

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

ARMS#

13058



0 - FRONT

UNITED STATES FOOD AND DRUG ADMINISTRATION  
**CONSUMER COMPLAINT/INJURY REPORT**

1. COMPLAINT NUMBER **EDR-2606**  
 2. DATE OF COMPLAINT **5/19/98**

FORM OF COMPLAINT (1)  TELEPHONE (4)  OTHER  
 (2)  LETTER (3)  VISIT

4. SOURCE OF COMPLAINT  CONSUMER  TRADE  
 GOVERNMENT  OTHER  
 LOCAL  STATE  FEDERAL

5. COMPLAINANT IDENTIFICATION  
 a. NAME AND ADDRESS [REDACTED]  
 b. TELEPHONE NUMBER  
 HOME [REDACTED]  
 WORK [REDACTED]

6. COMPLAINT OR INJURY  
 a. DESCRIPTION OF COMPLAINT/INJURY Complainant called to report that she suspects the severe erratic change in behavior (for the worst) of her 15 year old daughter [REDACTED] is the result of the consumption of product. Unknown to complainant [REDACTED] was taking product along with Dexatrim to loose weight for an unknown amount of time. Child, on the honor roll last semester has failed all her exams, does not sleep at night, nice one minute and in a split second cursing at her parents and siblings. Complainant has an appointment to have a phychological exam of her daughter tomorrow and will bring this to their attention.  
 b. DOES COMPLAINANT EXPECT FURTHER FDA CONTACT?  NO  YES (If YES, explain in remarks)

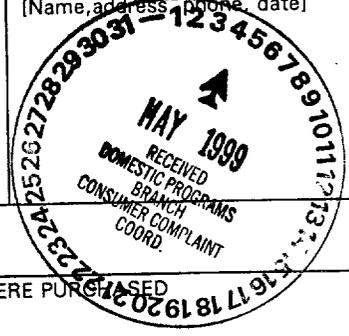
7. INJURY OR ILLNESS RESULTED  
 (1)  NO  
 (2)  YES (complete 7a through 7d)

1. DEIO/EMOPS (HFC-130) NOTIFIED?  
 (1)  NO  
 (2)  YES  
 DATE

b. SYMPTOMS ONSET (HRS)  
 (1)  VOMITING  
 (2)  NAUSEA  
 (3)  DIARRHEA  
 (4)  FEVER  
 (5)  SKIN/EYE IRR.  
 (6)  HEADACHE  
 (7)  OTHER

c. ATTENDING HEALTH PROFESSIONAL  
 (1)  NO (2)  YES  
 (Name, address, phone)

d. HOSPITALIZED  
 (1)  NO (2)  YES  
 (Name, address, phone, date)



8. PRODUCT AND LABELING  
 a. BRAND NAME **Twin Labs**  
 b. PRODUCT NAME **Metabolift Dietary Supplement**  
 c. SIZE AND PACKAGE TYPE **60 caps**  
 d. NAME AND LOCATION OF STORE WHERE PURCHASED [REDACTED]  
 e. LOT / SERIAL NUMBER. **79065**  
 f. DATE PURCHASED **unknown**  
 g. PRODUCT USED (1)  NO (2)  YES  
 h. AMT REMAINING **approx 1/2**  
 EXP / USE BY DATE **none**  
 DATE

9. MANUFACTURER / DISTRIBUTOR OF PRODUCT  
 a. HOME DISTRICT **NYK**  
 b. CFN **2421049**  
 c. NAME AND LOCATION OF FIRM **Twin Labs, Inc. Ronkonkoma, NY 11779**  
 d. IMPORT PRODUCT (1)  NO (2)  YES

10. INITIAL EVALUATION AND DISPOSITION  
 a. PROBLEM KEYWORD  
 (1) CODE **RX** (2) DESCRIPTION **mood swings**  
 b. EVALUATION  
 (1)  NOT AN FDA OBLIGATION  
 (2)  OBLIGATION, NO VIOLATION  
 (3)  FDA ACTION INDICATED  
 (4)  INSUFFICIENT INFORMATION UNABLE TO EVALUATE  
 c. DISPOSITION  
 (1)  IMMEDIATE FOLLOW-UP  
 (2)  F/U NEXT EI  
 (3)  CLOSED WITHOUT FURTHER INVESTIGATION  
 (4)  REFERRED TO OTHER FEDERAL AGENCY  
 (5)  REFERRED TO STATE / LOCAL AGENCY  
 (6)  REFERRED TO OTHER FDA DISTRICT **NYK**  
 (7)  REFERRED TO OCI

11. PRODUCT CODE **54Y--99**  
 12. INFORMATION COPIES TO  
 HFC-130  HFD-730  
 HFM-650  HFS-635  
 HFV-210  HFZ-530  
 OTHER

REMARKS **Complainant also wants to know what FDA is going to do about the fact that container says "Not Intended For Persons Under 18" and her daughter was able to purchase. I mailed a Med-Watch form to complainant for completion by physician.**

NAME AND TITLE **Janet Rowe, CCC, EMOPS** DATE **05/20/98**

CFSAW

FDA Use Only  
Triage unit sequence # **88059**  
**13058**

### A. Patient information

1 Patient identifier	2 Age at time of event: <b>15</b> or Date of birth: [redacted]	3 Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight <b>133</b> 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 _____ (mo/day/yr)	<input checked="" type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input checked="" 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) **2/1/98**

4 Date of this report (mo/day/yr) **8-8-98**

5 Describe event or problem

My daughter had purchased medication without my consent. I notice a change in her behavior. Irratic sleeping patterns & mood swings (dramatic). Grades in school were dropping. I found med & confronted her. An argument followed. I had to take her to a counsellor. She also showed signs of withdrawal. Product was sold to a minor.

