

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

ARMS#

12843



0 - FRONT

# COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER  
**LOS 7710**

2. DATE OF COMPLAINT (Month/Day/Year)  
**4/9/98**

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

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

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

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

6. COMPLAINT OR INJURY  
 18 yr old [REDACTED] collapsed during an [REDACTED] on 4/6/98. Taken to [REDACTED] & treated by Dr. [REDACTED]. Transferred to [REDACTED] on Wed. 4/8/98. In a coma from Monday to Thursday 4/9/98 AM when she died. Dg. screen revealed no other drugs in her system.

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: **4/10/98**

b. TYPE SYMPTOMS ONSET (HR.)  
 1  VOMITING  
 2  NAUSEA  
 3  DIARRHEA  
 4  FEVER  
 5  SKIN/EYE IRR.  
 6  HEADACHE  
 7  OTHER  
**See Above & Cont. sheet.**

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

d. HOSPITALIZATION REQUIRED  
 (1)  NO (2)  YES (If "yes" give name, address, phone no. and dates)  
 [REDACTED] (See Remarks)

8. PRODUCT AND LABELING  
 a. BRAND NAME: **Rx TwinLab**  
 b. PRODUCT NAME: **Ripped Fuel**  
 c. SIZE AND PACKAGE TYPE: **Unk.**  
 d. NAME AND LOCATION OF STORE WHERE PURCHASED: **Unk. (See Cont. Sheet)**  
 e. PACKAGE CODE/SERIAL NUMBER/ETC.: **Unk.**  
 f. DATE PURCHASED: **Unk.**  
 g. PRODUCT USED (If "yes" enter date): **Unk.**  
 h. AMT. REMAINING: **Unk.**

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, R 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: **54FEE 09**  
 12. INFORMATION COPIES TO:  
 HFN - 355  HFZ - 343 (Biologics)  
 HFZ - 400  
 HFN - 730  HFC - 161  
 HFN - 333  **HFS-636**  
 HFV - 236

REMARKS  
 7d. [REDACTED]

NAME AND TITLE  
**William R. Bowman, CSO**

86/C/4 RECEIVED  
 CLINICAL RESEARCH & RESEARCH  
 000001

**COMPLAINT / INJURY FOLLOW-UP**

1. COMPLAINT NUMBER  
LC3 7710

**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

4/10/98

(d) PRODUCT NAME

Ripred 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)

(b) DESCRIPTION OF ACTION TAKEN

4/10/98: Contacted [redacted] at home [redacted] She's the [redacted] for the [redacted] at [redacted] which also includes the [redacted] at [redacted] business telephone# [redacted] telephone# [redacted] The [redacted] is closed today but will be open on Monday, 4/13/98. She related the following information:

[redacted] 15-year old female, good physical condition and good [redacted], collapsed while [redacted] during an [redacted] on Monday 4/6/98 between 5-7PM. Taken to [redacted] and treated by Dr. [redacted] Rm. Physician. (His office No. [redacted] and his office is at [redacted] She was transferred to [redacted] She was in a coma until Thursday AM, 4/9/98 when she died.

See complaint continuation sheet.

(c) ACTION OFFICIAL'S NAME AND TITLE: William R. Bowman, CSO  
(d) ACTION DISTRICT: LOS/DO  
(e) DATE COMPLETED: 4/20/98

5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE  
(a) HOME DIST. LOS/DO  
(b) CF NO. 212049  
(c) NAME AND ADDRESS: Twin Laboratories, 2120 Smithtown Ave., Ronkonkoma, NY 11770  
6. PROGRAM DATA  
(a) OPERATION: 13  
(b) PAC: 21R803  
(c) PRODUCT CODE: 54FF00  
(d) EMP. HOME DIST. LOS/DO  
(e) EMP. NO. 300  
(f) POS CL: 2  
(g) HO: 32

7. EVALUATION  
(1)  PENDING  
(2)  NO ACTION INDICATED (NAI)  
(3)  VOLUNTARY ACTION INDICATED (VAI)  
(4)  OFFICIAL ACTION INDICATED (OAI)  
(5)  NOT AN FDA OBLIGATION  
(6)  REFERRED TO HOME DISTRICT  
(7)  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  
 HFB-11  
 HFD-7  
 HFV-23  
 HFZ-34  
 HFC-16

