

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

ARMS#

13083



0 - FRONT

1. COMPLAINT NUMBER

LOS 6792 / 3083

2. DATE OF COMPLAINT (Month / Day / Year)

8/24/98

COMPLAINT / INJURY REPORT

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

4. SOURCE OF COMPLAINT
(4) : other: father of consumer.

a. (1) CONSUMER (3) TRADE SOURCE
(2) GOVERNMENT (4) OTHER (FATHER)
 L S F (Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION
Son/MOTHER:

a. NAME AND ADDRESS (Include ZIP Code)
Father: [REDACTED]

b. AREA CODE AND TELEPHONE NUMBER
HOME [REDACTED] father
WORK [REDACTED] son & mother

6. COMPLAINT OR INJURY
INGREDIENTS INCLUDE: MaHuang extract 334 mg standardized for 6% ephedrine; Guarana extract 910 mg standardized for 22% caffeine; per tab.

a. DESCRIPTION OF COMPLAINT / INJURY
[REDACTED] collapsed on field during football practice evening 8/20/98. Father claims ephedrine-containing product is responsible. Son claims that he had not used product for about one week prior to incident. He said that he had used product regularly during the two months preceding the week of abstinence.

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) NO (2) YES
(If "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) YES
(2) NO
DATE: 8-25

b. TYPE SYMPTOMS ONSET (HR.)
(1) VOMITING
(2) NAUSEA
(3) DIARRHEA
(4) FEVER
(5) SKIN/EYE IRR.
(6) HEADACHE
(7) OTHER
Fainting, chest pain

c. ATTENDING HEALTH PROFESSIONAL?
(1) NO (2) YES
(If "Yes" give name, address, and phone number)
Dr. [REDACTED]

d. HOSPITALIZATION REQUIRED?
(1) NO (2) YES
(If "Yes" give name, address, phone number and dates)

8. PRODUCT AND LABELING

a. BRAND NAME: Twinlab metabolic enhancer thermogenic formula Rip Fuel
b. PRODUCT NAME: [REDACTED]
c. SIZE AND PACKAGE TYPE: Bottle 120 tablets
d. NAME AND LOCATION OF STORE WHERE PURCHASED: [REDACTED]
e. PACKAGE CODE / SERIAL NUMBER / ETC.: NOT AVAILABLE
f. DATE PURCHASED: NOT SURE
g. PRODUCT USED (If "Yes" enter date) (1) NO (2) YES
Date: Aug 6, 98
h. AMT. REMAINING: [REDACTED]

9. MANUFACTURER / DISTRIBUTOR OF PRODUCT

a. HOME DISTRICT: New York
b. C.F. NO.: 2421049
c. NAME AND LOCATION OF FIRM (Include ZIP Code): Twin Labs Inc, 2120 Smithtown Ave Ronkonkoma, NY 11779
d. IMPORT PRODUCT (1) NO (2) YES

10. EVALUATION AND DISPOSITION

a. PROBLEM KEY WORD
(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

b. 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
(7) REFERRED TO OCI

11. PRODUCT CODE: 549CA99
12. INFORMATION COPIES TO:
 HFM-660 HFD-343
 HFD-730 HFC-161
 HFV-210 HFS-635
 OTHER OSN

13. REMARKS 6.b. Complainant is very upset and "wants something done" about this type of product. I will stay in touch with him.

14. NAME AND TITLE OF DISPOSITION OFFICIAL
Randall N Johnson RANDALL N JOHNSON, CSO

15. DATE
8/27/98

COMPLAINANT INJURY FOLLOW-UP

1. COMPLAINT NUMBER

LOS 6792

2.a. ACTION REQUESTED

- (1) INVESTIGATION
- (2) COLLECT SAMPLE
- (3) INSPECTION
- (4) OTHER:

2.b. REMARKS (Additional details)

Obtain info for Adverse Event Questionnaire for OSN's evaluation per guidance memo of 9/24/96, attached.

2.c. REQUESTING OFFICIAL'S NAME AND TITLE

Randall N. Johnson CSO

2.d. DATE REQUESTED

8/25/98

2.e. PRODUCT NAME

Twinlab Rip Fuel

3.a. ASSIGNED TO:

R N Johnson

3.b. DUE BY:

ASAP

4.a. ACTION TAKEN

- (1) INVESTIGATION
- (2) SAMPLE COLLECTED
- (3) INSPECTION
- (4) NONE

4.b. SAMPLE NUMBER(s)

none

4.c. DESCRIPTION OF ACTION TAKEN

The complaint and much of the related information given on the complaint form came from Mr. [redacted] His son [redacted], who [redacted] stated suffered an adverse reaction to the Rip Fuel, lives at another residence with Mr. [redacted] ex-wife. The latter two provided some information at first, but minimized the importance of and usage of the product alleged to have caused the problem.

