 type="checkbox"/>	

PLEASE TYPE OR USE BLACK INK

FDA MEDWATCH or FAX to: 1-800-FDA-0178
5600 Fishers Lane
Rockville, MD 20852-9787
FDA MEDICAL PRODUCTS REPORTING PROGRAM

Adverse Event Questionnaire

ARM 5 13335

TRIAGE # [redacted]

Complaint Number: ARM 5-13335

Investigator: _____

Consumer Information

Date of Report: 01/06/99 MM/DD/YY	Initial Report Source: <input type="checkbox"/> ORA Consumer Injury <hr/> <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: 38
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: 01/06/99 (12-30-98)	Give the site of consumption/ingestion (e.g. home, restaurant, office): home
Previous Adverse Effects to Product Type: <input type="checkbox"/> Yes <input 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):
acute onset A-fib (Atrial Fibrillation) w/ a fast ventricular response of around 200 bpm starting metabolite for weight loss admitted to hospital for treatment. Tx w/ lanoxin, convert / cardioversion

How long did the symptoms last? Started product on Friday - presented w/ symptoms Monday - and converted

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

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

V Accupril 20mg, B12, Centrum, Vit E
Timoptic 0.5% eye sol, Amoxic 100mg capsules

in
Symptoms noted on med 2 days

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?: Yes No
 Give health care provider's name, address and telephone number:
 Urgent Care [redacted]

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

What medical tests were performed and what were the results? CBX, SMA12, TSH, Thyroid Profile, Cardio enzyme
 Were all NI 2 Decho unremarkable
 What was the medical diagnosis? CxR - Cardio megn, E
 What treatment(s) was given (e.g., drugs, other)? (Event - premon -

Were there any preexisting condition(s)/treatment(s)? Obesity, Hypertension
 (If YES, list them including allergies, and chronic diseases): Yes No

000002

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

FROM: Constance J. Hardy



DATE: 6/7/99

SUBJECT: ARMS 13335

On 6/7/99 I called the office of Dr. [REDACTED] who submitted MedWatch report (ARMS #13335) to see if it was possible to obtain any additional medical record documentation of the adverse event he reported. Dr. [REDACTED] had reported an acute onset of atrial fibrillation associated with the use of Metabolife 365 in a 38 year old man. I spoke to Ms. [REDACTED] his office assistant. Ms. [REDACTED] stated that Dr. [REDACTED] was this patient's usual physician and had evaluated the patient prior to admitting him to the hospital. She also clarified that the patient was first seen for this episode by another physician at the Urgent Care center.

Ms. [REDACTED] agreed to discuss FDA's request for additional information about this adverse event with Dr. [REDACTED]. This was to include asking the patient whether he would be willing to sign a medical release form so that pertinent hospital and clinic records could be released to FDA.

000004

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

FROM: Constance J. Hardy

CJ Hardy

DATE: July 28, 1999

SUBJECT: ARMS 13335

I called Mr. [REDACTED] on July 26, 1999 in order to clarify the length of time he had used the product Metabolife 356 before experiencing the reported adverse event mentioned in ARMS 13335. He stated he had used the product for four days before the event occurred. He also stated that he took 1 capsule before each meal.

File name [REDACTED]

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