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

ARMS#

13165

0 - FRONT

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

Page CFSAN

Form Approved OMB No 0910-0291 Expires 12/31/94
See OMB statement on reverse

FDA Use Only (AHFS)
Triage unit sequence # 91668
13165

A. Patient information

1 Patient identifier: [redacted] In confidence

2 Age at time of event: 21 YR. or Date of birth:

3 Sex: [X] female [ ] male

4 Weight: ___ lbs or 95 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): 10/6/98

4 Date of this report (mo/day/yr): 10/21/98

5 Describe event or problem

PATIENT ON DIET FOR A COUPLE OF MONTHS. LOST 40 lbs in 2 MONTHS. TOOK THIS PRODUCT. ADMITTED TO E.R. c CARDIAC ARRHYTHMIAS. SEE OVER FOR CONTENTS OF THERMOLIFT. THIS MAY NOT HAVE BEEN ONLY PROBLEM. EVENTUALLY REQUIRED PACEMAKER.

6 Relevant tests/laboratory data, including dates

↓ K^+ — 2.7 mEQ/L.
↓ Mg^{++} — 1.6 mg/dL.

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

OCT 28 1998

MEDWATCH CTU

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler if known)
#1 THERMOLIFT – CHANGES INTERNAL
FORT WALTON BEACH, FLORIDA.

2 Dose, frequency & route used
#1
#2

3 Therapy dates (if unknown, give duration) from/to (or best estimate)
#1
#2

4 Diagnosis for use (indication)
#1
#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
#2

7 Exp. date (if known)
#1
#2

8 Event reappeared after reintroduction
#1 [ ] yes [ ] no [ ] 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)
OTC – COLD MEDICATION

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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E. Reporter (see confidentiality section on back)

1 Name, address & phone #
[redacted]

2 Health professional? [X] yes [ ] no

3 Occupation: PHARMACIST

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. [ ]

FDA

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.

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CTU 91668

THERMOLIFT (1-850-837-1956) CONTENTS:
HERB ENERGIZER & HIGH FAT BURNER

MA HUANG EXTRACT
CALCIUM PICOLINATE
GUARANA EXTRACT
WHITE WILLOW BARK
BLADDER WRACK
REISHI MUSHROOM
GOTU KOLA
SIBERIAN GINSENG
REHMANNIA ROOT
GINGER ROOT
LICORICE ROOT
ASTRALAGUS
BEE POLLEN

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RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-452

Notes on Telephone Conversation
Clinical Research and Review Staff

13165

Date	11/27/98	Phone No.	[redacted]
Name	Mr. [redacted]	Fax No.	
Affliation	Pharmacist, [redacted]		
Address	[redacted]		
FDA Representatives	Dr. Nanwar		
Question/Subject	to get information (name, address, phone) of the patient mentioned in this report # 13165 for field staff.		

Discussion	Called & left a message with Ms. [redacted] for Mr. [redacted], asking for above mention information for further F/U for field staff.
*	12/17/98. I Called again to get the above mentioned information Ms. [redacted] will call with the information
*	12/17/98 Mr. [redacted] Called & told me that any particular of the patient in this chart can not be revealed due to Confidentiality.

Follow up	

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Signed: Nanwar MD

Date: 11/27/98

* 12/17/98