

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

ARMS#

12946



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MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

CFSAN

For VOLUNTARY report by health professionals of events and product problems



APPENDIX

Individual Safety Report



3091067-4-00

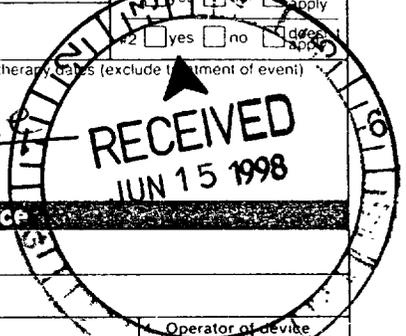
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A. Patient information			
1 Patient identifier	2 Age at time of event: 37	3 Sex: <input checked="" type="checkbox"/> female	4 Weight: 238 lbs
In confidence			
Date of birth: [redacted]			
B. Adverse event or product problem			
1 <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2 Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (mo/day/yr)		<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: see below			
3 Date of event (mo/day/yr): 11-26-97	4 Date of this report (mo/day/yr): 6-2-98		
5 Describe event or problem			
<p>37yo ♀ starting taking OTC Natural Trim Thermogen pills for weight loss. After 1 week of taking 1 po BID she devel came to office complaining dizzy, blurred vision + feeling sick. I stopped the pills & all symptoms went away within 24° of stopping. BP 120/82</p> <p>all symptoms started in medication a few days after starting the pills. No fever. No signs or symptoms of other cause.</p>			
6 Relevant tests/laboratory data, including dates			
None			
7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)			
None otherwise healthy			

C. Suspect medication(s)			
1 Name (give labeled strength & mlr/labeler if known)			
#1 Ephedra in "Natural Trim Thermogen" sold OTC			
#2			
2 Dose, frequency & route used		3 Therapy dates (if unknown, give duration) (mo/day/yr) (or best estimate)	
#1 1 po BID		#1 11-19-97 to 11-26-97	
#2		#2	
4 Diagnosis for use (indication)		5 Event abated after use stopped or dose reduced	
#1		#1 <input 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)	7 Exp date (if known)	8 Event reappeared after reintroduction	
#1	#1	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input 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)			
10 Concomitant medical products and therapy dates (exclude treatment of event)			
None			
D. Suspect medical device			
1 Brand name			
2 Type of device			
3 Manufacturer name & address			Operator of device
REC'D. JUN 11 1998			<input type="checkbox"/> health professional
MEDWATCH CTU			<input type="checkbox"/> lay user/patient
5 Expiration date (mo/day/yr)			<input type="checkbox"/> 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)			
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (mo/day/yr)			
10 Concomitant medical products and therapy dates (exclude treatment of event)			

E. Reporter (see confidentiality section on back)			
1 Name [redacted]			
2 Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		3 Occupation: M.D.	
4 Also reported to		5 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input checked="" type="checkbox"/>	
<input type="checkbox"/> manufacturer		<input type="checkbox"/> user facility	
<input type="checkbox"/> distributor			



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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