

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

ARMS#

12948



0 - FRONT

COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER
DAL8-9126

2. DATE OF COMPLAINT (MONTH/DAY/YEAR)
4/29/98

3. FORM OF COMPLAINT	(1) <input checked="" type="checkbox"/> TELEPHONE (2) <input type="checkbox"/> LETTER (3) <input type="checkbox"/> VISIT	4. SOURCE OF COMPLAINT	(1) <input checked="" type="checkbox"/> CONSUMER (3) <input type="checkbox"/> TRADE SOURCE (2) <input type="checkbox"/> GOVERNMENT (4) <input type="checkbox"/> OTHER [] [] [] F (Indicate in Remarks)
5. COMPLAINT IDENTIFICATION	a. NAME AND ADDRESS (Include Zip Code)		b. AREA CODE AND TELEPHONE NUMBER HOME [] [] [] [] WORK [] [] [] []
6. COMPLAINT OR INJURY	a. DESCRIPTION OF COMPLAINT/INJURY Started taking "escalation" on 3/18/98. Suffered a "grand mal siezure" on March 28. She was taken to Emergency room at [] [] [] [] for that siezure. Suffered 2nd siezure next day. Taken to [] [] [] [] for that siezure.		b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES <i>(Explain in Remarks)</i>
7. INJURY OR ILLNESS RESULTED	a. DEIO (HFC-130) NOTIFIED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES DATE: 5/7/98	b. TYPE SYMPTOMS 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 Siezure	c. ATTENDING HEALTH PROFESSIONAL (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES <i>(If "yes" give name and address, and phone number)</i> Emergency Room Physicians
8. PRODUCT AND LABELING	a. BRAND NAME Enzymatic Therapy	b. PRODUCT NAME Escalation	
	c. SIZE AND PACKAGE TYPE 120 capsule plastic jar	d. NAME AND LOCATION OF STORE WHERE PURCHASED [] [] [] []	
	e. PACKAGE CODE/SERIAL NUMBER/ETC. 821 P.S.E.LG EXP/USE BY DATE:	f. DATE PURCHASED Early March 1998	g. PRODUCT USED (If "yes" enter date) (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES from 3/18
9. MANUFACTURER/DISTRIBUTOR OF PRODUCT	a. HOME DISTRICT Minneapolis B	c. NAME AND LOCATION OF FIRM (Include Zip Code) Enzymatic Therapy 825 Challenger Drive Green Bay, WI 54305	
10. EVALUATION AND DISPOSITION	b. C.F. NO. 2128693	d. IMPORT PRODUCT (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES	
	a. PROBLEM KEYWORD (1) CODE RX (2) DESCRIPTION Reaction	c. DISPOSITION (1) <input checked="" type="checkbox"/> IMMEDIATE FOLLOW-UP (2) <input type="checkbox"/> F/U NEXT EI (3) <input type="checkbox"/> CLOSED WITHOUT FURTHER INVESTIGATION (4) <input type="checkbox"/> REFERRED TO OTHER FEDERAL AGENCY (Closes File) (5) <input type="checkbox"/> REFERRED TO STATE/LOCAL AGENCY (Closes File) (6) <input type="checkbox"/> REFERRED TO OTHER FDA _ DISTRICT	
b. EVALUATION (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		11. PRODUCT CODE 54FCE09	
REMARKS F/U report will be sent asap.		12. INFORMATION COPIES TO: <input type="checkbox"/> HFM-650 <input type="checkbox"/> HFZ-530 <input type="checkbox"/> HFD-730 <input type="checkbox"/> HFS-106 <input type="checkbox"/> HFV-210 <input checked="" type="checkbox"/> HFC-995 HFS 6X	
NAME AND TITLE Margarito J. Uribe - CCC-DAL/DO			DATE 5/7/98

FORM FDA 2516 (1/90)

Circle Appropriate Copy:

White copy (Original)

Pink Copy

Orange Copy

Green Copy

Yellow Copy

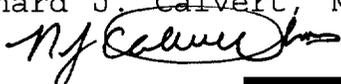
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Memorandum of Telephone Conversation:

Date: 8-7-98

To: Mrs. [REDACTED] consumer, ARMS #12948

From: Richard J. Calvert, M.D., Research Medical Officer,
CRRS



I spoke by phone to Mrs. [REDACTED] today to ask whether she still had some of the "escalation" ephedrine alkaloid dietary supplement that was associated with two seizures she experienced in March of 1998. She reported she still had the product, and would be willing to give it to an FDA inspector for analysis for ephedrine alkaloids.