Mr. [redacted] stated that there are some unresolved custody issues involving the children, as the divorce took place recently, within the past year or so. He felt that this might contribute to a lack of cooperation between his child, ex-wife, and the FDA. At first, [redacted] gave me some label information from the product. Later, his mother telephoned me and said that the product had been thrown away.

I attempted to obtain a signed consent form from Mr. [redacted] for his son's medical records, but he handled that himself at [redacted] obtained some medical information there, and faxed it to me at PHX RP. It is attached and appears to be partial information (e.g. no blood/lab results attached). Further attempts can be made to obtain the complete records if OSN deems it necessary.

Between Mr. [redacted] the partial medical records, and some information obtained by telephone from [redacted] and [redacted] I completed as much of the adverse event questionnaire as possible. It is attached for review by OSN.

4.d. ACTION OFFICIAL'S NAME AND TITLE

Randall N. Johnson, Consumer Safety Officer

4.e. ACTION DISTRICT

LOS

4.f. DATE COMPLETED

8/27/98

5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE

5.a. HOME DIST.

NY NY

5.c. NAME AND ADDRESS

Twin Labs Inc., 2120 Smithtown
Ronkonkoma, NY 11779

6. PROGRAM DATA

6.a. OPERATION

Ave, 13

6.b. PAC

56R801

6.c. PRODUCT CODE

54YCA99

5.b. CF NO.

2421049

6.d. EMP. HOME DIST.

LOS

6.e. EMP. NO.

648

6.f. POS CL.

2

6.g. HOURS

3

7. EVALUATION

- (0) PENDING REVIEW BY OSN
- (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.
- (7) REFERRED TO OCI

8. FINAL DISPOSITION

- (1) FOLLOW-UP NEXT E1
 - (2) WARNING LETTER
 - (3) CITATION
 - (4) SEIZURE
 - (5) INJUNCTION / PROSECUTION
 - (6) REFERRED TO OTHER AGENCY
 - (7) RECALL
 - (8) NO ACTION
- (Indicate Agency in Remarks)

9. INFO.

COPIES TO:

- HFB-100
- HFD-730
- HFV-236
- HFZ-343
- HFC-161
- HFS-635
- OSN
- _____
- _____
- _____
- _____
- _____
- _____

REMARKS

Pending review by OSN, final disposition delayed. However, verbal information from hospital records and ER staff shows that no tox/drug screen was performed in [redacted] This lack of blood data, combined with [redacted] statement that he had not used the product for a week prior to the incident, makes connection of the product to the adverse event more difficult. *RN Johnson 8/27/98*

NAME AND TITLE OF DISPOSITION OFFICIAL

DISPOSITION

DISPOSITION DATE

Adverse Event Questionnaire

Complaint Number: LOS 6992

Investigator: RANDALL W. JOHNSON CSD Mgr.

Consumer Information		
Date of Report: <u>08/24/98</u> MM/DD/YY	Initial Report Source: <input type="checkbox"/> ORA Consumer Injury <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: [REDACTED]	Gender: <input type="checkbox"/> F <input checked="" type="checkbox"/> M	Age: <u>17</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 <input checked="" type="checkbox"/> 9-Unknown		
Information on Adverse Event		
Date of Adverse Event: <u>8/20/98</u> 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): <u>NOT CLEAR - SEE 'PRODUCT CATEGORIES' #3</u>	
The following information relates to the consumers' use of the product.		
Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): <u>COLLAPSED ON FOOTBALL FIELD DURING TRAINING - FAINTED.</u>		
How long did the symptoms last? <u>UNCONSCIOUS 5 MIN</u>		
Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.).		
List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: <u>UNKNOWN</u>		
Did event abate after use of suspected product stopped or dose reduced: <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" 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		
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. [REDACTED]		
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) _____		
What medical tests were performed and what were the results?		
What was the medical diagnosis? <u>VASO-VAGAL SYNCOPES - (FAINTING)</u>		
What treatment(s) was given (e.g., drugs, other)? <u>FIELD IV NS (?) 50 cc</u>		
Were there any preexisting condition(s)/treatment(s)? (If YES, list them including allergies, and chronic diseases): <input type="checkbox"/> Yes <input type="checkbox"/> No		

⊕ COMPLAINANT IS FATHER OF [REDACTED]

000003

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):

NON-CUSTODIAL FATHER CLAIMS RIP FUSE CAUSED PROBLEM. MOTHER AND SON MINIMIZE THIS. (ACC 2516a). NO BLOOD TOX/DRUG SCREEN WAS PERFORMED

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):

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

Check here if ingredients are unknown

PER TABLET: MA HUANG 334 MG STANDARDIZED AS 6% EPINEPHRINE

CAFFEINE STANDARDIZED 22% (GUARANO 910 MG)

ALSO 1-2 VITAMINS/MINERALS/ETC

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 SEE ABOVE INGREDIENTS

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) ER TREATMENT/ EXAM

Required intervention to prevent permanent impairment/damage: Yes No

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

000004