

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

ARMS#

13272



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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. 0910-0291 Expires: 4/30/99
See OMB statement on revers

FDA Use Only

Triage unit sequence # 95199
13272

A. Patient information

1. Patient identifier [redacted] In confidence	2. Age at time of event: <u>43 Years</u> or Date of birth: [redacted]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight <u>140</u> lbs or _____ kgs
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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)

<input type="checkbox"/> death _____ (mm/dd/yyyy)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input checked="" type="checkbox"/> other: _____

3. Date of event (mm/dd/yyyy) <u>10/01/98</u>	4. Date of this report (mm/dd/yyyy) <u>12/28/98</u>
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5. Describe event or problem (up to a total of 6400 characters allowed)
Dizziness, nervousness, increased heart rate
I have no known illness, heart or blood pressure problems. The product label states that it contains 8% Mahuang extract (ephedra sinica)

Changes International, Ft. Walton Beach, FL

6. Relevant tests/laboratory data, including dates (a total of 1000 characters allowed)

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7. Other relevant history, including preexisting medical conditions (up to a total of 500 characters allowed)

C. Suspect medication(s)

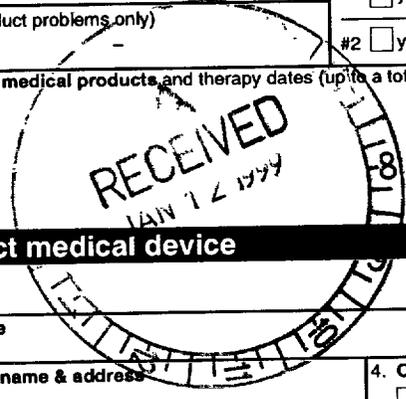
1. Name (Product Name) (Labeled Strength) (Mfr/Labeler) #1 <u>Thermo-Lift</u> / / <u>Changes International</u>	2. Dose/Frequency/Route used #1 <u>oral / 2capsul / esdail /</u>	3. Therapy dates (if unknown, give duration) From To (or best estimate) #1 <u>Less than one week</u>
#2	#2	#2

4. Diagnosis for use (separate indications with commas) #1 <u>herbal energizer & super fat burner</u>	5. Event abated after use stopped or dose reduced #1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply

6. Lot # (if known) #1 <u>4709L</u>	7. Exp. date (if known) #1 <u>11/99</u>	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2	#2	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply

9. NDC # (for product problems only)
#1 _____ #2 _____

10. Concomitant medical products and therapy dates (up to a total of 1000 characters)



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 (mm/dd/yyyy) _____

6. model # _____
7. If implanted, give date (mm/dd/yyyy) _____

8. If explanted, give date (mm/dd/yyyy) _____

9. Device available for evaluation? (Do not send device to FDA)
 yes no returned to manufacturer on _____ (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (up to a total of 1000 characters)
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E. Reporter (see confidentiality section on back)

1. Name _____ phone # _____
Address _____ E-mail (for electronic acknowledgement) _____

2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation Other Health Professional _____	4. Also reported to <input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor
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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 (WWW)

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