

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

ARMS#

13062



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COMPLAINT AND INJURY REPORT		COMPLAINT NUMBER: [REDACTED]	
		COMPLAINT DATE: 06/29/1998	
COMPLAINT INFORMATION	FORM OF COMPLAINT: TELEPHONE	SOURCE OF COMPLAINT:	
COMPLAINANT AND INJURED INFORMATION	INJURED PARTY:		COMPLAINANT: [REDACTED]
	H:	W:	H: [REDACTED] W:
	AGE:	SEX:	REGION: 0 COUNTY: [REDACTED]
INJURY OR ILLNESS RESULTED	TYPE SYMPTONS:		
	ATTENDING PHYSICIAN:		HOSPITAL:
PRODUCT AND LABELING	PRODUCT: Diet		PRODUCT CODE:
	PKG CODE:		
	PKG CODE/ SERIAL #:		EXP DATE: //
	DATE USED: 04/12/1998		DATE PURCHASED: //
	AMT REMAINING: ?		SAMPLE #:
MANUFACTURER/ DISTRIBUTOR OF PRODUCT	MANUFACTURER:		DISTRIBUTOR: [REDACTED]
	DESCRIPTION OF COMPLAINT/INJURY See attached sheet		
COMPLAINT OR INJURY	VALID: .F.	NOTICE GIVEN: .F.	DAYS
NAME TITLE	[REDACTED] senior pharmacist		
EVALUATION AND DISPOSITION	DIVISION: DRUGS		INJURY CLASS: 0
	STATUS: OPEN		DATE INVEST: //
	FOLLOW-UP: .F.	ASSIGNED TO:	
	REVIEWER:		DATE: \ / /
	REFERRED TO:		DATE: / /
	DISPOSITION: SEE ATTACHED SHEET		

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COMPLAINT INVESTIGATION

# 13062 Filed 8/30/98

[Redacted]

June 30, 1998

Investigator: [Redacted]  
COMPLAINT [Redacted]

**SUMMARY OF INVESTIGATION:**

On June 29, 1998, Mrs. [Redacted] called to report an injury associated with a dietary supplement she had taken. She stated that this diet supplement (Metabolife or Metabolic life) made it hard for her to wake the next morning. When she did awaken, she was disoriented and incoherent. After she got to her job, she experienced nausea and vomiting. Mrs. [Redacted] stated that she went to the [Redacted] Emergency Room where she was diagnosed with a vascular spasm transient ischemic attack (TIA). The neurologist attributed the TIA to the ephedrine in the dietary supplement.

On June 30, 1998, I investigated this complaint in Mrs. [Redacted] home. She granted permission for me to enter her residence and signed the attached *Permission to Enter Private Residence and Surrounding Premise for Health Inspection* form.

On Easter Sunday, April 12, 1998, Mrs. [Redacted] took two Metabolife Dietary Supplement 356 capsules around 10:30 a.m. Mrs. [Redacted] showed me the bottle from which she took the capsules from and allowed me to take the bottle as a sample. I recorded the information from the bottle to the attached [Redacted].

She stated that they gave her burst of energy which was her primary reason for taking the product. She stated that she lost the effects from the first dose and proceeded to take another two capsules at 3:30 p.m. Around 7:30 p.m., Mrs. [Redacted] went to bed. The first thing she remembers the next morning is that she was late for work. The events between 4:00 a.m. and 7:30 a.m. were not clear to Mrs. [Redacted] so she asked me to speak to her husband, Mr. [Redacted].

Mr. [Redacted] stated that he tried to wake her up around 4:00 a.m. so she could get ready for work -- Mrs. [Redacted] is an elementary school teacher. He stated that he attempted to wake her up for forty-five minutes, then he went to get her sister, Ms. [Redacted]. Ms. [Redacted] lives in the same household with Mr. and Mrs. [Redacted]. Mr. [Redacted] stated that they both tried to wake her up for about an hour to an hour and a half. During this time, he stated that she occasionally had her eyes opened but she was incoherent. He stated that it was after 7:00 a.m. before she regained consciousness.

Mrs. [Redacted] stated that she felt awful, sluggish, and weak, but she went to work anyway. At school, she stated that she became nauseated and began to vomit. She stated that she was ill the rest of the day with bouts of weakness, tiredness, and sluggishness. However, she remained at school the entire day. She stated that she called her husband around 3:30 p.m. and asked him to come pick her up.

After her and her husband spoke about the morning events, Mrs. [Redacted] became frightened and worried about what was happening to her. Mrs. [Redacted] stated that her sister called her primary care physician, Dr. [Redacted] who instructed Ms. [Redacted] to take Mrs. [Redacted] to the emergency room.

