

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

ARMS#

12464



0 - FRONT

COMPLAINT / INJURY REPORT

<p>3. FORM OF COMPLAINT</p>	<p>a. (1) <input checked="" type="checkbox"/> TELEPHONE (2) <input type="checkbox"/> LETTER (3) <input type="checkbox"/> VISIT</p>	<p>4. SOURCE OF COMPLAINT</p>	<p>a. (1) <input type="checkbox"/> CONSUMER (3) <input type="checkbox"/> TRADE SOURCE (2) <input type="checkbox"/> GOVERNMENT (4) <input checked="" type="checkbox"/> OTHER <input type="checkbox"/> L <input type="checkbox"/> S <input type="checkbox"/> F (Indicate in Remarks)</p>
<p>5. COMPLAINANT IDENTIFICATION</p>	<p>a. NAME AND ADDRESS (Include ZIP Code) [redacted] for his 23yr old son [redacted] [redacted]</p>		<p>b. AREA CODE AND TELEPHONE NUMBER HOME ([redacted]) WORK ()</p>
<p>6. COMPLAINT OR INJURY</p>	<p>a. DESCRIPTION OF COMPLAINT / INJURY Complainant stated his son has been taking 6 capsules and more per day of Twin Labs. Metabolic Enhancer Ripped Fuel, for the past two years. The son told his mother he can not stop using the product, he becomes sick - Mr. [redacted] feels his son's reaction is the same as a drug addicts' withdrawal sym. Also, the son is not looking for work because he is exp. hair loss, facial twitching, glassy eyes.</p> <p>b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES (If "Yes" Explain in Remarks)</p>		
<p>7. INJURY OR ILLNESS RESULTED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES *(If "yes" complete items a through d)</p>	<p>a. EIB (HFC - 161) NOTIFIED (1) <input type="checkbox"/> NO (2) <input type="checkbox"/> YES DATE: _____</p>	<p>b. TYPE SYMPTOMS ONSET (HR.) (1) <input type="checkbox"/> VOMITING _____ (2) <input type="checkbox"/> NAUSEA _____ (3) <input type="checkbox"/> DIARRHEA _____ (4) <input type="checkbox"/> FEVER _____ (5) <input type="checkbox"/> SKIN/EYE IRR. _____ (6) <input type="checkbox"/> HEADACHE _____ (7) <input checked="" type="checkbox"/> OTHER facial twitching/hair loss</p>	<p>c. ATTENDING HEALTH PROFESSIONAL? (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES (If "Yes" give name, address, and phone number)</p> <p>d. HOSPITALIZATION REQUIRED? (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES (If "Yes" give name, address, phone number, and dates)</p>
<p>8. PRODUCT AND LABELING</p>	<p>a. BRAND NAME Twin Labs</p> <p>c. SIZE AND PACKAGE TYPE 60 capsules/334 mg</p> <p>e. PACKAGE CODE / SERIAL NUMBER / ETC. LOT #74623</p> <p>EXP. / USE BY DATE: _____</p>	<p>b. PRODUCT NAME Ripped Fuel (Ma Huang;Guaranaetc)</p> <p>d. NAME AND LOCATION OF STORE WHERE PURCHASED [redacted]</p> <p>f. DATE PURCHASED 2 wks ago</p> <p>g. PRODUCT USED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES Date: _____</p> <p>h. AMT. REMAINING unknown</p>	
<p>9. MANUFACTURER / DISTRIBUTOR OF PRODUCT</p>	<p>a. HOME DISTRICT NYK</p> <p>b. C.F. NO. 2421049</p>	<p>c. NAME AND LOCATION OF FIRM (Include ZIP Code) Twin Labs Ronkonkoma NY 11779</p>	<p>d. IMPORT PRODUCT (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES</p>
<p>10. EVALUATION AND DISPOSITION</p>	<p>a. PROBLEM KEY WORD (1) CODE RX (2) DESCRIPTION face twitch</p> <p>b. EVALUATION (1) <input type="checkbox"/> NOT AN FDA OBLIGATION (2) <input type="checkbox"/> OBLIGATION, NO VIOLATION (3) <input checked="" type="checkbox"/> FDA ACTION INDICATED (4) <input type="checkbox"/> INSUFFICIENT INFORMATION UNABLE TO EVALUATE</p>	<p>b. DISPOSITION (1) <input type="checkbox"/> IMMEDIATE FOLLOW-UP (2) <input checked="" type="checkbox"/> F / U NEXT EI (3) <input type="checkbox"/> CLOSED WITHOUT FURTHER INVESTIGATION (4) <input type="checkbox"/> REFERRED TO OTHER FEDERAL AGENCY (Closes File) (5) <input type="checkbox"/> REFERRED TO STATE / LOCAL AGENCY (Closes File) (6) <input type="checkbox"/> REFERRED TO OTHER FDA DISTRICT (7) <input type="checkbox"/> REFERRED TO OCI</p>	<p>11. PRODUCT CODE 60CBE21</p> <p>12. INFORMATION COPIES TO: <input type="checkbox"/> HFM-660 <input type="checkbox"/> HFZ-343 <input type="checkbox"/> HFD-730 <input type="checkbox"/> HFC-161 <input type="checkbox"/> HEV-210 <input checked="" type="checkbox"/> HFS-635 <input type="checkbox"/> OTHER _____</p>
<p>13. REMARKS Consumer stated he still cannot believe his son, MBA student (College in [redacted]) for 2 yrs taking unknown amount of capsules ec. day and is now addicted to product. Consumer is working w/his pharmacist to obtain an medical facility/physician to help his son. Son, [redacted] will not go to a private physician and will not work. He can not control the facial twitching he has been exp. and now hair loss. Father took 3 caps and told me he</p>			
<p>14. NAME AND TITLE OF DISPOSITION OFFICIAL was high for hours after and call [redacted] Twin Labs and make a report, but not satisfied w/firm response. Complainant and literature on ephedra products from NYK-DO PAS to be sent to Mr. Marlene H. Doherty, CSI/CCC</p>	<p>15. DATE 6/30/97</p>		

