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

ARMS#

13331

0 - FRONT

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

Page CFSAN CFSAN

Form Approved: OMB No. 0910-0291 Expires: 4-3 See OMB statement on rev

FDA Use Only

Image unit sequence # 96930 13331

A. Patient information

1 Patient identifier: In confidence

2. Age at time of event: 16 yo or Date of birth:

3. Sex: ☐ female ☑ male

4 Weight: ___ 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)
- ☐ death ___ mo/day/yr
- ☐ life-threatening
- ☑ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ___

3. Date of event mo/day/yr: 2/2/99

4 Date of this report mo/day/yr: 2/3/99

5. Describe event or problem

16 yo 03 Had argument c̄ mother and took 70 "health food" pills. Approx 20 of Metabolift.
c/o Headache, mild dyspnea
HR 90-95 169/92
Pt given 50 gm Charcoal c̄ Sorbitol

6 Relevant tests/laboratory data, including dates

Tox Screen ⊕ Bar Amphetamines

REC'D. FEB 04 1999 MEDWATCH CTU

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

FEB 3 '99 2:19

RECEIVED FEB 08 1999

MEDWATCH THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

HF-2

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)
#1
#2

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 ☐ does apply
#2 ☐ yes ☐ no ☐ does apply

6 Lot # (if known)
#1
#2

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

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ does apply
#2 ☐ yes ☐ no ☐ does 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: Metabolift

2. Type of device: Caplet

3. Manufacturer name & address: Metabolife International

REC'D. FEB 04 1999 MEDWATCH CTU

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)

E. Reporter (see confidentiality section on back)

1 Name & address: [redacted] phone # [redacted]

000001

2. Health professional? ☑ yes ☐ no

3. Occupation: Physician

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

FDA

CTCI 96930

TO: Lori Love, M.D., Ph.D.

FROM: Constance J. Hardy CJH

DATE: February 3, 2000

SUBJECT: ARMS 13331

I spoke today to Ms. [redacted] secretary for Dr. [redacted], the reporter for ARMS 13331. She clarified that Dr. [redacted] had made an error when he mentioned both Metabolife and Metabolife International in ARMS 13331. She stated that the product involved was Metabolife 356, made by Metabolife International and not Metabolift.