

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

ARMS#

12871



0 - FRONT

COMPLAINT/INJURY FORM

1. COMPLAINT NUMBER
LOS-8119

2. DATE OF COMPLAINT (Month/Day/Year)
04/24/98

3	FORM OF COMPLAINT (1) <input type="checkbox"/> TELEPHONE (2) <input checked="" type="checkbox"/> LETTER (3) <input type="checkbox"/> VISIT	4.	SOURCE OF COMPLAINT (1) <input type="checkbox"/> CONSUMER (2) <input checked="" type="checkbox"/> GOVERNMENT (3) <input type="checkbox"/> TRADE SOURCE (4) <input type="checkbox"/> OTHER <input type="checkbox"/> L <input type="checkbox"/> S <input checked="" type="checkbox"/> F <i>(Indicate in Remarks)</i>
5.	COMPLAINANT IDENTIFICATION a. NAME AND ADDRESS (Include Zip Code) [REDACTED] (parents)		b. AREA CODE AND TELEPHONE NUMBER HOME: [REDACTED] WORK: ()
6.	COMPLAINT OR INJURY a. DESCRIPTION OF COMPLAINT/INJURY [REDACTED] (complainant's son) was reported to be taking Ripped Fuel, a dietary supplement and died.		b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES <i>(Explain in Remarks)</i>
7.	INJURY OR ILLNESS RESULTED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES <i>(If "yes" complete items a through d)</i>	a. EIB (HFC-161) NOTIFIED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES DATE 04/27/98	b. TYPE SYMPTOM 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 DEATH
		c. ATTENDING HEALTH PROFESSIONAL (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES <i>(If "yes" give name, address, and phone number)</i> [REDACTED]	d. HOSPITALIZATION REQUIRED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES <i>(If "yes" give name, address, phone number and dates)</i> [REDACTED]
8.	PRODUCT AND LABELING a. BRAND NAME TWINLABS		b. PRODUCT NAME RIPPED FUEL
		c. SIZE AND PACKAGE TYPE TO BE DETERMINED	d. NAME AND LOCATION OF STORE WHERE PURCHASED TO BE DETERMINED
		e. PACKAGE CODE/SERIAL NUMBER/ETC. TO BE DETERMINED EXP/USE BY DATE:	f. DATE PURCHASED UNKNOWN
		g. PRODUCT USED (If "yes" enter date) (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES	h. AMT REMAINING UNKNOWN
9.	MANUFACTURER/DISTRIBUTOR OF PRODUCT a. HOME DISTRICT NYK-DO (D) b. C.F. NO. 2421049	c. NAME AND LOCATION OF FIRM (Include Zip Code) TWIN LABS INC. RONKONKOMA, NY 11779	
		d. IMPORT PRODUCT (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES	
10.	EVALUATION AND DISPOSITION a. PROBLEM KEYWORD (1) CODE (2) DESCRIPTION DT DEATH	c. DISPOSITION (1) <input checked="" type="checkbox"/> IMMEDIATE FOLLOW-UP (2) <input type="checkbox"/> F/U NEXT E1 (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	11. PRODUCT CODE 54FEA09 12. INFORMATION COPIES TO: <input type="checkbox"/> HFB-100 <input type="checkbox"/> HFZ-343 <input type="checkbox"/> HFD-730 <input checked="" type="checkbox"/> HFC-161 <input type="checkbox"/> HFV-236 <input checked="" type="checkbox"/> HFS-636

REMARKS
 Block # 4. The source of complaint was [REDACTED] CDC, and sister of of the deceased.
 ATTACHED: Memo, From: CFSAN/OFP/Domestic Program Branch, To: DIB LOS-DO (HFR-250), Subject: Request for Expedited Investigation-- Ripped Fuel Death [REDACTED] dated April 24, 1998.

NAME AND TITLE
 HENRY E. CARRILLO, CSI

DATE
 4/27/1998

000001

COMPLAIN / INJURY FOLLOW-UP

1. COMPLAINT NUMBER
LOS-8119

2.a. ACTION REQUESTED

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

2.f. .MARKS (Additional Details)

Please collect any additional information from the parents of the deceased.

2.c. REQUESTING OFFICIAL'S NAME AND TITLE

Henry Carrillo, CCC, LOS-DO

2.d. DATE REQUESTED

4/26/98

2.e. PROUCT NAME

Ripped Fuel

3.a. ASSIGNED TO:

David Hernandez, CSI Los-DO

3.b. DUE BY:

4/30/98

4.a. ACTION TAKEN

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

4.b. SAMPLE NUMBER(s)

5211

4.c. DESCRIPTION OF ACTION TAKEN

On 4/24/98, CSI Hernandez and CSO Fritz collected a blood serum sample at the hospital's blood bank. The 46 year old male had surcumed to what is believed to have been a blood clot to the brain. Sample of blood was collected and shipped via Federal Express to a private lab. The lab is [redacted] located in [redacted]. In addition, an assignment was issued to San Do, for the collection of Ripped Fuel and possibly other food supplement products which Mr. [redacted] (victim) had taken. The remaining products was taken by a relative of the [redacted] family, who lives in [redacted].

