

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

ARMS#

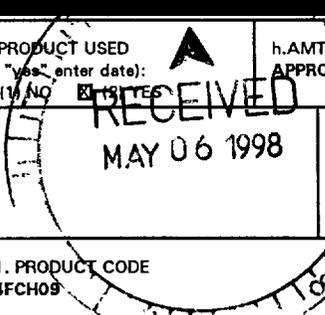
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COMPLAINT/INJURY REPORT

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COMPLAINT/INJURY REPORT		1. COMPLAINT NUMBER RUF-7840	
		2. DATE OF COMPLAINT (MM/DD/YY) 4/29/98	
3. FORM OF COMPLAINT	<input checked="" type="checkbox"/> (1) TELEPHONE <input type="checkbox"/> (3) VISIT <input type="checkbox"/> (2) LETTER	4. SOURCE OF COMPLAINT	<input checked="" type="checkbox"/> (1) CONSUMER <input type="checkbox"/> (3) TRADE SOURCE <input type="checkbox"/> (2) GOVERNMENT <input type="checkbox"/> (4) OTHER <input type="checkbox"/> L <input type="checkbox"/> S <input type="checkbox"/> F <small>(Indicate in Remarks)</small>
5. COMPLAINT IDENTIFICATION	a. NAME AND ADDRESS (Include Zip Code) [REDACTED]		b. AREA CODE AND TELEPHONE HOME [REDACTED] WORK ()
6. COMPLAINT OR INJURY	a. DESCRIPTION OF COMPLAINT/INJURY Complainant called to report a serious adverse reaction experienced by his 18 y.o. son, [REDACTED]. He reports [REDACTED] began taking "RIPPED FUEL" on approximately 4/7/98, taking 2-4 capsules per day (less than the labeled dosage), for about 3 weeks. Shortly after he began taking the product, he exhibited symptoms of nervousness, restlessness, tremors and heart palpitations. This progressed to extreme mood swings, feeling out of control, chest pains, labored breathing. He was taken to the hospital emergency room. (see continuation sheet)		
	DOES COMPLAINT EXPECT ADDITIONAL FDA CONTACT?		<input checked="" type="checkbox"/> NO <input type="checkbox"/> YES (Explain in Remarks)
7. INJURY OR ILLNESS RESULTED <input type="checkbox"/> (1) NO <input checked="" type="checkbox"/> (2) YES <small>(If "YES" complete items a through d)</small>	a. EIB (HFC-161) NOTIFIED <input type="checkbox"/> (1) NO <input checked="" type="checkbox"/> (2) YES DATE 4/30/98 via fax	b. TYPE SYMPTOMS ONSET (HR.) <input type="checkbox"/> (1) VOMITING - <input type="checkbox"/> (2) NAUSEA - <input type="checkbox"/> (3) DIARRHEA - <input type="checkbox"/> (4) FEVER - <input type="checkbox"/> (5) SKIN/EYE IRR. - <input type="checkbox"/> (6) HEADACHE - <input checked="" type="checkbox"/> (7) OTHER_	c. ATTENDING HEALTH PROFESSIONAL <input checked="" type="checkbox"/> (1) NO <input type="checkbox"/> (2) YES (If "yes" give name address, and phone no.)
			d. HOSPITALIZATION REQUIRED <input type="checkbox"/> (1) NO <input checked="" type="checkbox"/> (2) YES (If "yes" give name address, and phone no. and dates) [REDACTED] 4/28/98 + 4/30/98
8. PRODUCT AND LABELING	a. BRAND NAME RIPPED FUEL (METABOLIC ENHANCER)		b. PRODUCT NAME DIETARY SUPPLEMENT CONTAINING MA HUANG, GUARANA, L-CARNITINE & CHROMIUM PICOLINATE
	c. SIZE AND PACKAGE TYPE 60 SOFT-GEL CAPSULES PER BOTTLE		d. NAME AND LOCATION OF STORE WHERE PURCHASED [REDACTED]
	e. PACKAGE CODE/SERIAL NUMBER/ETC. 76315 EXP/USE BY DATE:	f. DATE PURCHASED O/A 5/7/98	g. PRODUCT USED (If "yes" enter date): <input type="checkbox"/> (1) NO <input checked="" type="checkbox"/> (2) YES
h. AMT REMAINING APPROX. 25 CAPSULES			
9. MANUFACTURER/DISTRIBUTOR OF PRODUCT	a. HOME DISTRICT NYK-DO		
		c. NAME AND ADDRESS OF FIRM (Include Zip Code) FIRM ON LABEL: TWIN LABORATORIES, RONKONKOMA, NY 11779	
10. EVALUATION AND DISPOSITION	a. PROBLEM KEYWORD (1) CODE (2) DESCRIPTION RX SEE ABOVE	c. DISPOSITION <input type="checkbox"/> (1) IMMEDIATE FOLLOW-UP <input type="checkbox"/> (2) F/U NEXT EI <input type="checkbox"/> (3) CLOSED WITHOUT FURTHER INVESTIGATION <input type="checkbox"/> (4) REFERRED TO OTHER FEDERAL AGENCY (Closes file) <input type="checkbox"/> (5) REFERRED TO STATE/ LOCAL AGENCY <input checked="" type="checkbox"/> (6) REFERRED TO OTHER FDA_NYK-DO_DISTRICT	
	b. EVALUATION <input type="checkbox"/> (1) NOT AN FDA OBLIGATION <input type="checkbox"/> (2) OBLIGATION, NO VIOLATION <input checked="" type="checkbox"/> (3) FDA ACTION INDICATED <input type="checkbox"/> (4) INSUFFICIENT INFORMATION UNABLE TO EVALUATE	11. PRODUCT CODE 54FCH09	
		12. INFORMATION <input type="checkbox"/> HFM - 660 (Biologics) <input type="checkbox"/> HFD - 730 <input checked="" type="checkbox"/> HFS - 835 <input type="checkbox"/> HFV - 210	COPIES TO: <input type="checkbox"/> HFZ - 530 <input checked="" type="checkbox"/> HFC-161 <input type="checkbox"/> NYS&M <input type="checkbox"/> _
REMARKS SEE ATTACHED CONTINUATION SHEET TIC to Ron Roy, CFSAN, 4/29/98			
NAME AND TITLE Joan Trankle JOAN B. TRANKLE, CONSUMER COMPLAINT COORDINATOR			DATE 4/29/98

