

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

ARMS#

12886



0 - FRONT

# COMPLAINANT INJURY REPORT

1. COMPLAINT NUMBER  
LOS 7711 12886

2. DATE OF COMPLAINT (Month/Day/Year)  
4/29/98

3. FORM OF COMPLAINT  
 (1)  TELEPHONE (3)  VISIT  
 (2)  LETTER

4. SOURCE OF COMPLAINT  
 (1)  CONSUMER (3)  TRADE SOURCE  
 (2)  GOVERNMENT (4)  OTHER  
(Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION

a. NAME AND ADDRESS (Include Zip Code)  
[REDACTED]

b. AREA CODE AND TELEPHONE NO.  
HOME ( [REDACTED] )  
WORK ( )

6. COMPLAINT OR INJURY

a. DESCRIPTION OF COMPLAINT/INJURY  
 This is the second incident involving a [REDACTED] student regarding the use of Ripped Fuel. The incident occurred on 8/14/97 when he was a Junior. He had taken 4 capsule on an empty stomach before breakfast. At about 11 AM he took a 5th capsule at school. Within one hour he experienced being hot&cold, being shaky, feeling like he was going to black out, and being short of and gasping for breath.  
 See Continuation Sheet.

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?  
 (1)  NO (2)  YES  
(Explain in Remarks)

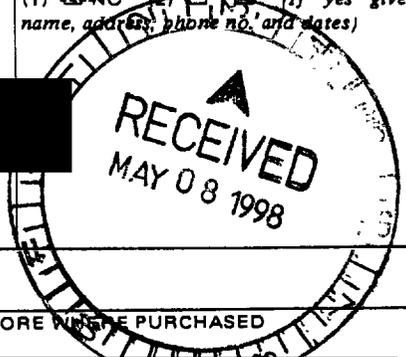
7. INJURY OR ILLNESS RESULTED  
 (1)  NO  
 (2)  YES  
(If "YES" complete Items a through d)

a. EIB (HFC-161) NOTIFIED  
 (1)  NO  
 (2)  YES  
 DATE 4/30/98

b. TYPE SYMPTOMS ONSET (HR.)  
 1  VOMITING \_\_\_\_\_  
 2  NAUSEA \_\_\_\_\_  
 3  DIARRHEA \_\_\_\_\_  
 4  FEVER \_\_\_\_\_  
 5  SKIN/EYE IRR. \_\_\_\_\_  
 6  HEADACHE \_\_\_\_\_  
 7  OTHER \_\_\_\_\_  
 See 6a.

c. ATTENDING HEALTH PROFESSIONAL  
 (1)  NO (2)  YES (if "yes" give name, address, and phone no.)  
 [REDACTED]

d. HOSPITALIZATION REQUIRED-  
 (1)  NO (2)  YES (If "yes" give name, address, phone no. and dates)



8. PRODUCT AND LABELING

a. BRAND NAME: TwinLab  
 b. PRODUCT NAME: Ripped Fuel  
 c. SIZE AND PACKAGE TYPE: 60 capsule plastic btl.  
 d. NAME AND LOCATION OF STORE WHERE PURCHASED: [REDACTED]  
 e. PACKAGE CODE/SERIAL NUMBER/ETC.: Unk. No lot no. on btl.  
 f. DATE PURCHASED: 7/97  
 g. PRODUCT USED (If "yes" enter date): 8/14/97  
 (1)  NO (2)  YES  
 h. AMT REMAINING: None  
 EXP/USE BY DATE:

9. MANUFACTURER/DISTRIBUTOR OF PRODUCT

a. HOME DISTRICT: NYK/DO  
 b. C.F. NO.: 2421049  
 c. NAME AND ADDRESS OF FIRM (Include Zip Code): Twin Laboratories, 2120 Smithtown Ave., Rondonkoma, NY 11779  
 d. IMPORT PRODUCT: (1)  NO (2)  YES

10. EVALUATION AND DISPOSITION

a. PROBLEM KEYWORD  
 (1) CODE: Rx  
 (2) DESCRIPTION: reaction

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 (Closes file)  
 (5)  REFERRED TO STATE/LOCAL AGENCY (Closes file)  
 (6)  REFERRED TO OTHER  
 FDA \_\_\_\_\_ DISTRICT