The follow-up with the parents was not very productive, in that most of the informantion which was known to them had previously provided by the hospital and other members of the family.

No further action is planned on this case.

4.d. ACTION OFFICIAL'S NAME AND TITLE

David Y. Hernandez, CSI

4.e. ACTION DISTRICT

LOS

4.f. DATE COMPLETED

4/28/98

5. MANUFACTURER/DISTRIBUTOR/DEALER RESPONSIBLE

5.a. HOME DIST.

NYK-DO

5.c. NAME AND ADDRESS

TWIN LABS
RONKONKOMA, NY 11779

6.

PROGRAM DATA

6.a. OPERATION

13

6.b. PAC

54R801

6.c. PRODUCT CODE

54FEA09

5.b. CF NO.

2421049

6.d. EMP. HOME DIST.

A

6.e. EMP. NO.

983

6.f. POS CL.

9

6.g. HOURS

6

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.
- (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
(Indicate Agency in Remarks)
- (7) RECALL
- (8) NO ACTION

9. INFO.

COPIES TO:

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

REMARKS

Referred to CFSAN for disposition.

NAME AND TITLE OF DISPOSITION OFFICIAL

Henry Carrillo, CCC, LOS-DO

DISPOSITION

DISPOSITION DATE

4/28/98

COMPLAINT / INJURY FOLLOW-UP

1. COMPLAINT NUMBER
LOS-8119

AZMS-12871

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

(a). REMARKS (Additional details)

(b) REQUESTING OFFICIAL'S NAME AND TITLE

Jim Foster, Facilitator, & C Moss, DIB

(c) DATE REQUESTED

4-27-98

(d) PRODUCT NAME

Ripped Fuel

3. ASSIGNED TO:

KMO

(a) DUE BY

ASAP

4. ACTION TAKEN

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

(a) SAMPLE NUMBER(s)

5316/5320 (5 spls)

(b) DESCRIPTION OF ACTION TAKEN

I met [redacted] cousin of the deceased, on 4-29-98 on the island of [redacted] in [redacted] at her place of business. During our conversation on 4-27-98, she asked for information on ma huang so copies of HHS News dated 4-10-98 FDA Statement on Street Drugs containing Botanical Ephedrine and HHS News P97-15 FDA Proposes Safety Measures for Ephedrine Dietary Supplements were given to her. She had 5 previously opened btls containing varying amounts of the labeled products in her possession and all 5 products were sampled as follows:

1. Spl #5316, Diet Fuel (labeled as containing ma huang);
2. Spl #5317, Powerhouse Sports Recovery;
3. Spl #5318, EAS HMB capsules;
4. Spl #5319, Creatine Monohydrate powder; and
5. Spl #5329, Chromium Picolinate tablets.

She prepared a one page letter detailing the events as she remembered them and signed an affidavit. FDA 484 was also issued to her. The spls were sent to SEA-DO for analysis. Attached are copies of the C/R's, btl labels, [redacted] ltr, affidavit, e-mail assignment copies, FDA 484, and copies of the HHS news furnished to her.

(c) ACTION OFFICIAL'S NAME AND TITLE

Kenneth M. Okihara, CSO

Kenneth M. Okihara

(d) ACTION DISTRICT

SAN-DO

(e) DATE COMPLETED

5-4-98

5. MANUFACTURER/DISTRIBUTOR/DEALER RESPONSIBLE

(a) HOME DIST.

NYK

(b). CF NO.

2421049

(c) NAME AND ADDRESS

Twin Labs, Inc.
Ronkonkoma, NY 11779

6. PROGRAM DATA

(a) OPERATION

13

(b) PAC

03R801

(c) PRODUCT CODE

54FCE09

(d) EMP. HOME DIST.

SAN

(e) EMP. NO.

SAN

(f) POS CL.

