

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

ARMS#

12444



0 - FRONT

COMPLAINT/INJURY REPORT

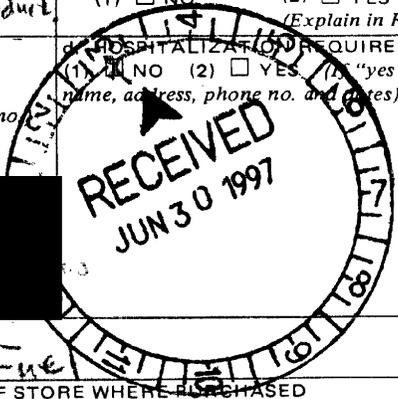
1. COMPLAINT NUMBER  
 LOS-7850/12444  
 2. DATE OF COMPLAINT (Month/Day/Year)  
 6/24/97

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

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  
 a. DESCRIPTION OF COMPLAINT/INJURY  
 Complaint received 6/23 from State [Redacted]. Complainant had been taking 4 capsules/day of product (rec. dosage 3/meal) for a week when she felt dizzy and blacked out. She was transferred to [Redacted] via ambulance where a blood test revealed hypoglycemia. Complainant received IV's and was discharged after attending physician advised her to stop using product.  
 b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? (1)  NO (2)  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)  NO (2)  YES DATE 6/24/97  
 b. TYPE SYMPTOMS ONSET (HR.)  
 1  VOMITING  
 2  NAUSEA  
 3  DIARRHEA  
 4  FEVER  
 5  SKIN/EYE IRR.  
 6  HEADACHE  
 7  OTHER Dizziness/black out insomnia  
 c. ATTENDING HEALTH PROFESSIONAL (1)  NO (2)  YES (if "yes" give name, address, and phone no.)  
 Dr. [Redacted]  
 d. HOSPITALIZATION REQUIRED (1)  NO (2)  YES (if "yes" give name, address, phone no. and dates)



8. PRODUCT AND LABELING  
 a. BRAND NAME Twin Labs  
 b. PRODUCT NAME Diet Fene  
 c. SIZE AND PACKAGE TYPE 120 caps. / glass bottle  
 d. NAME AND LOCATION OF STORE WHERE PURCHASED [Redacted]  
 e. PACKAGE CODE/SERIAL NUMBER/ETC. 6B461  
 f. DATE PURCHASED 6/10/97  
 g. PRODUCT USED (If "yes" enter date) (1)  NO (2)  YES  
 h. AMT REMAINING

9. MANUFACTURER/DISTRIBUTOR OF PRODUCT  
 a. HOME DISTRICT NYK  
 b. C.F. NO. 2421049  
 c. NAME AND ADDRESS 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 KEYWORD (1) CODE (2) DESCRIPTION  
 RX : blackout  
 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 NYK DISTRICT  
 11. PRODUCT CODE 54YEE99  
 12. INFORMATION COPIES TO:  
 HFN - 355  HFZ - 343 (Biologics)  
 HFN - 730  HFZ - 400  
 HFN - 333  HFC - 161  
 HFV - 236

REMARKS  
 (a) cont'd) Attending physician stated that she was aware of 3 cases of women overdosing on the product and believed it contained amphetamines. State lab analysis revealed ephedrine and caffeine in the product (25mg ephedrine and 140 mg caffeine at recommended dosage level.)  
 (2) Complaint taken by State of [Redacted] Food & Drug Branch 6/17/97 (see attached) Ref'd by State to [Redacted] 6/23/97  
 000001

NAME AND TITLE G. Steven Condrey ACCC DATE 6/24/97

COMPLAINT

Date: 6-17-97

Time: 1645

Complaint Number: [REDACTED]

Taken By: [REDACTED]

ID: [REDACTED]

Telephone  Visit  Letter

District Number: [REDACTED]

Program: [REDACTED]

Inv. Time: \_\_\_\_\_

Complainant Name: [REDACTED]