6. Relevant tests/laboratory data, including dates

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

**N/A**

**REC'D.**

**AUG 17 1998**

**MEDWATCH CTU**

### C. Suspect medication(s)

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

#1 **Metabolift**

#2 \_\_\_\_\_

2 Dose (frequency & route used)

#1 **? ? PO**

#2 \_\_\_\_\_

3 Therapy dates (if unknown, give duration from to (or best estimate))

#1 **? maybe 6 months**

#2 \_\_\_\_\_

4 Diagnosis for use (indication)

#1 **weight loss**

#2 **energy**

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 **Bar Code #**

#2 **2743400191**

7 Exp. date (if known)

#1 \_\_\_\_\_

#2 \_\_\_\_\_

8 Event reappeared after reintroduction

#1  yes  no  doesn't apply

#2  yes  no  doesn't apply

9 NDC # (for product problems only)

**Herbal medication**

10 Concomitant medical products and therapy dates (exclude treatment of event)

**purchased at [redacted] at [redacted]**

### 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)

**000002**

### E. Reporter (see confidentiality section on back)

1 Name, address & phone #

[redacted]

2. Health professional?  yes  no

3 Occupation **Pharmacy Tech.**

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 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.

CTU 88059

# ADVICE ABOUT VOLUNTARY REPORTING

## Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

## Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

## Report even if:

- you're not certain the product caused the event
- you don't have all the details

## Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

## How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

## Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

## If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

**Confidentiality:** The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

The public reporting burden for this collection of information has been estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send your comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Reports Clearance Officer, PHS  
Hubert H. Humphrey Building,  
Room 721-B  
200 Independence Avenue, S.W.  
Washington, DC 20201  
ATTN: PRA

and to:  
Office of Management and  
Budget  
Paperwork Reduction Project  
(0910-0230)  
Washington, DC 20503

Please do NOT  
return this form  
to either of these  
addresses.

FDA Form 3500-back

Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail

## Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Rockville, MD 20857

## Official Business

Penalty for Private Use \$300

**BUSINESS REPLY MAIL**

FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

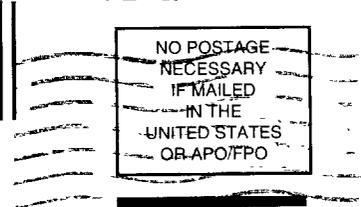
**MEDWATCH**

The FDA Medical Products Reporting Program

Food and Drug Administration

5600 Fishers Lane

Rockville, MD 20852-9787



RECEIVED  
CLINICAL RESEARCH  
& REVIEW/OSN HFS-452



000003

## Adverse Event Questionnaire

Complaint Number: 98-0214

Investigator: Wimberly

Consumer Information		
Date of Report: <u>09/30/98</u> MM/DD/YY	Initial Report Source: <input type="checkbox"/> ORA Consumer Injury	
<input type="checkbox"/> Telephone <input type="checkbox"/> Correspondence <input checked="" type="checkbox"/> MedWatch <input type="checkbox"/> USP <input type="checkbox"/> PQRS <input type="checkbox"/> Poison Control <input type="checkbox"/> CDC		
Name: <span style="background-color: black; color: black;">[REDACTED]</span>	Gender: <input checked="" type="checkbox"/> F <input type="checkbox"/> M	Age: <u>15</u>
Race: <input checked="" type="checkbox"/> 1-White <input type="checkbox"/> 2-Black <input type="checkbox"/> 3-Asian/Pacific Islander <input type="checkbox"/> 4-Native American <input type="checkbox"/> 5-Hispanic <input type="checkbox"/> 8-Other <u>4198</u> <input type="checkbox"/> 9-Unknown		
Information on Adverse Event		
Date of Adverse Event: <u>4/98</u>	Give the site of consumption/ingestion (e.g. home, restaurant, office):	
Previous Adverse Effects to Product Type: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<u>home</u>	
<p>The following information relates to the consumers' use of the product.</p> <p>Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):  <u>mother observed unexplained erratic behavior in 15 year old daughter, including rebelliousness and erratic sleep patterns</u>            How long did the symptoms last?            Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.): <u>not known, daughter taking dietary supplement without parental consent</u>            List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:  <u>no meds</u>            Did event abate after use of suspected product stopped or dose reduced: <input checked="" type="checkbox"/>Yes <input type="checkbox"/>No <input type="checkbox"/>Unknown            Did symptoms reoccur after reintroduction of suspected product: <input type="checkbox"/>Yes <input type="checkbox"/>No <input type="checkbox"/>Unknown <input checked="" type="checkbox"/>Not Applicable            Did symptoms reoccur after using other products with the same ingredients: <input type="checkbox"/>Yes <input type="checkbox"/>No <input type="checkbox"/>Unknown <input checked="" type="checkbox"/>Not Applicable         </p>		
Medical Information		
Was a health care provider seen?: <input type="checkbox"/> Yes <input type="checkbox"/> No <u>mother took daughter to counselor</u>		
Give health care provider's name, address and telephone number: <u>to treat erratic behavior. name, address, and telephone number not determined</u>		
Occupation of Health Care Provider: <input type="checkbox"/> MD <input type="checkbox"/> Osteopath <input type="checkbox"/> Naturopath <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input checked="" type="checkbox"/> Other (specify) <u>counselor</u>		
What medical tests were performed and what were the results?		
What was the medical diagnosis?		
What treatment(s) was given (e.g., drugs, other)? <u>not determined</u>		
Were there any preexisting condition(s)/treatment(s)? (If YES, list them including allergies, and chronic diseases): <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		

