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

ARMS#

12816

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MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

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Form approved: OMB No. [illegible] Expires [illegible] See OMB statement #

FDA Use Only

Triage unit sequence # 78093

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A Patient information

1. Patient identifier: In confidence
2. Age at time of event: 34 or Date of birth:
3. Sex: [X] female [ ] male
4. Weight: 186 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
   - [ ] hospitalization – initial or prolonged
   - [ ] disability
   - [ ] congenital anomaly
   - [ ] required intervention to prevent permanent impairment/damage
   - [X] other:
3. Date of event (mo/day/yr): Early Jan. 98
4. Date of this report (mo/day/yr): 2-25-98
5. Describe event or problem

Pt. had been using dano-crine for endometriosis and was also taking Thermolift from a health food store. described as a fat burner + appetite suppressant. Pt started having muscle cramps Stopped both pills Jan 7. - ~~[illegible]~~ cramps went away. Restarted Danocrine (week later + cramps did not return.

6. Relevant tests/laboratory data, including dates

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

REC'D. FEB 27 1998 MEDWATCH CTU

C Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Thermolift
   #2
2. Dose, frequency & route used
   #1 [illegible]
   #2
3. Therapy dates (if unknown, give dura[illegible] (mo/day/yr or best estimate)
   #1
   #2
4. Diagnosis for use (indication)
   #1 Fat Burner
   #2 Metabolic Booster
5. Event abated after u[illegible] stopped or dose redu[illegible]
   #1 [X] yes [ ] no [ ] [illegible]
   #2 [ ] yes [ ] no [ ] [illegible]
6. Lot # (if known)
   #1
   #2
7. Exp. date (if known)
   #1
   #2
8. Event reappeared af[illegible] reintroduction
   #1 [ ] yes [ ] no [X] [illegible]
   #2 [ ] yes [ ] no [X] [illegible]
9. NDC # (for product problems only)
10. Concomitant medical products and therapy dates (exclude treatment of event)

D Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address

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4. Operator of device
   - [ ] health professio[illegible]
   - [ ] lay user/patient
   - [ ] other:
5. Expiration date (mo/day/yr)
6. model # ___ catalog # ___ serial # ___ lot # ___ other #
7. If implanted, give [illegible] (mo/day/yr)
8. If explanted, give [illegible] (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: [redacted] mp
   phone # [redacted]
2. Health professional? [X] yes [ ] no
3. Occupation: Doctor.
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. [X]

PLEASE TYPE OR USE BLACK INK

FDA

Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 1/96

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the even[illegible]