

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

ARMS#

13413



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# MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

CFSAN

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

FDA Use Only  
 Triage unit sequence # **99384**  
**13413**

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CFSAN

### A. Patient information

1 Patient identifier	2 Age at time of event: or Date of birth:	3 Sex	4 Weight
	31	<input checked="" type="checkbox"/> female <input type="checkbox"/> male	180 lbs or ___ kgs

### 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	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other

3 Date of event (mo/day/yr) **1-12-98**

4 Date of this report (mo/day/yr) **3-9-99**

5 Describe event or problem

I was taking Metabolife when I got a lump the size of a pea within a week it grew to the size of a tennis ball and hurt terribly. I went to the doctors & he thought it was a hernia so he sent me to a surgeon they said they thought it was a strangulated hernia they rushed me in for emergency surgery. When the doctors were done they said it was not a strangulated hernia it was something else. They didn't know what it was. It could have been a tumor. I still don't know what it was but I do know I never had any problems before I took that Metabolife. The infectious disease people came in to my room asking questions day after day & I had no idea what they didn't know what it was either. Besides the two bottles mentioned I finished one other bottle and finished it but threw the bottle away.

6 Relevant tests/laboratory data, including dates

Rushed in for emergency surgery.

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

None

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### C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)

#1 Metabolife

#2 Metabolife

2 Dose, frequency & route used

#1 1 before each meal 3 times a day

#2 1 before each meal 3 times a day

3 Therapy dates (if unknown, give duration)

#1 N/A

#2 N/A

4 Diagnosis for use (indication)

#1 To lose weight

#2 To lose weight

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 A804

#2 C825

7 Exp. date (if known)

#1 1/01

#2 3/01

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)

### 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 #

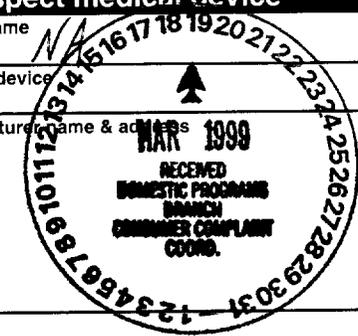
7 If implanted, give date (mo/day/yr)

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

2 Health professional?  yes  no

3 Occupation

oper. Engineer

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