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Assignment 98-0214  
EXHIBIT 2  
Page 1 of 2

Product Category

1. Adverse event attributed to:

Medical Food (under medical supervision)  Infant Formula

Dietary Supplement (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)

Other (traditional food) \_\_\_\_\_

Other Product Problems

2.  Foreign Object  
(specify): \_\_\_\_\_

3.  Other (specify): \_\_\_\_\_

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

*METABOLIFT manufactured by TwinLab, Inc. Ranonkoma, NY 11779  
2 capsules before each meal not to exceed 6 capsules*

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):

Check here if ingredients are unknown

*MctHone extract, Goring Extract*

*Chromium (from Chromic fuel) patented chromium picolinate*

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

Aspartame

Color Additive (please specify) \_\_\_\_\_

Monosodium Glutamate

Sulfite

Other \_\_\_\_\_

Unknown

Is the product label available, if yes submit a quality copy along with this questionnaire:  Yes  No

Unknown Product Sample Available:  Yes  No  Unknown

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records)

Death:  Yes  No

Life-Threatening:  Yes  No

Hospitalization:  Yes  No (if YES, indicate if initial or prolonged) \_\_\_\_\_

Required intervention to prevent permanent impairment/damage:  Yes  No

Did the adverse event result in a congenital anomaly:  Yes  No

000005



*Read  
11/30/98  
J. DOEY*

**Memorandum**

*File*



Date October 26, 1998

From Marion Wimberly, CSO

Subject Assignment 98-0214

To Gregory Dixon, SCSO

CFSAN assignment 98-0214 is a report of [redacted] adverse reaction to Metabolift. [redacted] is aged 15. I interviewed her mother, Mrs. [redacted] on October 21, 1998, Mrs. [redacted] believes her daughter purchased Metabolift at a [redacted] located in the [redacted] at [redacted]. Mrs. [redacted] believes her daughter took Metabolift for weight control. She describes her daughter as approximately 5 feet 8 inches tall and approximately 135 pounds.

The interview found Mrs. [redacted] observed a change in her daughter's behavior while using Metabolift. She describes her behavior as characterized by dramatic mood swings and erratic sleeping patterns. Mrs. [redacted] was not able to determine how long her daughter took Metabolift or how many tablets she took. An Adverse Events Questionnaire is attached to this Memorandum as EXHIBIT two. Reportedly [redacted] father found a bottle of Metabolift in [redacted] bedroom.

TO: HFS-636

11/25/98

Attached is the available information collected per CFSAN ARMS Project assignment 13058. Medical records were not available as the patient's mother could not recall the name of the patient's therapist. The patient is a minor child.

Gregory D. Dixon  
KAN-DO Supervisory Investigator

*CC: HFS-636 (all)  
CC: KAN files*

**000006**

My examination of the consumer bottle found thirty three remaining capsules in a sixty capsule bottle. The labeled ingredients included Ma Huang extract, Guarana extract, and patented chromium picolinate. I was not able to collect the label from the consumer's bottle. Mrs. [REDACTED] insisted on keeping the bottle for "evidence". I purchased a bottle of Metabolift containing sixty capsules from the [REDACTED] in the [REDACTED]. A photo copy of the label is attached to this memorandum as EXHIBIT one.

Reportedly, Mrs. [REDACTED] took her daughter to a counselor for treatment of her erratic behavior. Mrs. [REDACTED] was not able to recall the counselor's name or address. Additionally there was no billing information available from the counselor. Mrs. [REDACTED] found the counselor's name in a telephone directory. Reportedly the counselor treated [REDACTED] for approximately four hours. To the best of Mrs. [REDACTED] knowledge the counselor did not administer a physical examination.

Mrs. [REDACTED] agreed to continue to search for the identity of the counselor who treated her daughter.

Mrs. [REDACTED] does not permit her daughter to use additional Metabolift. Reportedly her daughters' behavior returned to normal.

*Marion Wimberly*  
Marion Wimberly (295)  
KAN-DO CSO

EXHIBITS:

1. Product label Metabolift
2. Adverse Reaction Questionnaire

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