

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

ARMS#

12488



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**COMPLAINT/INJURY REPORT**

*Rec'd  
8/20/97*

1. COMPLAINT NUMBER  
DAL 7-6046 12488  
2. DATE OF COMPLAINT (Month/Day/Year)  
6-5-96

3. FORM OF COMPLAINT	(1) <input checked="" type="checkbox"/> TELEPHONE	4. SOURCE OF COMPLAINT	(1) <input type="checkbox"/> CONSUMER	(3) <input type="checkbox"/> TRADE SOURCE
	(2) <input type="checkbox"/> LETTER		(2) <input type="checkbox"/> GOVERNMENT	(4) <input checked="" type="checkbox"/> OTHER
	(3) <input type="checkbox"/> VISIT		<input type="checkbox"/> L <input type="checkbox"/> S <input type="checkbox"/> F	(Indicate in Remarks) <b>Physician</b>

5. COMPLAINANT IDENTIFICATION	a. NAME AND ADDRESS (Include Zip Code)		b. AREA CODE AND TELEPHONE NUMBER	
	[REDACTED]		HOME ( )	WORK ( [REDACTED] )

6. COMPLAINT OR INJURY	a. DESCRIPTION OF COMPLAINT/INJURY		b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES (Explain in Remarks)
	<p>Dr. [REDACTED] has a 36 year old male patient who may be suffering a reaction to EPHEDRA. The man is catatonic and the Dr. is trying to get him admitted to a local hospital in [REDACTED]. The man is currently at his residence. A nurse has been sent to the home.</p>		

7. INJURY OR ILLNESS RESULTED	a. EIB (HFC-161) NOTIFIED	b. TYPE SYMPTOMS ONSET (HR.)	c. ATTENDING HEALTH PROFESSIONAL	d. HOSPITALIZATION REQUIRED
	(1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES (If "yes" complete items a through d)	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 type="checkbox"/> OTHER _____ Catatonic	(1) <input type="checkbox"/> NO (2) <input type="checkbox"/> YES (If "yes" give name, address, and phone number)  Dr. [REDACTED] See Blk 5.	(1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES (If "yes" give name, address, phone number and dates) Pt. will be admitted to a local hospital in [REDACTED] as soon as arrangements can be made.

8. PRODUCT AND LABELING	a. BRAND NAME	b. PRODUCT NAME	RECEIVED CLINICAL RES. AND & REVIEW/OSM HHS-452 AUG 19 1997
	c. SIZE AND PACKAGE TYPE	d. NAME AND LOCATION OF STORE WHERE PURCHASED	
	e. PACKAGE CODE/SERIAL NUMBER/ETC.	f. DATE PURCHASED	
	D & E Ephedra Nature's Super Caps	Ephedra	
	250/950 mg caps bottle	Unknown	
	Unk EXP/USE BY DATE:	g. PRODUCT USED (If "yes" enter date) date unk (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES	h. AMT REMAINING Unk

9. MANUFACTURER/DISTRIBUTOR OF PRODUCT	a. HOME DISTRICT	c. NAME AND LOCATION OF FIRM (Include Zip Code)	d. IMPORT PRODUCT
	b. C.F. NO.	DNE Pharmaceuticals, Inc. (See Remarks) Div. of D & E Pharm., 206 Macopin Rd. Bloomingdale, NJ 07043	(1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES
	NWK-DO		
	NOCF		

10. EVALUATION AND DISPOSITION	a. PROBLEM KEYWORD (1) CODE (2) DESCRIPTION	c. DISPOSITION	11. PRODUCT CODE
	RX Reaction	(1) <input checked="" type="checkbox"/> IMMEDIATE FOLLOW-UP (2) <input type="checkbox"/> F/U NEXT EI (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	54FCA09
	b. EVALUATION		12. INFORMATION COPIES TO;
	(1) <input type="checkbox"/> NOT AN FDA OBLIGATION (2) <input type="checkbox"/> OBLIGATION, NO VIOLATION (3) <input checked="" type="checkbox"/> FDA ACTION INDICATED (4) <input type="checkbox"/> INSUFFICIENT INFORMATION UNABLE TO EVALUATE		<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"/> _____ MIN-DO