REMARKS  
  
**000002**

NAME AND TITLE OF DISPOSITION OFFICIAL: \_\_\_\_\_ DISPOSITION: \_\_\_\_\_ DISPOSITION DATE: \_\_\_\_\_

# Adverse Event Questionnaire

Complaint Number: LOS 7710

Investigator: W.R. Bowman

Consumer Information	
Date of Report: <u>041598</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 checked="" type="checkbox"/> F <input type="checkbox"/> M      Age: <u>15</u>
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: <u>4/6/98</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>Unknown</u>
<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):                      While playing in an [REDACTED] on 4/6/98, she collapsed. CPR started by [REDACTED] rushed to [REDACTED] by Paramedics. Remained in a coma. Transferred to [REDACTED] on 4/8 &amp; died 4/9/98.                      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.).                      Unknown. Coroners report will be available in 7-10 days. Coronor's preliminary info incl. product being taken 7-10 days before incident. Parents unaware of her taking product.</p> <p>List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:                      Breakfast: Partial bowl of Toasted Oatmeal Cereal with milk. Lunch: Burrito purchased [REDACTED]. Snack: 2 homemade choc. chip cookies &amp; milk. Had not eaten dinner yet. No medications, diet supp. taken. Previous food history could not be recalled.                      Did event abate after use of suspected product stopped or dose reduced: <input type="checkbox"/> Yes <input checked="" 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 checked="" 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? <u>Remained in coma fm 4/6-4/9/98 and died.</u>	
What was the medical diagnosis? What treatment(s) was given (e.g., drugs, other)?	
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	

## 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, 120 cap btl., Twin Laboratories, 2120 Smithtown Ave, Rondonkoma, NY 11779. 2 caps before AM workout & 2 caps before afternoon & evening meals. Max. 6 caps daily. Metabolic enhancer.

No bottle of product obtained. Capsules obtained from friends/other athletes.

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

Check here if ingredients are unknown

MaHuang Extract 334 mg, Guarana Extract 910 mg., L-Carnitine 100 mg.,

Chromium 200 mcg.

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 (Ephedra Alkaloids)

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 Medical records and emergency room records are being obtained.

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

000004

LOS 7710 #3b Continued:

Her parents are [REDACTED] and [REDACTED] [REDACTED] home telephone No. [REDACTED] Ms. [REDACTED] said they are making funeral arrangements today and may not be at home.

Mrs. [REDACTED] said the whereabouts of the Ripped Fuel container [REDACTED] had taken the capsules from is unknown. She believes it may be in her purse or [REDACTED] which her parents now have.

Mrs. [REDACTED] said she did not know why, how long she had been taking the product or the dosage. Monday was the first day she and her parents knew she was taking the product. She said other [REDACTED] may be taking the product.

The [REDACTED] told Dr. [REDACTED] about the product at the emergency room in [REDACTED] and had obtained a bottle of it from the [REDACTED] in [REDACTED] for the doctor. Mrs. [REDACTED] said she and Dr. [REDACTED] believe the product may have contributed to [REDACTED] death.

Mrs. [REDACTED] briefly discussed another situation involving a [REDACTED] [REDACTED] taking the product and seeing her about shortness of breath. I told her I would follow up on this in the immediate future.

4/10/98: Telephone call to Dr. [REDACTED] I identified myself and he provided the following: He had not known [REDACTED] before he treated her on Monday at the [REDACTED] [REDACTED] He said she had taken at least 2 tablets of the product that day and had not eaten much. Some of the other [REDACTED] said they were taking it for weight control. He said the label made mention of taking it for extra energy and weight control.

He said it was 10-15 minutes before the paramedics treated her with heart shock treatment. She had low potassium levels, without pulse and brain dead upon arrival. She was transferred to [REDACTED] on Wed., 4/8/98. Physician treating her there is UNKNOWN.

He performed a drug screen and found no drugs of any kind in her system.

He requires a medical release from the parents before he can release any records.

4/13/98. Received a telephone call from Mr. [REDACTED]

Coroner Investigator, [REDACTED] about [REDACTED]. He said she died from a massive heart attack. May have been having heart problems up to 2 weeks before without her knowing it. The hospital had thrown out her stomach contents. He was performing serum run, toxicology and micro analysis. He said her death may have been contributed to by ephedra in the Ripped Fuel product. He said the autopsy report will be completed in 7 to 10 days and a copy will be sent to me.

4/14/98: Visited and interviewed the parents, [REDACTED] Mr. [REDACTED] described his daughter as being in good condition, 5'4", between 115-120 lbs. She was on the [REDACTED] by Mr. [REDACTED].

[REDACTED] She was also on the [REDACTED]. Both parents confirmed she had no allergies, had no chronic diseases, or other medical problems. She was not taking any OTC or Rx drugs. She would occasionally take a multiple vitamin manufactured by [REDACTED] (bottle could not be located). Mrs. [REDACTED] said she had noticed [REDACTED] appetite had been off for the past two weeks. She said she would eat when she was hungry but not always finish her breakfast or meals and sometimes go without breakfast including not eating bananas. However, she would finish all her favorite foods like pasta, pizza, hamburgers, and snack foods. They described her appetite as that of a typical teenager. On the day of her death, for breakfast she had eaten a portion of a bowl of Toasted Oatmeal Cereal and milk; for lunch she had eaten a burrito purchased at the [REDACTED]; and [REDACTED] for a snack she had eaten two homemade chocolate chip cookies Mrs. [REDACTED] had made and milk. She would have eaten dinner after the [REDACTED]. The parents could not recall what foods she had eaten the days before her death.