[Redacted]

COMPLAINT INVESTIGATION

[REDACTED]

June 30, 1998

Investigator [REDACTED]  
COMPLAIN [REDACTED]

On Tuesday, April 14, 1998, Ms. [REDACTED] and Mr. [REDACTED] picked up Mrs. [REDACTED] from the school and took her to [REDACTED] Emergency Room where Ms. [REDACTED] and Mr. [REDACTED] explained to the Emergency Room (ER) doctor about the Monday morning events. When the ER doctor asked her if she had taken any new medications or eaten anything new, it dawned on her that it could have been the Metabolife she had taken on Sunday. The ER doctor ordered a CT scan which was inconclusive. Mrs. [REDACTED] stated that the neurologist who read her scan stated the she may have waited to long to come to the ER, but stated that all the symptoms she experienced add up to a text book case of vascular spasm transient ischemic attack (TIA). The neurologist told her to stop taking the Metabolife and recommended a follow-up visit with her primary care physician. Mrs. [REDACTED] authorized me to obtain a copy of the emergency room records and signed the attached *Authorization for Medical Records Disclosure* form.

On Monday, April 20, 1998, Mrs. [REDACTED] saw her primary care physician, Dr. [REDACTED] Mrs. [REDACTED] stated that her doctor performed a general physical and asked how she was feeling. She stated that she was still feeling weak and disoriented. Dr. [REDACTED] did not prescribe any medications and told her not to work for a couple of weeks.

**EXHIBITS:**

1. Emergency Room records from [REDACTED] These records show that Mrs. [REDACTED] received medical attention after taking Metabolife. The documented diagnosis as written in the medical records was TIA due to a dietary supplement containing ephedrine. (12 pages)
2. Medical records from Mrs. [REDACTED] primary care physician, Dr. [REDACTED] These records show that Mrs. [REDACTED] followed up with her primary care physician. (12 pages)

**ATTACHMENTS:**

- *Permission to Enter Private Residence and Surrounding Premise for Health Inspection* form
- *Authorization for Medical Records Disclosure* form
- [REDACTED]
- Business card of Dr. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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CLINICAL RESEARCH  
& REVIEW/OSN HF S-457



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

DALLAS DISTRICT OFFICE

**m e m o r a n d u m**

Date: November 2, 1998

From: Tramelle M. Thomas  
CSO  
FDA - DAL-DO

Subject: Metabolife Follow-Up Investigation

To: William D. Aken  
SCSO  
FDA - DAL-DO

*Reed 11/5/98*



Upon request from Ms. Bridgette M. Wallace, HFS-636, Adverse Reaction Monitoring System (ARMS) monitor for the Center for Food Safety and Applied Nutrition (CFSAN), a consumer complaint investigation was conducted in support of project number 13062, (per DAL-DO Assignment number 99009).

On June 29, 1998, [redacted] Investigator - [redacted] [redacted] received a telephone call from Mrs. [redacted] whom reported injuries associated with the dietary supplement Metabolife.

On June 30, 1998, Mr. [redacted] conducted a complaint investigation at the home of Mrs. [redacted]. During the investigation, Mrs. [redacted] revealed that she had suffered side effects from the dietary supplement which included: nausea, vomiting, and disorientation. Mrs. [redacted] also stated that on April 14, 1998, she was seen by a neurologist at the [redacted] where she was diagnosed with a vascular spasm, Transient Ischemic Attack (TIA), possibly attributed to a dietary supplement containing ephedrine.

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DATE: 11-2-98

TO: B. Wallace, HFS-636  
*Labeling as requested.*

*William D. Aken*  
FROM: William D. Aken, SCSO

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On October 19, 1998, accompanied by FDA Consumer Safety Officer Travis R. Hunt, LT. USPHS, I traveled to the home of Mrs. [REDACTED]. Upon arrival, credentials were presented to Mr. [REDACTED]. Mr. [REDACTED] was informed of our reason for visiting, and allowed us to enter his residence for further questioning.

We were later joined by Mrs. [REDACTED] whom we informed of our intent to obtain a copy of the Metabolife label in order to conduct a follow-up investigation of her complaint. Mrs. [REDACTED] stated that she had given the product to an investigator with the [REDACTED].

On October 22, 1998, a letter (Exhibit 1) and the Metabolife label (Exhibit 2) was received from Mr. [REDACTED]. As requested by Ms. Wallace this documentation will be forwarded to her.

Exhibits

Exhibit 1 [REDACTED] Letter  
Exhibit 2 Matabolife Label

O: B. WALLACE (HFS-636)  
CC: J. Uribe (DAL-DO)  
T. THOMAS (DAL-DO)  
T. HUNT (DAL-DO)

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