REMARKS  
On 6-9-97, Dr. [REDACTED] contacted the [REDACTED] and reported he had contacted [REDACTED] and now felt the patient might be reacting to Yohimbine.  
PRODUCT: Gorilla Nitro Plus with yohimbe, 2 fl. oz (60 ml), lot unk.  
DISTR BY: Val Vadet, N. D. Vital Products, Inc.  
PIC: 54FCL29

NAME AND TITLE	DATE
Bonnie L. Fry, CSO <i>Bonnie L. Fry</i>	6-5-97 <i>below</i>

RECEIVED  
AUG 11 1997

**COMPLAINT / INJURY FOLLOW-UP**

1. COMPLAINT NUMBER  
DAL 7-6046

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

(a) REMARKS (Additional details)

(b) REQUESTING OFFICIAL'S NAME AND TITLE  
Bonnie L. Fry, CSO

(c) DATE REQUESTED  
6-5-97

(d) PRODUCT NAME  
Ephedra

3. ASSIGNED TO:  
  
Bonnie L. Fry

(a) DUE BY  
  
ASAP

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

(a) SAMPLE NUMBER(s)  
  
N/A

(b) DESCRIPTION OF ACTION TAKEN

On 6-5-97, I interviewed Dr. [REDACTED]. Dr. [REDACTED] is employed by the [REDACTED].  
Dr. [REDACTED] was seeking any available information on the effects of Ephedra. He stated his patient may be reacting to Ephedra.

I referred Dr. [REDACTED] to the [REDACTED] in [REDACTED] and to the [REDACTED].

See Memo to Accompany DAL 7-6046 for f/u.

(c) ACTION OFFICIAL'S NAME AND TITLE

Bonnie L. Fry, CSO

*Bonnie L. Fry*

(d) ACTION DISTRICT  
DAL-DO

(e) DATE COMPLETED  
8-2-97

5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE

6. PROGRAM DATA

(a) HOME DIST.

(c) NAME AND ADDRESS

(a) OPERATION  
13

(b) PAC

(c) PRODUCT CODE  
54FCA09

(b) CF NO.

DNE Pharmaceuticals, Inc.  
Div. of D & E Pharm.  
206 Macopin Road (See Remarks)  
Bloomington, NJ 07043

(d) EMP. HOME DIST.  
7

(e) EMP. NO.  
422

(f) POS CL.  
2

(g) HOURS  
10

7. EVALUATION

8. FINAL DISPOSITION

- (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.

- (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
- MIN-DO

REMARKS

On 6-9-97, Dr. [REDACTED] reported the patient make be reacting to Yohimbine.  
PRODUCT: Gorilla Nitro Plus with yohimbe, 2 fl. oz (60 ml)  
DISTR BY: Val Vadet, N. D. Vital Products, Inc.

PIC: 54FCL29

NAME AND TITLE OF DISPOSITION OFFICIAL

DISPOSITION

DISPOSITION DATE

*[Signature]*

*Del*

*8/31/97*

TO: John W. Thorsky, SCSO, [REDACTED]

DATE: 8-2-97

FR: Bonnie L. Fry, CSO, [REDACTED]

SJ: Memo to Accompany DAL7-6046

Complainant: [REDACTED]

On 6-5-97, Dr. [REDACTED] reported he had a catatonic patient who had been using Ephedra. He believed the patient was reacting to something which he had taken, and he thought it might be the Ephedra. The patient, however, was taking multiple supplements as well as ephedra. Dr. [REDACTED] was seeking help in obtaining any known effects to Ephedra. This individual had not been his patient prior to the incident. The family had contacted him because they believed he was suffering from psychological factors. Dr. [REDACTED] stated, however, it appeared more to be a reaction to something he had consumed.