They said the last time she was ill was three weeks ago when she complained of a headache. She took two Tylenol tablets and it went away. Before that she had a cold in either August or Sept. 1997. Her family physician is Dr. [REDACTED].

Both parents said they were not aware that she was taking Ripped Fuel. The first they became aware of it was on 4/6/98. Mr. [REDACTED] said he had talked to the [REDACTED] that were in the [REDACTED]. He said several said she had been taking the product Ripped Fuel. He said one of the [REDACTED] went with him to the [REDACTED] in [REDACTED] and purchased a bottle of the product to show the

emergency room doctors who were not familiar with the product. He said the coroner now has that bottle.

Both parents described searching her room and belongings and having her [REDACTED] checked but not finding any of the product. They said [REDACTED] had not taken any [REDACTED], purse, etc to the [REDACTED] as the [REDACTED] is close to their home. Both parents said they believe she had been given the capsules by team members. He said she had performed in the [REDACTED] [REDACTED] on Saturday (4/4/98) and believes she may have received them more from somebody on the [REDACTED] than from the [REDACTED] [REDACTED]

Mr. [REDACTED] said he had received a telephone call from coroner [REDACTED] who said his preliminary results shows she had been taking Ripped Fuel for 7 to 10 days before she collapsed. She had heavy scarring of the heart. Also, that the hospital had found capsules of the product in her stomach contents.

Also present during the later part of the interview was Mr. [REDACTED]. He is the boyfriend to Mr. & Mrs. other daughter [REDACTED]. He said he had been using the product in the past including when he was at the same [REDACTED] last year as a [REDACTED]. He said he was requested to obtain the bottle he had been using. He showed me an empty bottle of Ripped Fuel, labeled as containing 120 capsules, Lot# 7A431. He said he attends [REDACTED] [REDACTED] where he keeps it.

Mr. [REDACTED] signed copies of the FD461-Authorization for Medical Records Disclosure and an affidavit (FD463a) dated 4/14/98 that describes some of the information discussed with me.

4/14/98. Visited the office of Dr. [REDACTED]. A note in the office window stated the office would be closed from 4/9-17 and would be back on 4/20/98. I will visit Dr. [REDACTED] office on 4/20/98 to obtain her records.

4/14/98. Visited Mrs. [REDACTED] at the [REDACTED] to obtain any additional information. She said there is a field behind their district office where [REDACTED] are held. She stated the death of [REDACTED] occurred during a [REDACTED]. She said the [REDACTED] was not associated with the [REDACTED]. She said she was not present when [REDACTED] collapsed but was at the [REDACTED] on 4/6/98. She said she and Mr. [REDACTED] questioned the [REDACTED] there and discovered she had been taking Ripped Fuel. She described how they are preparing a letter to be sent to the [REDACTED] parents on

counseling and talking to their children on drugs. Additionally, they will be preparing a video to broadcast over [REDACTED] on grief responses and education on OTC drugs.

I inquired about a previous incident she had mentioned to me when we first talked. She said the [REDACTED] was a [REDACTED] who was taking the product, became short of breath and had to have oxygen administered. Because of the [REDACTED] being a [REDACTED], she said she would talk to both him and his mother to obtain permission to discuss the incident and/or have them talk to me.

Later that day I called Mrs. [REDACTED] and inquired if [REDACTED] were required to have a physical before joining a [REDACTED]. She said they are required to have such a physical but that would have been performed early in the [REDACTED]. I requested a copy of the record showing who the physician was that gave the physical. She called back and left a message on my office answering machine that the [REDACTED] would need permission from the parents to release such a record. On 4/15/98 I spoke to Ms. [REDACTED] and faxed her a copy of the Authorization for Medical Records Disclosure. She said she would fax me a copy of the information.

4/14/98: I visited the [REDACTED] store at [REDACTED]. No Ripped Fuel was in stock. The store manager [REDACTED] said their last sale of the product was on 3/18/98.

4/14/98: Visited the [REDACTED] drug store (formerly called [REDACTED]). One 120 capsule bottle of Ripped Fuel, lot# 7A435 was in the back room. I inquired of Mr. [REDACTED] Chief Pharmacist, if it had been pulled off the shelf. He inquired of the asst. mgr as to its status. He said it was in the back room voluntarily to read the label but that they had not received any notice to pull the product.

