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

ARMS#

13168

0 - FRONT

09/02/98 1: [redacted]

Individual Safety Report

3125818-7-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

CDER

Page 1 of 1

Triage unit sequence # 88853

13168

2(3H)-Furanone di-hydro

A. Patient information

1. Patient identifier: [redacted] In confidence
2. Age at time of event: 18 or Date of birth: [redacted]
3. Sex: ☐ female ☒ male
4. Weight: ___ lbs or 96 kgs

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 (mo/day/yr)
   - ☐ life-threatening
   - ☒ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other:
3. Date of event (mo/day/yr): 9-1-98
4. Date of this report (mo/day/yr): 9-2-98
5. Describe event or problem

Agitation, N/V, Respiratory Depression (RR=8) muscle spasms, Confusion and Delirium required mechanical ventilation and sedation c̄ Versed 8mg and Diprivan gtt. admitted to ED at 2400 on 9-1-98.

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MEDWATCH THE FDA MEDICAL PRODUCTS REPORTING PROGRAM HF-2

6. Relevant tests/laboratory data, including dates

Drug Screen
(+) Cannabinoid
(+) Amphetamine (ephedra)
Etoh 0.023

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

pmh: depression
Exercise – wt. training takes supplements to enhance wt. training
Red alert, Thermadrine

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Renutrient® (www.renutrient®)
   #2 1980 N. Atlantic Ave, Suite 407, Cocoa Beach, FL
2. Dose, frequency & route used
   #1 32 ounces
   #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1 1600 on 9-1-98 32931
   #2
4. Diagnosis for use (indication)
   #1 euphoria (?)
   #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
   #2
7. Exp. date (if known)
   #1 None
   #2
8. Event reappeared after reintroduction
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # (for product problems only) – None –
10. Concomitant medical products and therapy dates (exclude treatment of event)

Red Alert
Thermadrine (ephedra/caffine/ASA)
Beer ≈ 2-3 [SPORTPHARMA]

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 # REC'D.
   catalog #
   serial # SEP 03 1998
   lot #
   other MEDWATCH CTU
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)

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E. Reporter (see confidentiality section on back)

1. Name, address & phone # [redacted]
2. Health professional? ☒ yes ☐ no
3. Occupation: Pharm. D.
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

FDA Form 3500 (5/93) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 88853

Notes on Telephone Conversation
Clinical Research and Review Staff

#13168

Date	11/25/98	Phone No.	[redacted]
Name	[redacted]	Fax No.	[redacted]
Affliation	[redacted]		
Address	[redacted]		
FDA Representatives	Call to get information (name, phone, address) of the patient in this med watch report.		
Question/Subject			

Discussion	Called and left the message on voice mail of Dr. [redacted] regarding above mention request.
*	12/14/98: I called again to get the information and talked with Mr. [redacted] He told me that he will call me with the information.

Follow up	

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Signed: [redacted]

Date: 11/25/98
12/14/98