BLOCK 6.A. DESCRIPTION OF COMPLAINT/INJURY (CONTINUED):

Mr. [REDACTED] described in son as athletic and very mellow and mild mannered. He reported that while taking Ripped Fuel, he observed dramatic changes in his son's personality.

Mr. [REDACTED] reported that [REDACTED] took his last dose of RIPPED FUEL on Monday, 4/27/98 (2 capsules in the morning). He reports [REDACTED] girlfriend took the bottle of pills away from him because of the personality changes she observed. NOTE that in addition to taking the RIPPED FUEL on a daily basis, [REDACTED] consumes 2-3 bottles of Mountain Dew, a heavily caffeinated soft drink, daily. Mr. [REDACTED] reported on Tuesday morning (approx. 9:30 a.m.) he received a telephone call from his son at work. Mr. [REDACTED] described his son as crying uncontrollably. Mr. [REDACTED] went to his son's place of employment around 11:00 a.m.

On the afternoon of 4/28/98 Mr. [REDACTED] took his son to the [REDACTED] Emergency Room. [REDACTED] was complaining of chest pains and labored breathing. Testing included an ekocardiograph, urine tests, and heart monitoring. The urinalysis revealed high levels of caffeine. Mr. [REDACTED] did not know if ephedra was found in the urine. Test results revealed no illegal drugs. Mr. [REDACTED] reports his son does not use illegal drugs.

I asked Mr. [REDACTED] if [REDACTED] may have taken any other dietary supplements, prescription medications or OTC medications - specifically cough/cold medicines during the time he was taking Ripped Fuel. Mr. [REDACTED] claims he did not.

Mr. [REDACTED] visited the health food store where his son purchased the product. When he asked the clerk for a bottle of Ripped Fuel, he reports she smiled and said he must be "looking for a good buzz today".

Mr. [REDACTED] is willing to cooperate should we wish to obtain further information or medical records. He will hold the opened bottle of Ripped Fuel should we need to sample the product.

Per the product label, the dosage is as follows:

Recommended dose: 2 capsules before morning workout on empty stomach; 2 capsules before afternoon, 2 capsules before the evening meal.

2 capsules contain:

Ma Huang Extract	334 mg
Guarana Extract	910 mg

L-Carnitine 100 mg
Chromium Picolinate 200 mg

On 4/30/98 I telephoned the consumer for some additional information. I spoke with [REDACTED] He reported he made another trip to the Emergency Room early this morning due to chest pain and trouble breathing. No additional medical tests were done. [REDACTED] was advised to take a few days off from work to rest.

Joan Trankle
Joan B. Trankle
Consumer Complaint Coordinator
BUFFALO

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Adverse Event Questionnaire

Complaint Number: BUF-7840

Investigator: FRANKLE

Consumer Information	
Date of Report: <u>04/29/98</u> MM/DD/YY	Initial Report Source: <input checked="" 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:	Gender: <input type="checkbox"/> F <input checked="" type="checkbox"/> M Age: <u>18</u> <i>6ft. 1" TALL 155 lbs</i>
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>4/28/98</u> Previous Adverse Effects to Product Type: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <i>1 1/2 years ago - nervousness</i>	Give the site of consumption/ingestion (e.g. home, restaurant, office): <i>home</i>
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): <i>See FD-2516</i>	
How long did the symptoms last? Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). <i>2 capsules, 2x day for 3 weeks.</i>	
List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used <u>at the time of the event</u> : <i>(None) (RIPPED FUEL) MOUNTAIN DEW</i>	
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 <i>Withdrawal symptoms when stopped.</i>	
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 type="checkbox"/> Not Applicable <i>- see FD-2516</i>	
Medical Information	
Was a health care provider seen?: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <i>ER</i>	
Give health care provider's name, address and telephone number: <i>DR. [REDACTED]</i>	
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? <i>Blood, Urine, EKG, cardiograph</i>	
What was the medical diagnosis? <i>↑ caffeine ↑ ephedrine - no illegal drugs</i>	
What treatment(s) was given (e.g., drugs, other)? <i>Instructed to gradually decrease Caffeine consumption</i>	
Were there any preexisting condition(s)/treatment(s)? <i>NO</i> (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):

RIPPED FUEL, METABOLIC ENHANCER - THERMOGENIC FORMULA
TWIN LABORATORIES, RONKONKOMA, NY 11779 - see FD-2516 Cont. sheet

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

MA HUANG EXTRACT - 334 mg	} per 2 capsule dose.
GUARANA EXTRACT 910 mg	
L-CARNITINE 100 mg	
CHROMIUM PICOLINATE 200 mg	

rec. 3x day before meals

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

- Aspartame
- Monosodium Glutamate
- Sulfite
- Other MA HUANG, GUARANA
- Unknown
- Color Additive (please specify) _____

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 - approx 4 hrs

Required intervention to prevent permanent impairment/damage: Yes No

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