2

(g) HOURS

6

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
 NYK
 LOS

REMARKS

Original will be sent to Brenda Alay (HFS-636) Stevens, CCC 5-7-98

000003

NAME AND TITLE OF DISPOSITION OFFICIAL

DISPOSITION

DISPOSITION DATE

Adverse Event Questionnaire

DHERNADY52-

Complaint Number: _____

Investigator: LOS 8119

Consumer Information	
Date of Report: <u>4/</u> MM/DD/YY	Initial Report Source: <input type="checkbox"/> ORA Consumer Injury <input 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>46</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 type="checkbox"/> 9-Unknown	
Information on Adverse Event	
Date of Adverse Event: <u>04-02-98</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>HOME</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): How long did the symptoms last? Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.). List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used <u>at the time</u> of the event: Did event abate after use of suspected product stopped or dose reduced: <input 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 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 type="checkbox"/> Not Applicable	
Medical Information	
Was a health care provider seen?: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Give health care provider's name, address and telephone number:	
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 type="checkbox"/> Other (specify)	
What medical tests were performed and what were the results? What was the medical diagnosis? What treatment(s) was given (e.g., drugs, other)?	
Were there any preexisting condition(s)/treatment(s)? <u>NONE</u> (If YES, list them including allergies, and chronic diseases): <input type="checkbox"/> Yes <input type="checkbox"/> No	

000004

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):

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

Check here if ingredients are unknown

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



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Proj. # 12871
205-8119

Public Health Service

Food and Drug Administration
Los Angeles District
Pacific Region
19900 MacArthur Blvd.
Suite 300
Irvine, CA 92612-2445

Telephone: 714-798-7600
FAX: 714-798-7690

To: CFSAN

May 5, 1998

From: David Hernandez, CSI
LOS-DO

Subject: Follow-up to Ripped Fuel Death

The follow-up to consumer complaint #LOS-8119, regarding the death of Mr. [REDACTED] has been completed. Samples of red blood cells and plasma were obtained at the hospital on 4/24/98. Investigators David Hernandez and Maxine Fritz obtained the sample and shipped them to private lab as requested on assignment (CFSAN).

Records from the hospital were obtained from the medical records office. We were able to obtain the records with no difficulty.

A request was made to the San Francisco office to obtain the records from [REDACTED]. The cousin of [REDACTED] is believed to have taken some of the suspect product home.

On 4/28/98, I visited the parents, Mr. [REDACTED] and [REDACTED]. Mr. [REDACTED] stated that he did not know much about the death of his son. He said that [REDACTED] lived about 2 miles from his home. Mr. [REDACTED] said that [REDACTED] basically lived his own life, had his own home and his own business. Mr. [REDACTED] stated that his son was in to bodybuilding and health. This is why he maintained a workout with a personal trainer. Mr. [REDACTED] was not aware of what his son was taking. He said he kept out of his son's personal life. I was not able to obtain much more information than I had already known.


David Hernandez, CSI

000006

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

FROM: Constance J. Hardy

DATE: July 27, 1999

SUBJECT: ARMS 12871

On 7/15/99 I called Ms. [REDACTED] the sister of Mr. [REDACTED] (ARMS 12871) in order to verify use of the product Ripped Fuel by Mr. [REDACTED]. Mr. [REDACTED] had died as reported by Ms. [REDACTED] and in the MedWatch report; the product listed Ripped Fuel as the product name. However, throughout the rest of the medical record chart there is no further mention of the product. Ms. [REDACTED] stated her sister Ms. [REDACTED] (W)] knew more of the details and consequently I talked to her on July 19, 1999. Ms. [REDACTED] stated that she and her cousin [REDACTED] had found numerous products in her brother's residence, following his death. Although she was aware that the investigator Kenneth Okihara had collected numerous products from [REDACTED], she clarified that [REDACTED] had, prior to the collection, found three other products, which she [REDACTED] had thrown away. Ms. [REDACTED] specifically stated one of the products was Ripped Fuel and she clearly remembered an image of a well-developed body on the label. The other two products were a single ingredient "ma huang product" and a single ingredient "guarana product".

Ms. [REDACTED] stated her brother Mr. [REDACTED] and [REDACTED] (H)] possibly might have other information. I spoke to Mr. [REDACTED] the same day and he stated he likewise did not know his brother was taking dietary supplement products. He did know that he had been working out at the gym for approximately 6-7 months. He referred me to Ms. [REDACTED] one of the trainers that his brother had been working with at [REDACTED]. I contacted Ms. [REDACTED] on July 22, 1999 and she stated that she had started working as trainer with Mr. [REDACTED] approximately 3 ½ months prior to his death. She was not aware of his use of dietary supplements but did say that he had changed his eating habits since training with her. During the time she had known Mr. [REDACTED] he had changed his eating habits by restricting high fat/red meat foods, stopped smoking totally, and cut back on his alcohol intake. She stated he had lost 10 pounds since she started working with him.

I again spoke to Ms. [REDACTED] on July 27, 1999 at which time she stated that another trainer who had worked with Mr. [REDACTED] had quit working at [REDACTED] about 1 year ago. She stated that no one seemed to know where that trainer had gone to. In addition, after talking to several persons at [REDACTED] she verified that she was unable to attain any dietary supplement usage information concerning Mr. [REDACTED].

000007