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

ARMS#

13271

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MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

CFSAN

See OMB statement on reverse

FDA Use Only

Triage unit sequence # 95125

13271

CFSAN Page 1 of 1

A. Patient information

1. Patient identifier: [redacted] In confidence
2. Age at time of event: 24 or Date of birth:
3. Sex: [X] female [ ] male
4. Weight: 160 lbs or ___ kgs

B. Adverse event or product problem

1. [X] 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
   - [X] hospitalization – initial or prolonged
   - [ ] disability
   - [ ] congenital anomaly
   - [ ] required intervention to prevent permanent impairment/damage
   - [ ] other:
3. Date of event (mo/day/yr): 1-4-99
4. Date of this report (mo/day/yr): 1-4-99
5. Describe event or problem

Purchased this product OTC for weight loss. Took one dose (2 capsules) developed anxiety, Dizziness, shortness of breath, audible wheezes. Needed evaluation in heath care facility observed and discharged. Symptomatic treatment with Xanax. Took 2 capsules as directed on label. Label reads:
Xenadrine RFA/1
pharmaceutical grade Rapid Fat Loss
each dose contains
citrus audium 4% synephrine standardized 125mg
ma Huang 6% ephedrine standardized 335mg
guarana 22% standardized 910mg.
White willow Bark 105mg Salicylin.

6. Relevant tests/laboratory data, including dates

Heart Rate 68
Blood pressure 140/70

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

Healthy person no other medications, overweight.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Xenadrine RFA/1
   #2
2. Dose, frequency & route used
   #1 2 capsules bid
   #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1 1-4-99 @ 8 Am one dose
   #2
4. Diagnosis for use (indication)
   #1 weight loss
   #2
5. Event abated after use stopped or dose reduced
   #1 [X] yes [ ] no [ ] doesn't apply
   #2 [ ] yes [ ] no [ ] doesn't apply
6. Lot # (if known)
   #1 63278
   #2
7. Exp. date (if known)
   #1 11/00
   #2
8. Event reappeared after reintroduction
   #1 [ ] yes [ ] no [X] doesn't apply
   #2 [ ] yes [ ] no [ ] doesn't apply
9. NDC # (for product problems only)
   – –
10. Concomitant medical products and therapy dates (exclude treatment of event)

NONE, no OTC, no RX meds.

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 # ___ catalog # ___ serial # ___ lot # ___ other # ___
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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JAN 05 1999

MEDWATCH CTU

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
   [redacted]
2. Health professional? [X] yes [ ] no
3. Occupation [redacted]
4. Also reported to Ø
   - [ ] manufacturer
   - [ ] user facility
   - [ ] distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. [ ]

FDA

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.

CTU 95125

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