4/14/98: Visited [REDACTED] and obtained the medical records of [REDACTED]. From [REDACTED] review of the medical records shows complications with full arrest with collapse during [REDACTED] with seizure activity; hypokalemia (2.7 on admission); severe acute respiratory distress syndrome on admission; right pneumothorax; elevated CPK at 37k; cerebral hypoxia, severe, with cheyne-stoke's breathing. Negative CT; right lower extremity possible arterial occlusion secondary to failed right arterial line placement; left pneumothorax. Record states she had taken approximately 2-4 Ripped Fuel pills

for energy. This is felt to be the cause of her arrest. See medical records attached to this complaint.

4/14/98: Visited [REDACTED] to obtain the [REDACTED] medical records. They are to be ready tomorrow, 4/15/98.

4/14/98: Called Mr. [REDACTED] of the [REDACTED] [REDACTED] was a [REDACTED]. He confirmed the incident occurred during the [REDACTED]. Inquiry was made if a physical was required of the [REDACTED]. He described how they rely on the [REDACTED] obtaining a physical for them to be on the [REDACTED] and not having to repeat it. Inquiry was made if he had ever seen [REDACTED] taking any of the Ripped Fuel or ever seeing such a product in her possession. He said he never saw her taking any drug or the product/bottle in question.

4/15/98: Updated Raphael Davy, CFSAN/DPB/FHS-636. He directed that no sample be collected from any stores as the bottle product came from cannot be specifically identified.

4/15/98: Received a telecon from Mark Fow, HFC-310 and updated him on the investigation.

4/15/98: Obtained medical records from [REDACTED] Correspondence Clerk at [REDACTED] Brisk review shows she was admitted with a history of an anoxic brain injury status post resuscitation for suspected arrhythmia. Assessment: "Limb ischemia of the right lower extremity with thrombosis of the femoral and proximal probable iliac artery. Severe limb ischemia." Patient is unable to respond to any directed commands in order to directly test for any motor or sensory function. Patient died on 4/9/98. Absence of flow and uptake in brain c/w brain death. Main death declared at 11:50 PM.

4/15/98: A faxed copy of the Health Statement and Parent Consent card was received covering the physician's [REDACTED] report for [REDACTED]. It is attached to this complaint. The physician was Dr. [REDACTED]

[REDACTED] Mrs. [REDACTED] said Dr. [REDACTED] gives free [REDACTED] physicals to the [REDACTED]. The report shows the physical was given on 8/12/97. An ankle sprain was the only physical condition noted. It is signed by the physician certifying that the [REDACTED] is physically fit to [REDACTED]

Clarification was made as to Mrs. [REDACTED] initial

description of the product being referred to Ripped Fuel 200. She said that is how it was described in the internet information she had received. A fax copy of the 2 internet pages is attached.

4/20/98: Interviewed Dr. [REDACTED] at his office located [REDACTED]. I identified myself and explained the reason for the visit as well as giving him a copy of the Authorization for Medical Records Disclosure. Even though [REDACTED] medical records go back to [REDACTED] he has only treated her on 6/30/95 and 6/24/95 for ear infection. Previous physicians from this location had treated her. He is the only physician currently at this office. A quick review shows she was treated for bronchitis in 1986 and 1987. [REDACTED] medical records were collected and are attached to this complaint. He stated he was not informed of the incident or her condition until she was transferred to the [REDACTED] on Wed., 4/8/98.

The most current medical record in the file is dated 1/6/97 from a Dr. [REDACTED] who practices at another location. She was seen for skin problems. This was the same physician who performed the [REDACTED] for the [REDACTED].

4/20/98: Visited Dr. [REDACTED] at [REDACTED]. I identified myself and explained the purpose of the visit. She said she moved to her current location in January 1997 and does not have her file. She verified she had only seen [REDACTED] twice. Once for the skin treatment on 1/6/97 and giving her a physical in order for her to [REDACTED]. She said the [REDACTED] include checking the heart, pulse, temperature, and other vital signs. I inquired if she recalls [REDACTED] having any heart murmurs or other heart conditions, had any eating disorders, or other chronic diseases. She said she would not know about any eating disorders but described that any abnormalities would have been noted in the [REDACTED]. This card entitled, "HEALTH STATEMENT AND PARENT'S CONSENT" had been collected from Mr. [REDACTED] and only references an ankle sprain. This card is attached to the complaint follow up.

  
William R. Bowman, CSO  
LOS/DO Med. Device Team

Enclosures:

Adverse Event Questionnaire

Affidavit FD463a dated 4/14/98.

Health Statement and Parent Consent

2 internet pages regarding Ripped Fuel

Medical records from [REDACTED]

Medical records from [REDACTED]

Medical records from Dr. [REDACTED]