

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

ARMS#

13256



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UNITED STATES FOOD AND DRUG ADMINISTRATION  
**CONSUMER COMPLAINT/INJURY REPORT**

1. COMPLAINT NUMBER  
 MIN-9324

2. DATE OF COMPLAINT  
 11/9/98

3. FORM OF COMPLAINT	(1) <input checked="" type="checkbox"/> TELEPHONE (4) <input type="checkbox"/> OTHER	4. SOURCE OF COMPLAINT	<input checked="" type="checkbox"/> CONSUMER	<input type="checkbox"/> TRADE SOURCE
	(2) <input type="checkbox"/> LETTER		<input type="checkbox"/> GOVERNMENT	<input type="checkbox"/> OTHER
	(3) <input checked="" type="checkbox"/> VISIT		<input type="checkbox"/> LOCAL	<input type="checkbox"/> STATE

5. COMPLAINANT IDENTIFICATION	a. NAME AND ADDRESS	b. TELEPHONE NUMBER
	[REDACTED]	HOME: [REDACTED] WORK: [REDACTED]

6. COMPLAINT OR INJURY	a. DESCRIPTION OF COMPLAINT/INJURY
	After taking Metabolife for several months Ms. [REDACTED] began to feel unwell. On 09/30/98 she began having chest pains and chest "heaviness" making it difficult to breath. She felt her symptoms were similar to a heart attack so she went to the emergency room. A chest x-ray and EKG were done, but no abnormalities were found, she was treated with pain medication and released. On 10/02/98 her symptoms described above again became so intense that she went to the emergency room near her home. Again an EKG was normal, she was treated with nitroglycerin and indigestion medication and sent home. She visited Dr. [REDACTED] on 10/07/98, an echocardiogram was done showing no abnormalities. She stopped taking all meds and the symptoms ceased.
	b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? <input type="checkbox"/> NO <input type="checkbox"/> YES (If Yes, explain in Remarks)

7. INJURY OR ILLNESS RESULTED	a. DEIO/EMOPS (HFC-130) NOTIFIED	b. TYPE SYMPTOM ONSET (HR.)	c. ATTENDING HEALTH PROFESSIONAL	d. HOSPITALIZATION REQUIRED
	(1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES <i>(If "yes" complete items a through d)</i>	(1) <input type="checkbox"/> VOMITING (2) <input type="checkbox"/> NAUSEA (3) <input type="checkbox"/> DIARRHEA (4) <input type="checkbox"/> FEVER (5) <input type="checkbox"/> SKIN/EYE IRR. (6) <input type="checkbox"/> HEADACHE (7) <input checked="" type="checkbox"/> OTHER Chest pain	3.5 months	(1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES <i>(If "yes", give name, address, phone, date)</i>

8. PRODUCT AND LABELING	a. BRAND NAME	b. PRODUCT NAME
	Metabolife 356	Dietary Supplement
	c. SIZE AND PACKAGE TYPE	d. NAME AND LOCATION OF STORE WHERE PURCHASED
	90 caplet bottle	Purchased by mail from [REDACTED]
	e. LOT/SERIAL NUMBER	[REDACTED]
	EXP/USE BY DATE:	f. DATE PURCHASED
		6/98
		g. PRODUCT USED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES
		DATE 6/98 to 10/98
		h. AMT REMAINING
		90 caplets
		20

9. MANUFACTURER/DISTRIBUTOR OF PRODUCT	a. HOME DISTRICT	c. NAME AND LOCATION OF FIRM	d. IMPORT PRODUCT
	LOS-DO	Metabolife International, Inc. 5070 Santa Fe Street San Diego, CA 92109 address is for corporate office	(1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES
	b. CFN		

10. EVALUATION AND DISPOSITION	a. PROBLEM KEYWORD	c. DISPOSITION	11. PRODUCT CODE
	(1) CODE (2) DESCRIPTION	(1) <input type="checkbox"/> IMMEDIATE FOLLOW-UP (2) <input type="checkbox"/> FU NEXT EI (3) <input type="checkbox"/> CLOSED WITHOUT FURTHER INVESTIGATION (4) <input type="checkbox"/> REFERRED TO OTHER FEDERAL AGENCY (5) <input type="checkbox"/> REFERRED TO STATE/LOCAL AGENCY (6) <input type="checkbox"/> REFERRED TO OTHER FDA DISTRICT (7) <input type="checkbox"/> REFERRED TO OCI	
	b. EVALUATION		12. INFORMATION COPIES TO:
	(1) <input type="checkbox"/> NOT AN FDA OBLIGATION (2) <input type="checkbox"/> OBLIGATION, NO VIOLATION (3) <input checked="" type="checkbox"/> FDA ACTION INDICATED (4) <input type="checkbox"/> INSUFFICIENT INFORMATION UNABLE TO EVALUATE		<input type="checkbox"/> HFC-130 <input type="checkbox"/> HFD-730 <input type="checkbox"/> HFM-650 <input type="checkbox"/> HFS-635 <input type="checkbox"/> HFV-210 <input type="checkbox"/> HFZ-530 <input type="checkbox"/> OTHER