11. PRODUCT CODE: 54FREE09

12. INFORMATION COPIES TO:  
 HFN - 355  HFZ - 343 (Biologics)  
 HFN - 730  HFZ - 400  
 HFN - 333  HFC - 401/30  
 HFV - 236  HFS-636

REMARKS

NAME AND TITLE: William R. Bowman, CSO  
 DATE: 4/29/98  
 000001

LOS 7711 FD2516 Continued:

#6a. The [REDACTED] and paramedics were called and oxygen was administered by the fire department. Paramedics advised him to go to the [REDACTED]. His mom was at the school that morning and took him to see their family physician Dr. [REDACTED] instead of taking him to the hospital. He said he was given an injection but did not know what it was. He said he slept the rest of the day and did not wake up until the following night.

He said he had been taking Ripped Fuel as a metabolic enhancer for body building. He said he purchased the 60 capsule bottle of Ripped Fuel from [REDACTED] and had consumed 30 of the 60 capsules. He said he had taken 60 capsules from another 60 capsule Ripped Fuel bottle in the 30-45 days previous to purchasing the last bottle.

At the time of the incident he said he was also taking Ibuprofen 600 mg. 4X per day for a right knee ligament strain. He was prescribed this by Dr. [REDACTED]. He had taken 2 tablets that morning. He had taken the 5<sup>th</sup> Ripped Fuel capsule while attending classes.

Food history: Mr. [REDACTED] said he had a Roman Meal bread, Total cereal and milk that morning which he normally has. The day before may have included a banana as well as orange juice. He was not sure about the rest of the food history from the previous days before the incident but he described usually having the same things for breakfast as well as consuming ½ gal of orange juice per day and drinking lots of water. He said he may have had spaghetti and tuna sandwiches in the days before the incident. Additionally, he said he ate nutritional supplements including: 1. Met-Rx Nutritional Food Bars of various flavors (chocolate, vanilla, and peanut butter). These are vitamin/mineral bars manufactured for Met-Rx USA, Irvine, CA. 2. Mus-L Blast body building formula powder containing vit/min/proteins. Product is manufactured by MLO Products, Fairfield, CA 94533. 3. He takes multi-vitamin/mineral tablets but does not recall the brand name. Amounts are uncertain.

He said he was not taking any other Rx drugs besides the Ibuprofen, nor any OTC drugs, or any illegal drugs.

000002

**COMPLAINT / URGENCY FOLLOW-UP**

**1. COMPLAINT NUMBER**  
LOS 7711

- 2. ACTION REQUESTED**
- (1)  INVESTIGATION
  - (2)  COLLECT SAMPLE
  - (3)  INSPECTION
  - (4)  OTHER

**(a). REMARKS (Additional details)**

**(b) REQUESTING OFFICIAL'S NAME AND TITLE**  
W. R. Bowman, CSO

**(c) DATE REQUESTED**  
4/29/98

**(d) PRODUCT NAME**  
Ripped Fuel

**3. ASSIGNED TO:**  
W. R. Bowman

**(a) DUE BY**  
ASAP

- 4. ACTION TAKEN**
- (1)  INVESTIGATION
  - (2)  SAMPLE COLLECTED
  - (3)  INSPECTION
  - (4)  NONE

**(a) SAMPLE NUMBER(s)**  
None available

**(b) DESCRIPTION OF ACTION TAKEN**

On 4/29/98 I spoke by phone to Mr. [REDACTED] and interviewed him at [REDACTED] to obtain information about the incident. He signed a FD463a affidavit and signed FD-461 Authorization for Disclosure.

Before and after I interviewed [REDACTED], I spoke with [REDACTED] at the high school. She additionally described [REDACTED] condition on 8/14/97 as worsening with shortness of breath, being clammy, nervous, and very sleepy. She said she had to keep coaxing [REDACTED] to tell her what he had taken to cause his condition. She gave me a copy of the school report concerning the incident. (It is attached to this complaint.) The report states 2 Ripped Fuel capsules had been taken. During the interview with Mr. [REDACTED] I inquired three different times as to how many capsules of Ripped Fuel he had taken that day. All three times he reiterated taking five capsules that day at the rate of 4 before breakfast on an empty stomach and 1 capsule at about 11 AM that morning. The record shows BP at 150/88, pulse at 90, and later BP at 170/110. The record further states (See Complaint Continuation Sheet)

