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

ARMS#

12875

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APR 28 '98 07:45AM [redacted]

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

CFSAN CDER

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Form Approved: OMB No. P.1/1 Expires: 12/31/94

FDA Use Only

Triage unit sequence # 82126

12875

A. Patient information

1. Patient identifier: In confidence
2. Age at time of event: 37/40 or Date of birth: [redacted]
3. Sex: [X] female [ ] male
4. Weight: 125 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
   - [X] required intervention to prevent permanent impairment/damage
   - [X] other Cystitis - Ripped Fuel Severe Angina - Cipro Attacks
3. Date of event (mo/day/yr): #1 4/1995 #2 JAN 1998
4. Date of this report (mo/day/yr): 4/26/98
5. Describe event or problem

Ripped Fuel - Caused severe cystitis, Cysts in Breast, back near Left Kidney area, ovarian cysts that burst. This was due to taking Ripped Fuel for about 30 Days twice daily. This was even less than what directions said. Did not know affects related to taking product. nothing listed for fibercystic disease. NO WARNINGS

CIPROFLOXACIN - HCl

Cipro - Severe Angina Attacks reported to physician - immediately stopped taking - called pharmacy this was a side affect of 1% people.

6. Relevant tests/laboratory data, including dates

Ripped Fuel

Ultra sound - showed ovarian cysts burst, Mamogram showed fibercystic lumps in Breast, Due to high ent. of the Caffine + ephedrine. A deadly combination.

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

Fibercystic breasts,

RECEIVED MAY 06 1998

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   - #1 RIPPED FUEL - TWIN LABS 1995
   - #2 CIPRO - 500 MG - BAYER CORP - 1998
2. Dose, frequency & route used
   - #1 2 ea twice a day orally
   - #2 1 ea twice a day orally
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   - #1 1995
   - #2 JAN 10-23 1998
4. Diagnosis for use (indication)
   - #1 Weight Loss
   - #2 ANTIBIOTIC
5. Event abated after use stopped or dose reduced
   - #1 [X] yes [ ] no [ ] doesn't apply
   - #2 [X] yes [ ] no [ ] doesn't apply
6. Lot # (if known)
   - #1
   - #2 S50131/7ABA
7. Exp. date (if known)
   - #1
   - #2 1/00
8. Event reappeared after reintroduction
   - #1 [ ] yes [ ] no [X] doesn't apply
   - #2 [ ] yes [ ] no [X] doesn't apply
9. NDC # (for product problems only)
10. Concomitant medical products and therapy dates (exclude treatment of event)

RECD APR 29 1998

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address: MEDWATCH
4. Operator of device: [ ] health professional [ ] lay user/patient [ ] other:
5. Expiration date (mo/day/yr)
6. model # RECEIVED 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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E. Reporter (see confidentiality section on back)

1. Name, address & phone #: [redacted]
2. Health professional? [ ] yes [X] no
3. Occupation: Office Clerk
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 (6/93)

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