REMARKS

000001

NAME AND TITLE  
 Mary M. Finn, Investigator

*Mary M Finn*

DATE  
 1/4/1998

# Adverse Reaction Information Form A

Complaint Number: MIN-9324

Investigator: Mary M Finn

## Consumer Information

Date of Report: 01/04/99  
MM/DD/YY

Initial Report Source:  ORA Consumer Injury

Telephone  Correspondence  MedWatch  
 USP  PQRS  Poison Control  CDC

Name: [REDACTED]

Gender:  F  M

Age: 39 yrs

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

## Information on Adverse Reaction

Date of Adverse Reaction: 9/30/98 + 10/2/98  
Previous Reaction to Product Type:  Yes  No

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

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):  
Chest pains / heaviness in chest / hurt to breath / She felt the symptoms were similar to a heart attack  
How long did the symptoms last? She was out of work 2 weeks ... complete recovery in several months  
Give the circumstances of exposure (e.g., dose, route of exposure, frequency, etc.):  
approx 4 caplets a day, orally she did not always follow a rigid schedule in taking Metabolife

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

Rx Propylthiouracil for hyperthyroid

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:  
[REDACTED]

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

What medical tests were performed and what were the results?

Chest X-ray, EKG, Echo cardiogram, lab work: troponin, Anti-cardiolipin; all except anti-cardiolipin were normal

What was the medical diagnosis? - none

What treatment(s) was given (e.g., drugs, other)? morphine + pain medication

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

## Product Category

1. Adverse reaction 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): \_\_\_\_\_

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CFSAN #13256

03/02/99

HMF

Attachment 2

**Information on Suspected/Alleged Product**

Give the product name (including dose/serving size, duration of use, and reason for taking):

Metabolife 356

Metabolife International, Inc.  
5070 Santa Fe Street  
San Diego, CA 92109  
619-490-5222

1 to 2 caplets two to three times a day  
or every four hours, on an  
empty stomach one hour before  
meals. **DO NOT EXCEED  
EIGHT A DAY**

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

Check here if ingredients are unknown

<u>Vitamin E 6IU</u>	<u>Chromium Picolinate 75mg</u>	<u>Bac Pollex, Ginseng (root)</u>
<u>Magnesium chelate 75mg</u>	<u>Guava Concentrate (seed)</u>	<u>Ginger (root) Lactidin</u>
<u>Zinc chelate 5mg</u>	<u>Ma Hung Concentrate (aerial part)</u>	<u>Bovine Complex</u>
<u>Sarasa parilla (root)</u>	<u>Golden Seal (aerial part)</u>	<u>Damiana (leaf)</u>
<u>Gotu Kala (aerial part)</u>	<u>Nettles (leaf)</u>	<u>Spiculina Algae Royal Jelly</u>

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) \_\_\_\_\_

Product Label Available:  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  unknown

Hospitalization:  Yes  No (if YES, indicate if initial or prolonged) \_\_\_\_\_

Required intervention to prevent permanent impairment/damage:  Yes  No  unknown

Did the adverse reaction result in a congenital anomaly:  Yes  No

**000003**

CFSAN # L3256  
03/02/99  
NMF  
Attachment 2



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Memorandum

Date December 22, 1998
From Mary M. Finn
Subject Follow-up on MedWatch #70432
To Dorothy Olson

I first telephoned [redacted] on October 13, 1998 to find the name of the patient on MedWatch form 70432. Ms [redacted] was the reporter on this form. Ms [redacted] stated that although she could remember the situation, she could not remember the patients name. She said that she would check medical records and ask other staff members if they could remember the patients' name.

On November 9, 1998 I called [redacted] she was unable to remember or find that information about the patients name. In the course of our conversation she told me about a co-worker [redacted] experience with a dietary supplement called Metabolife. Metabolife is advertised on the radio as a weight reduction aid.

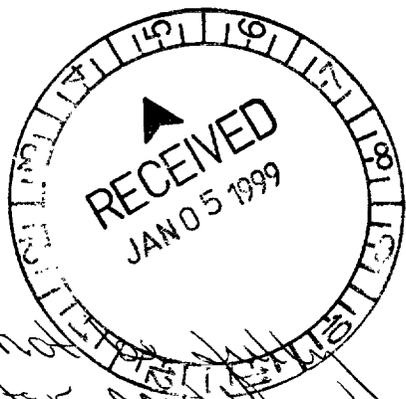
Ms [redacted] came to the phone and told me she heard about Metabolife on [redacted] radio. The radio station broadcasts a number where the product can be ordered. She took the supplement for 30 month when she started to feel a heaviness in her chest and a general feelings of ill health. On or about September 30, 1998 she experienced chest pains at work and went to the emergency room. There she was given an EKG and laboratory work was done. A few days later she had an electrocardiogram, the results were normal. When her doctor told her that he had seen reactions like hers in people taking digitalis and asked her about any medications or supplements she might be taking. She told the physician she was taking Metabolife. Her physician told her to cease using Metabolife, she has gradually been getting better. Ms [redacted] stated that she would fax labeling she had form Metabolife to me at MIN-DO.

