

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

ARMS#

13238



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# CFSAN

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Form Approved. OMB No. 0910-0291 Expires 4/30/96  
See OMB statement on reverse

# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

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FDA Use Only
Triage unit sequence #
13238
493767

1 Patient Identifier [Redacted]	2 Age at time of event: 36 Years or Date of birth: [Redacted]	3 Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4 Weight 250 lbs or [Redacted] kgs
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 (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 10/31/1998 (mm/dd/yyyy)	4. Date of this report 12/04/1998 (mm/dd/yyyy)		
5. Describe event or problem (up to a total of 6400 characters allowed)			
Marital Strife Disassociation with family and friends Denial of addiction to diet supplements Sleep of only 2-3 hours per night Memory Loss Easily Aggitated Aggressive behavior			
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)			



1. Name (Product Name) (Labeled Strength) (Mfr/Labeler) #1 Metabolife / / Metabolife Intl		
#2 / /		
2. Dose/Frequency/Route used #1 8 /per day/Oral		3. Therapy dates (if unknown, give duration) From To (or best estimate) #1 07/01/1998-10/23/1998
#2 / /		#2 -
4. Diagnosis for use (separate indications with commas) #1 weight loss		5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6. Lot # (if known) #1 G803	7. Exp. date (if known) #1 07/01/2001	
#2	#2	
8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply		
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply		
9. NDC # (for product problems only) - -		
10. Concomitant medical products and therapy dates (up to a total of 1000 characters)		
1. Brand name		
2. Type of device		
3. Manufacturer name & address		4. Operator of device <input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other
6. model # _____		5. Expiration date (mm/dd/yyyy)
catalog # _____		7. If implanted, give date (mm/dd/yyyy)
serial # _____		8. If explanted, give date (mm/dd/yyyy)
lot # _____		
other # _____		
9. Device available for evaluation? (Do not send device to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (mm/dd/yyyy)		
10. Concomitant medical products and therapy dates (up to a total of 1000 characters)		
1. Name		phone #
Address		E-mail (for electronic acknowledgement)
2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation Consumer/Non-Health Professional	4. Also reported to <input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor
5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>		



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.

CTU 99767

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# MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems  
Detail Reporter page - Page 2

[REDACTED]

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Last Name		First Name		Middle Initial
[REDACTED]		[REDACTED]		[REDACTED]
Title				
Consumer/Non-Health Professional				
Organization		Department		
[REDACTED]		[REDACTED]		
Mailing Address - Street name, number, PO Box, rural route, mail route code designator, etc.				
[REDACTED]				
City		State	Zip Code	Country (if not USA)
[REDACTED]		[REDACTED]	[REDACTED]	United States
Telephone	Country Code	Area Code	Phone Number	Extension
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Fax	Country Code	Area Code	Phone Number	Extension
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
E-mail Address				
[REDACTED]				



REC'D.

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