Address: [REDACTED]

ZIP: [REDACTED]

City: [REDACTED]

Work: [REDACTED]

Telephone: Home: [REDACTED]

PERSONAL INFORMATION RELEASABLE:

Referred By: [REDACTED] Phone: ( ) \_\_\_\_\_

Agency: \_\_\_\_\_

Injury or illness:  No  Yes If yes, complete the following items:

Symptoms/Onset (hours) Vomiting 7 Nausea \_\_\_\_\_ Diarrhea \_\_\_\_\_  
Fever \_\_\_\_\_ Irrit. \_\_\_\_\_ Headache \_\_\_\_\_ Other (specify) DIZZINESS, BLACKED OUT

Hospitalization: ER on 6/15

Attending Physician: TRANSFERRED VIA AMBULANCE

Commodity Code: \_\_\_\_\_

PRODUCT: DIETARY SUPPLEMENT

Lot/Code #: 6B461

Brand Name: TWIN LABS DIET FUEL

Quantity: 120 CAPSULES

Size: 120 CAPSULES GLASS

MANUFACTURER/DISTRIBUTOR: TWIN LABS

Address: NEW YORK

PURCHASE POINT: [REDACTED] Purchase Date: 1 WK AGO

Address: [REDACTED]

DETAILS (SEE REVERSE.): \_\_\_\_\_

SUPERVISOR REVIEW—By: [REDACTED] Date: 6/23/97 Priority: [REDACTED]

DISPOSITION—Refer To: [REDACTED] CASE #: \_\_\_\_\_

NAI  CLOSE OF \_\_\_\_\_

ASSIGNMENT TO: [REDACTED] Due Date: \_\_\_\_\_

Instructions: Determine if [REDACTED] is working on this  
if NO refer to PDA

(Investigator F/U and/or DISPO, see reverse.)

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CONSUMER:

[REDACTED]

Product - Twin Labs Diet Fuel Capsule  
Mfg'd by Twin Labs, N.Y.  
Lot # 6B461  
120 capsules glass container

Purchased early June, 1997 at [REDACTED] on [REDACTED]  
[REDACTED]

For 1 week Ms. [REDACTED] consumed 4 capsules/day;  
(recommended dosage 3 capsules/meal = 9 capsules/day)

On Sunday, June 15, 1997 at [REDACTED] [REDACTED] felt dizzy and blacked out. She was transferred to [REDACTED] ER via ambulance. She was treated and released (rec'd IV's and blood test revealed hypoglycemia). The MD informed Ms. [REDACTED] to stop taking Diet Fuel (MD found container in Ms. [REDACTED] backpack when returning her driver's license). The MD informed Ms. [REDACTED] that she has heard of 3 cases where women OD'd on this product since it contained amphetamines. Also Ms. [REDACTED] had o/o insomnia for 1 week - MD informed her will "cure" insomnia when she stops taking product.

No test conducted on Diet Fuel at ER. Ms. [REDACTED] still has product. (Ms. [REDACTED] state can release personal information to firm). Complaint received June 17, 1997.

On June 18th per [REDACTED] Investigator, discussed complaint with [REDACTED] Ph.D., [REDACTED] [REDACTED] stated product contains ephedrine and caffeine (25 mg ephedrine and 140 mg caffeine per serving - 3 capsules). FDA has published in Federal Register proposed rule on ephedrine and caffeine products. Will refer to FDA.

[REDACTED]

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RE: [REDACTED] COMPLAINT

Discussed with Ms. [REDACTED] status of complaint - referred to FDA. Informed Ms. [REDACTED] product contains ephedrine and caffeine, she stated she drinks decaffeinated coffee.

Per ER release form, the attending physician at [REDACTED] was Dr. [REDACTED]

Discussed complaint with Henry Carrillo, FDA Consumer Complaint Coordinator Los Angeles District who requested copy report. (phone [REDACTED])

[REDACTED]

June 23, 1997

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