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On December 21, 1998 I called Ms [redacted] and explained I hadn't received the labeling from Ms [redacted] Ms [redacted] stated that the product was now being sold in a kiosk in [redacted]. She also stated that she had a copy of the labeling which she faxed to me at MIN-DO. See attachment.

Mary M Finn

12-22-98



Handwritten notes: Medwatch # 13072 could not be followed up since the reporter could not remember the patients name. During the investigation information obtained regarding the possibility of Metabolife causing digitalis like symptoms. A sampling arrangement to be made for this product.

Handwritten signature: Dorothy Olson
O: MIN
cc: Monitor, New Rx Monitoring System DOEP HFS-636

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Memorandum

Date March 1, 1999
From Mary M. Finn, Investigator, MIN-DO/HRF850
Subject Adverse Reaction Request for Follow-up CFSAN project #13256
To Dirk Mouw, MIN-DO, Consumer Complaint Coordinator, MIN-DO/HRF850
Through Dorothy L. Olson, Acting Supervisor, Investigations, MIN-DO/HRF850

The information contained in this report is in response to a request for a field follow-up to CFSAN project 13256, an adverse event to Metabolife. Enclosed with this memo are: label from product collected from consumer; Consumer Complaint (FDA 2516); Adverse Event Questionnaire; medical records from [redacted] for 09/30/98 and 10/05/98; medical records from [redacted] for 10/02/98 and medical records from Dr. [redacted] for 10-12/98.

Information below is from an in person interview with Ms [redacted] on Jan. 4, 1998.

On January 4, 1999 I visited with [redacted] at [redacted] where she works as a Medical Sectary. According to Ms [redacted] she started taking Metabolife in June of 1998. She had heard an ad on [redacted] radio, called the number given in the advertisement [redacted] and ordered a supply of the supplement with her credit card. She believes she ordered from a company in [redacted]. She took four caplets of the supplement a day; two in the morning with breakfast and two at noon with or without lunch., there were some days she didn't take any. Ms. [redacted] also takes Proplthiouracil, which is a prescription drug used to treat her for a hyperthyroid condition.

ENDORSEMENT

3/5/99

Information obtained as requested for CFSAN project #13256 re Metabolife.

M. Edith Snyder
Supervisory Investigator

O: HFS 636
cc: MIN-DO (Dirk Mouw)

3/5/99
[Signature]

Ms [REDACTED] is going through testing prior to invitro fertilization. She told me at the beginning of June lab work showed her Anticardio Lipin to be 21 and a repeat of this test one month later showed it to be between 81 and 86 (I forgot to ask her the units).

In September of 1998 she didn't feel "well" and started to feeling chest pains. She was working at [REDACTED] on September 30, 1998 when she started experiencing severe chest pains and a chest "heaviness" that made it difficult to breathe. She also described a pain going down her left arm with heart attack type symptoms. Her co-workers took her to the emergency room where chest X-ray, EKG, and lab work was done. The results of the tests were normal. She was treated for pain with morphine, nitroglycerine and other pain medication and released (exhibit # 1).

At home, two days later on October 2, 1998 the pain got unbearable so she went to [REDACTED] which is an urgent care facility close to her home in [REDACTED]. Tests were run for a heart attack, but the results were normal. She was treated for pain with morphine, nitroglycerine, and other pain medications and released. (exhibit #2).

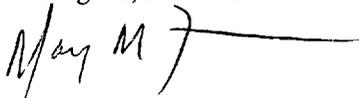
She had an appointment with Dr. [REDACTED] a rheumatologist, on October 7, 1998. Dr. [REDACTED] ordered an echocardiogram, which was performed on October 8, 1998. The results were normal. Dr. [REDACTED] asked Ms [REDACTED] what medications/supplements she was taking. He suggested she discontinue taking Metabolife, but not that she reduce or stop taking Propylthiourcil (exhibit #3).

Her symptoms gradually improved, lab work she had done in November 1998 showed her anticardio lipin to be down to 35 or 36. By December she was feeling normal.

In mid-December 1998 she resumed taking Metabolife, in two weeks symptoms started to reappear this time symptoms included joint pain. She went to Dr. [REDACTED] who removed fluid from her knee. She stopped taking Metabolife and symptoms are gone.

Ms [REDACTED] provided me with a sample of the product she was taking. She brought a bottle of Metabolife with her to work and I collected it from her at [REDACTED] on January 15, 1999. At MIN-DO I stripped the label from the bottle and mounted it on paper, sample #44236 (Exhibit #4). I disposed of the three remaining caplets. A copy of the Collection report and the original labeling is included with this report.

Mary M. Finn  
Investigator, MIN-DO



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ATTACHMENTS

1. Consumer Complaint (FDA 2516)
2. Adverse Event Questionnaire

EXHIBITS

1. Medical records from [REDACTED]  
[REDACTED] for 09/30/98 and 10/05/98, 18 pages.
2. Medical records from [REDACTED]  
[REDACTED] for 10/02/98 , 4 pages.
3. Medical records from [REDACTED] for 10-  
12/98, five pages.