He stated the patient had been taking DNE Ephedra Nature's Super Cap 250/950 mg; a water pill balancer, Mega Creatin Fuel Performance E, Gorillo Nitro Plus, and other supplements.

He promised to speak to the patient's family about meeting with me, but first, he needed to get the patient admitted to a hospital.

On 6-9-97, I again spoke with Dr. [REDACTED]. He told me the patient had been transported to the hospital in [REDACTED] and had arrived E. O. D. (Emergency Order of Detention). He had been placed under the care of his family's physician (not identified) who had prescribed sleeping medications.

He told me he had contacted Poison Control, [REDACTED] and [REDACTED] had informed him the symptoms resembled those caused by "yohimbine". Dr. [REDACTED] stated the patient had been taking "Gorillo Nitro Plus", distributed by [REDACTED] which contains yohimbine. (Common Name: Yohimbe. Yohimbi: contains toxic alkaloid yohimbine (quebrachine) and other alkaloids. From Corymanthe).

On 6-11-97, Dr. [REDACTED] informed me he had spoken to [REDACTED] the patient's mother. Mrs. [REDACTED] was willing to meet with me and would contact me. On 6-11-97, I was contacted by [REDACTED]. She stated that her son was [REDACTED]. They both resided in [REDACTED] but at different addresses. In lieu of providing residential addresses, Ms. [REDACTED] stated I could contact her at work. Mrs. [REDACTED] is the [REDACTED] at the

000003

[REDACTED] She informed me she was Dr. [REDACTED] boss.

According to Ms. [REDACTED] had never exhibited any signs of mental health problems prior to 5-16-97. On 5-16-97, he began to carry on conversations in other voices, and progressively experienced catatonic stages until finally, on Thursday, 6-5-97, he was admitted to [REDACTED]. She reported he was psychotic by Saturday. They obtained an E.O.D. from a judge and on Monday, 6-7-97, he was transferred to [REDACTED].

She said her son worked very long/hard hours as a construction worker and had been taking the different supplements to give him the energy to work the long hours. She did not think he was a member in any health club, but did have equipment to work-out at home.

She thought some of the supplements were ordered from catalogs and some were purchased at a local health food store. She identified them as follows:

[REDACTED]

She reported these supplements included DNE Ephedra Nature's Super Cap, a water balancer, Mega Creatin Fuel Performance E, and Gorillo Nitro Plus.

She stated that [REDACTED] girlfriend had told her she could tell when [REDACTED] had been taking them because he became hyper and wanted his own way.

Mrs. [REDACTED] also told me her younger son had seen [REDACTED] take a full dropper of Gorillo Nitro Plus three or four times/day, but the labeled dose was only 10 drops before a work-out.

According to Mrs. [REDACTED] has taken supplements for years, but his girlfriend had said he began to take "Gorillo Nitro Plus" about 3 months prior to the first of May.

This is the only new supplement which his mother was aware of him taking.

Mrs. [REDACTED] agreed to meet with me at her office on 6-13-97 to sign a medical release and to provide additional information.

On 6-13-97, I visited the [REDACTED]. Mrs. [REDACTED] was not there. She had been there, but had left before I arrived to conduct some business in [REDACTED].

Memo to Accompany DAL 7-6046, 6-5-97, p. 3

I did interview Dr. [REDACTED]. Dr. [REDACTED] had a large sack containing multiple containers of supplements which he said had been retrieved from the home of [REDACTED]. He stated this was not all of it. Dr. [REDACTED] allowed me to look at the supplements, but not photograph any labeling without Mrs. [REDACTED] being present to give her permission.