I also asked if she was still on antiseizure medication. She told me she had stopped this medication about June 1, and has had no further seizures. She has not used any more of the product since her episode of seizures in March. She denied any history of seizures prior to using the supplement.

I told her I would arrange for an inspector to contact her and set up a time to pick up the sample, and we concluded the conversation.

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TO: Lori Love, M.D., Ph.D
FROM: Constance J. Hardy
DATE: March 10, 1999
SUBJECT: ARMS 12948—Consumer Usage of Product

Ms. [REDACTED] left a message (3/10/99) on my answering machine stating that she never took more than 1 capsule of the product Escalation. [I had previously tried several times to get Ms. [REDACTED] but was unsuccessful. I finally contacted her husband and asked him to relay my question concerning his wife's use of the product.]

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

DALLAS DISTRICT OFFICE

memorandum

Date: June 2, 1998

From: Ronda Loyd
Consumer Safety Officer
Dallas District

Subject: Assignment #980349
Complaint #8-9126

To: William D. Aken
SCSO

Per DAL-DO assignment# 980361, a meeting was held with the complainant . Upon arrival at complainants home on May 19, 1998, credentials were shown to Ms. [REDACTED] I informed Ms. [REDACTED] that I was there to follow up on her complaint filed with the Food and Drug Administration. I asked if she would explain the events surrounding her seizures and the use of the product Escalation.

Ms. [REDACTED] stated that she had been taking Escalation on and off since she purchased the product on March 3, 1998 from [REDACTED] in [REDACTED] She stated she was using the product to boost her energy level and to motivate her to work out and burn fat. She stated on March 28, 1998, she had taken one capsule of the product. Her and her husband were in [REDACTED] visiting when she experienced her first seizure. Her husband rushed her to [REDACTED] in [REDACTED] She was released later that day. She stated the hospital accused her of being on drugs and stated she needed to get help. She informed them that the only thing she had taken was Escalation.

Upon her release she returned home to [REDACTED] Later that evening while at home she suffered another seizure. Her husband called 911 and she was rushed to [REDACTED] [REDACTED] She was kept over night in the hospital and released on March 29, 1998. She also told the doctors there that she had been taking Escalation. The doctor stated the product had possibly caused the seizure and she should stop taking it.

Ms. [REDACTED] stated that prior to this incident she had no other health problems. Ms. [REDACTED] stated she called the store where she purchased the product in [REDACTED] to report the incident. She stated the store told her they were sorry, and that they had not received any other complaints.

I asked Ms. [REDACTED] if she would sign a medical release form in order to obtain a copy of her

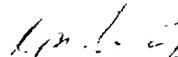
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medical records documenting her treatment for the two seizures, which she did. She asked if I would send her a copy of her medical records for her files.

I asked Ms. [REDACTED] to see the bottle of Escalation she had purchased. A full description of the label is attached. A copy of her medical records were obtained from [REDACTED]. [REDACTED] refused to release her medical records, stating I would need to get her signature on a [REDACTED] release form because of the sensitive information noted.

I went to [REDACTED] in [REDACTED]. I asked the cashier if they had any complaints or injuries reported from the use of Escalation, she stated no, Escalation was one of their best selling products. I checked the shelf to see if any product remained with Ms. [REDACTED] lot number and none was found.

Supervisor, Dave Aken stated there was no need to get Ms. [REDACTED] signature on the other release form. This concluded the investigation, medical records and label discription are attached.


Ronda Loyd
Investigator

Attachment:
Medical Records
Label description

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