

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

ARMS#

12527



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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

10:10
1
1. COMPLAINT NUMBER

C10-7519,2527

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

8/25/97

COMPLAINT / INJURY REPORT

3. FORM OF COMPLAINT

- a.
(1) TELEPHONE
(2) LETTER
(3) VISIT

4. SOURCE OF COMPLAINT

- a.
(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 NUMBER

HOME ([Redacted])
WORK ([Redacted])

6. COMPLAINT OR INJURY

a. DESCRIPTION OF COMPLAINT / INJURY

Mr. [Redacted] son & another boy (both 16 years old) took 6 capsules per day per labeling directions for 3 days. Both boys developed shingles, were wide eyed, hyperactive & had no appetite. The boys were not taking any (see Rmks)

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?

- (1) NO (2) YES
(If "Yes" Explain in Remarks)

7. INJURY OR ILLNESS RESULTED

a. EIB (HFC - 161) NOTIFIED

- (1) NO
(2) YES

DATE:

b. TYPE SYMPTOMS

- (1) VOMITING
(2) NAUSEA
(3) DIARRHEA
(4) FEVER
(5) SKIN/ EYE IRR.
(6) HEADACHE
(7) OTHER
See 6a

ONSET (HR.)

c. ATTENDING HEALTH PROFESSIONAL?

- (1) NO (2) YES

(If "Yes" give name, address, and phone number)

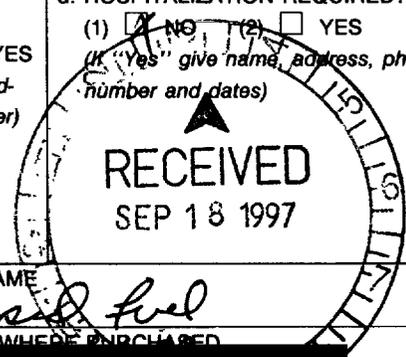
d. HOSPITALIZATION REQUIRED?

- (1) NO (2) YES

(If "Yes" give name, address, phone number and dates)

- (1) NO
(2) YES *

*(If "yes" complete items a through d)



8. PRODUCT AND LABELING

a. BRAND NAME

Twin Labs

b. PRODUCT NAME

Repeal fuel

c. SIZE AND PACKAGE TYPE

120 capsule bot.

d. NAME AND LOCATION OF STORE WHERE PURCHASED

[Redacted]

e. PACKAGE CODE / SERIAL NUMBER / ETC.

75253

EXP. / USE BY DATE:

f. DATE PURCHASED

8/22/97

g. PRODUCT USED

(If "Yes" enter date)
Date: 8/22/97

(1) NO (2) YES

h. AMT. REMAINING

Bottle only

9. MANUFACTURER / DISTRIBUTOR OF PRODUCT

a. HOME DISTRICT

NYK

b. C.F. NO.

2421049

c. NAME AND LOCATION OF FIRM (Include ZIP Code)

Twin Labs
Rochester, NY

d. IMPORT PRODUCT

- (1) NO
(2) YES

10. EVALUATION AND DISPOSITION

a. PROBLEM KEY WORD

- (1) CODE (2) DESCRIPTION
R/ ephedrine

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 NYK DISTRICT
(7) REFERRED TO OCI

11. PRODUCT CODE

54FCA09

12. INFORMATION COPIES TO:

- HFM-660 HFZ-343
 HFD-730 HFC-161
 HFV-210 HFS-635
 OTHER

13. REMARKS

other supplements. The ingredients listed on the label are: Maltin 334 mg, Guarana 910 mg, L-carnitine 100 mg & Picolinic

000001

14. NAME AND TITLE OF DISPOSITION OFFICIAL

David C Rolle PDM

15. DATE

9/12/97

Adverse Reaction Information Form A

CFSAN PJCT # 12527

Complaint Number: CIN-7519

Investigator: DAVID RADLE

Consumer Information	
Date of Report: <u>01/15/99</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: [REDACTED]	Gender: <input type="checkbox"/> F <input checked="" type="checkbox"/> M Age: <u>16</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 Reaction	
Date of Adverse Reaction: <u>8/25/97</u> Previous Reaction 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>
Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): <u>Rapid heart beat & increased sweating developed approx 1 hr after use.</u> How long did the symptoms last? <u>Rapid heart beat ~ 25 min. increased sweating ~ 3 days</u> Give the circumstances of exposure (e.g., dose, route of exposure, frequency, etc.): <u>2 capsules 3x per day</u> <u>Reaction occurred on 3rd day of use.</u> List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: <u>None</u>	
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	
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)? (If YES, list them including allergies, and chronic diseases): <input type="checkbox"/> Yes <input type="checkbox"/> No	
Product Category	
1. Adverse reaction to: <input type="checkbox"/> Medical Food (under medical supervision) <input type="checkbox"/> Infant Formula <input type="checkbox"/> 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.) <input type="checkbox"/> Other (traditional food) _____ <u>Other Product Problems</u> 2. <input type="checkbox"/> Foreign Object (specify): _____ 3. <input type="checkbox"/> Other (specify): _____	

Information on Suspected/Alleged Product

Give the product name (including dose/serving size, duration of use, and reason for taking): Rapid Fuel (Twelve Labs, Ronkonkoma, NY) labeling recommended dosage is 2 capsules 3x per day according to father. [redacted] was being used as an adjunct to physical training.

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

Check here if ingredients are unknown

- Ma Huang 334 mg
Guarana 910 mg
L-Carnitine 100 mg
Picolinate

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

- Aspartame
Sodium Glutamate
Caffeine
Other ephedrine
Unknown
Color Additive (please specify)

Product Label Available: 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 reaction result in a congenital anomaly: Yes No