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

NYK-3204

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

NYK-3204
Form Approved. OMB No. 0910-0291 Expires 12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 66968
12464

CFSP

Page 1 of 1

date 7/4/97

A. Patient information

1 Patient identifier [redacted] 2 Age at time of event: 22 3 Sex female male 4 Weight 175 lbs or ___ kgs

In confidence Date of birth: [redacted]

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) disability congenital anomaly life-threatening required intervention to prevent permanent impairment/damage hospitalization - initial or prolonged other

3 Date of event Ongoing for 1 yr 4 Date of this report 7/4/97

5 Describe event or problem

My name is [redacted] I am [redacted] father. My son is addicted to TwinLab Metabolic Enhancer "Ripped Fuel" Thermogenic formula. He buys this at [redacted]. He has a nervous condition caused by addictive usage. He can't stop flickering (twitching) his mouth, and his eyes are constantly watery. He can't get off it. He promises to get medical attention.

6 Relevant tests/laboratory data, including dates ~~but does not go to the DR. for this problem.~~

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

"Please help quickly"
"None", I fear my son will die from this drug. Please remove from over the counter purchase so our children don't die from it.

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known) 2 capsules (Pills)

#1 TwinLab, contains 6% Ephedrine,

#2 and 27% Caffeine

2 Dose, frequency & route used #1 6 to 12 pills daily #2 son's DR's nothing done. #2 did not state his addiction

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

4 Diagnosis for use (indication) #1 ? #2

5 Event abated after use stopped or dose reduced #1 yes no doesn't apply #2 yes no doesn't apply

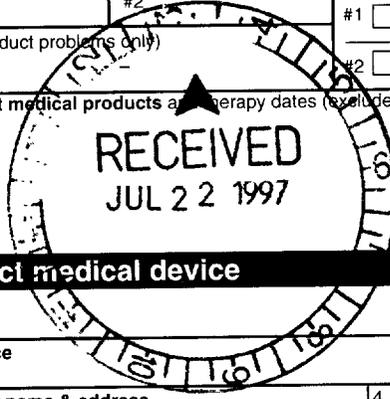
6 Lot # (if known) #1 6A317 #2

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)

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 # MEDWATCH CTU

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

REC'D. JUL 15 1997

E. Reporter (see confidentiality section on back)

1. Name, address & phone # [redacted]

2 Health professional? yes no

3 Occupation Bnks

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