

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

ARMS#

13503



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MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting
Health professionals report adverse
events and product problems

CFSAN

FDA Use Only
99879
135031

Page 1 of 1

A. Patient information

1. Patient Identifier	2. Age at time of event: 20	3. Sex: <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight: 170 lbs
In confidence	Date of birth:		or kg

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	<input type="checkbox"/> disability
<input 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 (month/year): 2/22/99

4. Date of this report (month/year): 3/23/99

5. Describe event or problem

possible seizure / altered consciousness

- Mother stated her son took Ephedra to keep him awake while driving a truck. It was purchased at a truck stop. (Ingestion time unknown)

- 2315 having intercourse and experienced SOB & chest pain. PT became unresponsive. The ambulance arrived & the patient was restless, combative. Pupils dilated, res. p20, pulse 110, BP 148/12, warm dry skin per ambulance staff.

- on arrival at hospital HR 117 BP 189/100, Pt put on O₂ 2L/min via NC - 100% S_O₂ hyperactive bowel sounds, pressure jumped around

- Pt kept in the hospital for observation until next AM.

- Cardiac Enzymes

- ECG: ST & ectopics

- Radiology: (chest, KUB/UA) - Normal

8. Relevant tests/laboratory data, including dates

- UA 02:20 on 2/23/99 (WNL)

- BCP-13 & CBC (WNL) except:

RBC 4.55
Hgb 14.1
Albumin 4.9
Calcium 8.8

- PT (WNL) except INR 0.85

- Substance Abuse Panel to [redacted] 02:20 on 2/23/99

All negative (Alc, Barbit, Bz, Cocaine, Marijuana, etc.)

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

- Hx of 2 1/2 years cigarettes smoking (pack per day, quit 6 months ago).

- Occasional alcohol use - none presently

C. Suspect medication(s)

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

#1 Ephedra

#2

2. Dose, frequency & route used

#1 PO

#2

3. Therapy dates (if unknown, give duration)

#1 Unknown

#2

4. Diagnosis for use (indication)

#1 to keep awake

#2

5. Event started 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. NDC # (for product problems only)

#1 ?

#2

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

0 medications

0 medical problems

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 #

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 #

(KAN-10)

2. Health professional? yes no

3. Occupation: Pharmacist

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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FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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CTU 99879

TO: Lori Love, M.D., Ph.D

FROM: Constance J. Hardy *CJA*

DATE: 6/8/99

SUBJECT: ARMS 13503

On May 10, 1999 I spoke to [REDACTED] RPh concerning whether she had been able to contact the patient reported in AERS 13503. At that time she told me that she had sent a certified letter to the address of the patient and subsequent to that the fiancée of the patient had called back stating that nothing had happened to the patient and that he refused to sign any forms. Ms. [REDACTED] faxed me a copy of the original letter that had been sent to the patient. Ms. [REDACTED] later tried to call the mother of the patient, she being the one who had previously reported the event. Ms. [REDACTED] informed me today that the mother also refused to be involved with getting any further information. Consequently, I am closing this case out.

File name:c:\connie\ephedrafu\fu13503.doc

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REPORT FAXED
REPORT FAXED

Subject: FDA review

Dear [REDACTED]

The Food & Drug Administration contacted the hospital pharmacy on 4/12/99. Our pharmacy, in compliance with state and federal regulations, reports adverse drug reactions. Your case is of interest to them because of the adverse effects (heart rate, blood pressure, & heart rhythm changes) noted from the herbal supplement you took to help you stay awake. Herbal products are regulated by the Dietary Supplement Health & Education Act. Herbal products do not require premarketing studies of safety and efficacy like medication. The burden of proof to demonstrate adverse reactions lie with the Food & Drug Administration rather than the manufacturer.

The purpose of this letter is to ask for a medical release of your case. At this point, you are not identified. The FDA is very confidential. A case investigator would review your file and potentially visit with you. Other questions are:

- 1.) How long did you take the product?
- 2.) How much of the product did you take?
- 3.) What was the name of the product that you took?
- 4.) Are there any samples left? (If so they will probably want to analyze them)

People have died from taking products like this. Herbal substance need to be regulated and standardized. I would like to encourage you to release your medical file to prevent future problems other individuals might experience. Enclosed is a consent for release form. Please sign it and return it in the enclosed envelop. I look forward to hearing from you in the near future. Thank you for your consideration in this matter.

Sincerely,

[REDACTED] R.Ph.

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