These supplements included the following:

\*\*\*D & E EPHEDRA Nature's SUPER CAP 250 CAPSULES 950 mg each NET WT. 237.5 gm EACH CAPSULE CONTAINS: Ephedra Extract: 833 mg\*\*\*dietary supplement\*\*\*Distributed by: [REDACTED]\*\*\*", lot 8172E6

\*\*\*Sport Pharma\*\*\*Thermogenic Stimulator Thermadrene\*\*\*60 CAPSULES 705 mg EACH\*\*\*Ephedra standardized extract 300 mg. guarana extract 150 mg. willow bark extract 75 mg. USP caffeine 80 mg. cayenne 60 mg. ginger 40 mg. md in USA by; SPORTPHARMA, USA, INC CONCORD, CA 94520 1-800-654-4246\*\*\*"

JBN\*\*\*Just Be natural\*\*\*ACTIVATOR\*\*\*60 Tablets - 30 Day Supply Vitamin/Mineral Complex\*\*\*"

\*\*\*GORILLA NITRO PLUS with yohimbe\*\*\*2 FL OZ. (60 ML)\*\*\*Yohimbe Bark Extract\*\*\*800 mg X 4\*\*\*suggested use, As a dietary supplement, place 10 -12 drops under tongue\*\*\*Distributed by [REDACTED]

\*\*\*Twin LAB PERFORMANCE ENHANCER 1200 mg MEGA CREATINE FUEL 120 CAPSULES\*\*\*Each capsule provides 1200 mg of creatine monohydrate\*\*\*Manufactured by TWIN LABORATORIES, INC. Rankonkoma, New York 11779\*\*\*"

BOLT NATURAL 100% ALL NATURAL\*\*\*Each tablet contains:\*\*\*Guarana Extract, Ma Huang,\*\*\*Take 1 or 2 tablets 3 times daily\*\*\*Distributed by: [REDACTED]\*\*\*"

\*\*\*JBN DIET hhas - H2O PILL Water Balancer 90 Tablets\*\*\*"

\*\*\*relief plus STA . AWARE\*\*\*200 mg Caffeine\*\*\*100 TABLETS Made in the USA FOR KMART CORPORATION TROY< MICHIGAN 48084\*\*\*"

Among these supplements, I observed one prescription from [REDACTED] for Claritan-D Tablets, 1 tab twice daily.

Dr. [REDACTED] also showed me two catalogs as follows:

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Memo to Accompany DAL 7-6046, 6-5-97, p. 4

JBN's \*\*\* 20 edition  
JBN Enterprises  
3864 Cortney St, Ste 140  
2 Cortney Place  
Bethlehem, PA 18017

Diet Nutrition And Energy New Disc.  
DNE Pharmaceuticals, Inc.  
Div of D & E Pharm.  
206 Macopin Road  
Bloomingdale, NJ 07043

Dr. [REDACTED] stated he had heard from the family that [REDACTED] had not been taking the supplements as labeled, but had increased both the dosage and frequency for using Gorillo Nitro Plus ie a full dropper several times/day. Also, several of the supplements contain Ephedra so he was taking an even larger amount of Ephedra than originally thought.

Dr. [REDACTED] stated it would not be possible to interview [REDACTED] at this time, nor could he provide medical information until Mrs. [REDACTED] signed a medical release. He did inform me that he was not currently treating [REDACTED]. He stated that Mr. [REDACTED] was in no condition to be interviewed. Dr. [REDACTED] indicated that [REDACTED] had apparently been abusing the supplements in an attempt to energize his body so he could work long/hard hours in construction.

He told me that Mrs. [REDACTED] would be in [REDACTED] on 6-16-97 and would probably contact me then.

After leaving Dr. [REDACTED] office, I visited [REDACTED]. I did not observe any of the Ephedra products or the Gorillo Nitro Plus in the store.

When I did not hear from Mrs. [REDACTED] I telephoned her office. I was told that Mrs. [REDACTED] was busy and could not take my call. I left a message requesting that she return my call. I have had no further contact with her.

*Bonnie L. Fry*  
Bonnie L. Fry  
Investigator

000006