**(c) ACTION OFFICIAL'S NAME AND TITLE**  
William R. Bowman, CSO

**(d) ACTION DISTRICT**  
LOS/DO

**(e) DATE COMPLETED**  
5/5/98

**5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE**

**6. PROGRAM DATA**

**(a) HOME DIST.**  
NYK/DO

**(c) NAME AND ADDRESS**  
Twin Laboratories  
2120 Smithtown Ave.  
Rondonkoma, NY 11779

**(a) OPERATION**  
13

**(b) PAC**  
21R803

**(c) PRODUCT CODE**  
54FEE09

**(b) CFNO.**  
2421049

**(d) EMP. HOME DIST.**  
LOS

**(e) EMP. NO.**  
390

**(f) POS CL.**  
2

**(g) HOURS**  
18

- 7. EVALUATION**
- (0)  PENDING
  - (1)  NO ACTION INDICATED (NAI)
  - (2)  VOLUNTARY ACTION INDICATED (VAI)
  - (3)  OFFICIAL ACTION INDICATED (OAI)
  - (4)  NOT AN FDA OBLIGATION
  - (5)  REFERRED TO HOME DISTRICT
  - (6)  INSUFFICIENT INFO. UNABLE TO EVAL.

- 8. FINAL DISPOSITION**
- (1)  FOLLOW-UP NEXT EI
  - (2)  WARNING LETTER
  - (3)  CITATION
  - (4)  SEIZURE
  - (5)  INJUNCTION/PROSECUTION
  - (6)  REFERRED TO OTHER AGENCY (Indicate Agency in Remarks)
  - (7)  RECALL
  - (8)  NO ACTION

- 9. INFO. COPIES TO**
- HFB-100
  - HFD-730
  - HFV-236
  - HFZ-343
  - HFC-161
  - \_\_\_\_\_
  - \_\_\_\_\_

**REMARKS**

**NAME AND TITLE OF DISPOSITION OFFICIAL**

**DISPOSITION**

**DISPOSITION DATE**

LOS 7711 FD2516a:

#3b continued:

on 8/16/98 (should be 8/16/97) that she talked to [REDACTED] about his condition. She also discussed the dangers of taking drugs and advised him to get rid of the Ripped Fuel.

[REDACTED] on the high school's wrestling team in 1997. A copy of his physical examination record from the school was obtained and is attached. It is dated 10/29/97. Although the form is written in Spanish, a comparison of this form was made to the same examination record written in English which is attached to LOS 7710 dtd 4/9/98. Essentially, the record certifies [REDACTED] was physically fit to engage in sports. The physical was given by [REDACTED] and the examination report is signed by Dr. [REDACTED]. This would be the only record of the physical as Dr. [REDACTED] does not maintain a separate record of the physical.

4/29/98: Interviewed Dr. [REDACTED]. Dr. [REDACTED] said Mr. [REDACTED] did not have a history of any chronic diseases or allergies. He first saw [REDACTED] on 8/12/96 for a right foot contusion. He next saw [REDACTED] on 8/1/97 for a pain in the right knee. He prescribed Ibuprofen 600 mg. q.i.d.. On 8/14/97 he saw [REDACTED] and believed the symptoms were that of an allergic reaction to the weight-gaining powder [REDACTED] had described as taking. He said [REDACTED] did not tell him he had been taking Ripped Fuel. He gave [REDACTED] an injection of Vistaril 50 mg. He told his mom to give him plenty of fluids and let him rest. [REDACTED] was to see him the next day but never returned.

4/30/98: Spoke to [REDACTED] about the incident. He said he made a report about the incident and would FAX it to me. Review of the fire department's report No. [REDACTED] (attached to complaint) shows they administered oxygen at 6L/minute. It states at 12:15 his BP was 130/90 with 104 pulse. It states his skin temp. was hot, he was light headed, had dry throat, patient took pill called Ripped Fuel and 1200 mg IB Prof 2 hrs later.

5/5/98: [REDACTED] made available the labeling information from the bottle of Ripped Fuel that he had been taking the capsules from when the incident occurred.

