

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

ARMS#

12942



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# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

CFSAN

Form FDA 1085  
Sequence # 30741  
12942

Page \_\_\_ of \_\_\_

**A. Patient information**

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

**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):  
 death  
 life-threatening  
 hospitalization - initial or prolonged  
 disability  
 congenital anomaly  
 required intervention to prevent permanent impairment/damage  
 other: \_\_\_\_\_

3. Date of event: about 3/15-20  
4. Date of this report: 3-30-98

5. Describe event or problem

Patient bought vitamins for weight loss from [redacted].  
 Vitamins labeled "Metabolic Nutrition Center".  
 List of ingredients "Ephedra" - small print indicates "not to take if hypertensive, has cardiovascular disease or has diabetes". Told by seller that vitamins were safe for persons with high blood pressure.

6. Relevant test/laboratory data, including dates

REC'D.  
 APR 14 1998  
 MEDWATCH CTU

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

NTN  
 DM  
 Obesity

Mail to: MEDWATCH  
 5630 Fishers Lane  
 Rockville, MD 20852-9787

OR FAX to:  
 1-800-FDA-0178

**C. Suspect medication(s)**

1. Name (give labeled strength & manufacturer, if known)  
 #1 Vitamin "Metabolic Nutrition Center"

2. Dose, frequency & route used  
 #1 by vial, sold  
 #2 as directed

3. Therapy dates (if unknown, give duration)  
 #1 March 15-20, 1998  
 #2 \_\_\_\_\_

4. Diagnosis for use (indication)  
 #1 Weight loss.  
 #2 \_\_\_\_\_

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) #1 None given  
 #2 on box product

7. Exp. date (if known) #1 None given  
 #2 on box product

8. Event reappeared after reintroduction  
 #1  yes  no  doesn't apply  
 #2  yes  no  doesn't apply

9. NDC # (for product problems only)  
None given on box

10. Concomitant medical products and therapy dates (exclude treatment of event)  
3/20-98 - 3/27-98  
Placebo on Calcium channel blocker for HTN

**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 (month/year)

6. model #  
 catalog #  
 serial #  
 lot #  
 other #

7. If implanted, give date (month/year)

8. If explanted, give date (month/year)

9. Device available for evaluation? (Do not send to FDA)  
 yes  no  returned to manufacturer on \_\_\_\_\_

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

**E. Reporter (see confidentiality section on back)**

1. Name, address & phone #  
 [redacted]

2. Health professional?  
 yes  no

3. Occupation  
Family Nurse Practitioner

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.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Memorandum

Date February 17, 1999  
From R. Edward DeBerry, CSO  
HFR-SE1525, [REDACTED]  
Subject MedWatch complaint 12942 investigation  
To Dawn L. Todd-Murrell, SI  
HFR-SE150, ATL-DO

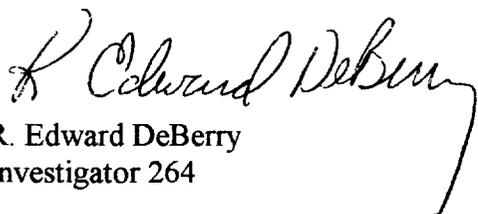
Acting supervisor Barbara T. Carmichael, ATL-DO, FAXed the referenced assignment to me on 2/1/99. The MedWatch complaint involved a female hypertension patient who purchased the subject food supplement even though the bottle labeling cited not for hypertensive people. My assignment was to interview the complainant, complete the adverse event questionnaire, and obtain medical records and product labeling.

I visited [REDACTED] FNPC, the complainant, on 2/2/99, at her place of employment, which was a doctor's office. Ms. [REDACTED] told me that she was not the patient, but that she filed the MedWatch complaint. She told me that a female patient of theirs had ordered the product through an 800-telephone number. Ms. [REDACTED] told me that the patient's blood pressure rose while taking the supplement and returned to her normal level once the product use stopped.

Ms. [REDACTED] would not give me any further information regarding the patient or product. She said that she no longer had the bottle, and that the patient did not intend to get involved.

I told Ms. [REDACTED] that there was little I could do without the patient's consent. I gave her my business card and asked her to have the patient call me if the patient wished to pursue this investigation further. Ms. [REDACTED] agreed.

It has been 15 days, without a response. I plan no further investigation.



R. Edward DeBerry  
Investigator 264

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