

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

ARMS#

13001



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~~SECRET~~ C FSAW

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

Form Approved OMB No. 0910-0291 Expires 12/31/94

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13001

Page CFSAN of

A. Patient information

1 Patient identifier [Redacted]	2 Age at time of event: 51 Date of birth:	3 Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4 Weight ____ lbs or ____ kgs
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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 (mo/day/yr)	<input type="checkbox"/> disability
<input checked="" type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3 Date of event: 6/22/98

4 Date of this report: 6/24/98

5 Describe event or problem

New onset Seizure after ingestion of "Health food" Product "Metabolife" containing ephedrine/caffeine



JUN 24 '98 AM 10:29

6 Relevant tests/laboratory data, including dates

CT Scan (-) } 6/22/98
Tox Screen (-) }
Diagnostic workup for Seizures (-)
PT. discharged To Home after 48h with No Recurrence of Seizures

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

None

JUN 24 '98 AM 10:30

C. Suspect medication(s)

1 Name (give labeled strength & mtr/labeler, if known)

#1 Metabolife (Mahuang/Caffeine)

#2 _____

2 Dose, frequency & route used

#1 _____

#2 _____

3 Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 _____

#2 _____

4 Diagnosis for use (indication)

#1 Herbal Supplement

#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 _____

#2 _____

7 Exp. date (if known)

#1 _____

#2 _____

8 Event reappeared after reintroduction

#1 yes no doesn't apply

#2 yes no doesn't apply

9 NDC # (for product problems only)

#1 _____

#2 _____

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

None

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 (mo/day/yr)

6 model #

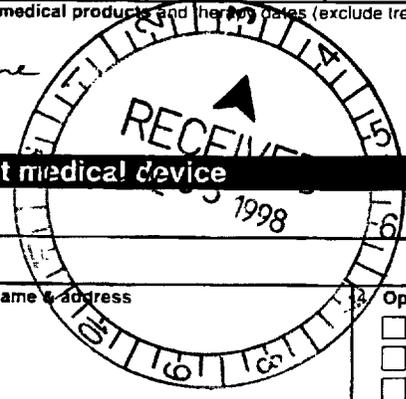
7 If implanted, give date (mo/day/yr)

8 If explanted, give date (mo/day/yr)

9 Device available for evaluation? (Do not send to FDA)

yes no returned to manufacturer on _____ (mo/day/yr)

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: Physician

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.



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

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PLEASE TYPE OR USE BLACK INK



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Memorandum

Date October 29, 1998
From David C. Radle (HFR-MA495)
Subject Status of assignment 13001
To Bridgette Wallace (HFS-636)

It appears that we will not be able to follow up on this report. After receiving your request on 9/22/98, I attempted to call Dr [REDACTED] to enlist his help in contacting the individual that experienced this reaction. However his telephone has been disconnected and directory assistance does not have any other listing for him. I waited several weeks and called the phone number again. I found that the phone number has been reassigned.

In light of these facts, I recommend this assignment be closed. If you have any questions or concerns, I may be reached at [REDACTED]

David C. Radle