000004

## Adverse Event Questionnaire

Complaint Number: LOS 7711

Investigator: William R. Bowman

Consumer Information	
Date of Report: 042998 MM/DD/YY	Initial Report Source: <input type="checkbox"/> ORA Consumer Injury <hr style="border-top: 1px dashed black;"/> <input checked="" type="checkbox"/> Telephone <input type="checkbox"/> Correspondence <input type="checkbox"/> MedWatch <input type="checkbox"/> USP <input type="checkbox"/> PQRS <input type="checkbox"/> Poison Control <input type="checkbox"/> CDC
Name: ██████████	Gender: <input type="checkbox"/> F <input checked="" type="checkbox"/> M      Age: 18
Race: <input type="checkbox"/> 1-White <input type="checkbox"/> 2-Black <input type="checkbox"/> 3-Asian/Pacific Islander <input type="checkbox"/> 4-Native American <input checked="" type="checkbox"/> 5-Hispanic <input type="checkbox"/> 8-Other <input type="checkbox"/> 9-Unknown	
Information on Adverse Event	
Date of Adverse Event: August 14, 1997 Previous Adverse Effects to Product Type: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Give the site of consumption/ingestion (e.g. home, restaurant, office): ██████████
<p><b>The following information relates to the consumers' use of the product.</b></p> <p>Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):                      Took 4 Ripped Fuel capsules in the AM before breakfast. Took a 5<sup>th</sup> capsule at 11 AM this same day at school. Within one hour of taking the last capsule, he started experiencing being hot &amp; cold, being shaky, started feeling like he was going to black out, and finally started gasping for breath. School nurse ██████████ additionally described his worsening condition to include being clammy, his heart was beating very hard, feeling very tired, and having difficulty breathing. Fire department and paramedics were called. Fire department administered oxygen and paramedics suggested he go to ██████████ His mom took him to family physician Dr ██████████ who gave him an injection of an antihistamine called Vistaril 50 mg. ██████████ stopped taking product after this incident.</p> <p>How long did the symptoms last? Saw Dr ██████████ within 2 hrs of incident &amp; no shortness of breath or syncope episodes witnessed per physician's record. Record states BB app. 150/90, skin somewhat clammy, other physical characteristics noted to be normal.</p> <p>Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.).                      See above. He had consumed 30 of the 60 capsules from same bottle before incident occurred. He had consumed another 60 capsule bottle of Ripped Fuel within the last 30-45 days.</p> <p>List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:                      Medications being taken at the time: Ibuprofen 600 mg 2 X per day.                      Dietary Supplements: A. Met-Rx Engineered Nutrition Food Bar (Various flavors such as vanilla, chocolate, peanut butter) manufactured for Met-Rx, Irvine, CA 92612. B. Mus-L Blast Body Building Formula powder containing vit/min/proteins. Manufactured by MLO Products, Fairfield, CA 94533.</p> <p>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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No Give health care provider's name, address and telephone number: Dr. ██████████	
Occupation of Health Care Provider: <input checked="" type="checkbox"/> MD <input type="checkbox"/> Osteopath <input type="checkbox"/> Naturopath <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other (specify)	

000005

What medical tests were performed and what were the results? None.

What was the medical diagnosis? Interview with Dr. [REDACTED] on 4/29/98 revealed Mr. [REDACTED] did not disclose he was taking Ripped Fuel but had taken some weight-gaining powder. Dr. [REDACTED] believed he was having an allergic reaction to the powder and gave an injection of an antihistamine.

What treatment(s) was given (e.g., drugs, other)? Injection of Vistaril, 50 mg. He was to see the physician the next day but never returned for F/U.

Were there any preexisting condition(s)/treatment(s)? Med. Record dtd 8/1/97 for pain in rt. knee. Ibuprofen 600 mg q.i.d. perscribed. 8/12/96 was seen for a right foot contusion. Tylenol #3 prescribed.

(If YES, list them including allergies, and chronic diseases):  Yes  No No known allergies or chronic diseases.

000006

**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):

Twinlab Ripped Fuel, 60 capsule bottle, Twin Laboratories, 2120 Smithtown Ave., Rondonkoma, NY 11779. 2caps before AM workout & 2 caps before afternoon & evening meals. Max. 6 caps daily. Metabolic enhancer.

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

Check here if ingredients are unknown

MaHuang Extract and Guarana Extract.

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 MaHuang extract
- 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    See attached photocopies of labeling.

**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