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

ARMS#

12589

0 - FRONT

[redacted]

PHONE NO. [redacted]

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

CFSAN Page 1 of ___

Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse

FDA Use Only
Triage unit sequence # 71465
12589

A. Patient information

1. Patient identifier: In confidence
2. Age at time of event: 41 or Date of birth: [redacted]
3. Sex: ☐ female ☑ male
4. Weight: 220 lbs or ___ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death (mo/day/yr) ___
   - ☑ life-threatening
   - ☐ hospitalization – initial or prolonged
   - ☑ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other: ___
3. Date of event (mo/day/yr): 6/21/97
4. Date of this report (mo/day/yr): 10/15/97
5. Describe event or problem

SEVERE REACTION AFTER PRODUCT DISCONTINUED CHEST PAINS, WITHDRAWL SYMPTOMS, ETC.

6. Relevant tests/laboratory data, including dates

8/97 UCSD MED CHECK

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 INFERNAL BLAST ALL AMERICAN PHARMACUTICAL CO
   #2
2. Dose, frequency & route used
   #1 2x24 PO
   #2
3. Therapy dates (if unknown, give duration) from/to (or dosing schedule)
   #1 4/97 - 6/97
   #2
4. Diagnosis for use (indication)
   #1 WEIGHT LOSS
   #2
5. Event abated after use stopped or dose reduced
   #1 ☐ yes ☐ no ☑ doesn't apply
   #2 ☐ yes ☐ no ☑ doesn't apply
6. Lot # (if known)
   #1 UNK
   #2 UNK
7. Exp. date (if known)
   #1 UNK
   #2 UNK
8. Event reappeared after reintroduction
   #1 ☐ yes ☐ no ☑ doesn't apply
   #2 ☐ yes ☐ no ☑ doesn't apply
9. NDC # (for product problems only) –
10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other: ___
5. Expiration date (mo/day/yr)
6. model # ___ catalog # ___ serial # ___ lot # ___ other # ___
7. If implanted, give date (mo/day/yr)
8. If explanted, give date (mo/day/yr)
9. Device available for evaluation? (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)
10. Concomitant medical products and therapy dates (exclude treatment of event)

REC'D. OCT 14 1997 MEDWATCH CTU

E. Reporter (see confidentiality section on back)

1. Name, address & phone # [redacted]
2. Health professional? ☐ yes ☐ no
3. Occupation: CONSULTANT
4. Also reported to
   - ☑ manufacturer
   - ☐ user facility
   - ☑ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☑

PLEASE TYPE OR USE BLACK INK

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Dear Mr. [redacted]

In March of 97, I purchased a weight loss product from [redacted] in [redacted] The product marketed as infernal Blast is sold over the Counter. It Contains epedra and Caffine. I purchased two Bottles that held 60 pills each. On the second day I felt mild chest discomfort, but it past. As I was into my second month using this product, I felt I was going to jump out of my skin. I returned both bottles for a refund. Over the next 3 days I underwent withdrawl, I suffered severe panic attacks and night sweats. On the second day it was later that night, I took a drive to get away from the house. I was at an intersection near my home when I thought I was having a heart Attack. I pulled over to the Curb and was struck by another Car.

RECEIVED 3/9/98 CRRS

I phoned and visited the store in [redacted] and learned that the company, [redacted] bought the product through a company in Montana. This company [redacted] is part of the Billion Dollar unregulated weight loss industry. There were no warnings on the label for me to make an informed decision. Although a pamplet warns the medical risks, the product when I purchased it was above eye level the pharmplet was close to the floor. I spoke to both the manufacturer, the distributor, and their Insurance Carrier. All of them are trying avoid responsibility by saying the food and drug Administration won't, or can't regulate them.

Congressman, would you ask the FDA and the FTC to investigate this matter on my behalf.

3

Thank you for your help in this matter.

Sincerely

[redacted]

COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER: LOS-3089

2. DATE OF COMPLAINT (Month/Day/Year): 10/15/97

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

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

5. COMPLAINANT IDENTIFICATION
a. NAME AND ADDRESS (Include Zip Code): [redacted]
b. AREA CODE AND TELEPHONE NO.
HOME [redacted]
WORK ( )

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT/INJURY
Complainant experienced angina, headache and nervous agitation while taking the product (2 caplets/day from April 1997 to 6/18/97. Complainant stated that he experienced mild angina on or about the second day and discontinued the product 6/18/97. From ~6/20-22/97 he claimed to experience drug withdrawal symptoms and experienced a strong angina attack that was associated with an automobile accident.

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 10/17/97
Fax 10/16/97 [illegible]

b. TYPE SYMPTOMS — ONSET (HR.)
1 ☐ VOMITING
2 ☐ NAUSEA
3 ☐ DIARRHEA
4 ☐ FEVER
5 ☐ SKIN/EYE IRR.
6 ☒ HEADACHE
7 ☒ OTHER
Angina

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

d. HOSPITALIZATION REQUIRED
(1) ☒ NO (2) ☐ YES (If "yes" give name, address, phone no. and dates)
Internal Blast

8. PRODUCT AND LABELING
a. BRAND NAME: So CAL Supplements
b. PRODUCT NAME: Nutritional Supplement, Thermogenic Fat Burner ~~Therm~~ [illegible] 10/17/97
c. SIZE AND PACKAGE TYPE: 6 caplet / Screw Cap Bottle
d. NAME AND LOCATION OF STORE WHERE PURCHASED: [redacted]
e. PACKAGE CODE/SERIAL NUMBER/ETC.: Unknown (Returned to Store)
EXP/USE BY DATE:
f. DATE PURCHASED: ~4/97
g. PRODUCT USED (If "yes" enter date) (1) ☐ NO (2) ☒ YES 4/97 - 6/18/97
h. AMT REMAINING: None

9. MANUFACTURER/DISTRIBUTOR OF PRODUCT
a. HOME DISTRICT: SEA / H
b. C.F. NO.: 3027901
c. NAME AND ADDRESS OF FIRM (Include Zip Code): All American Pharmaceuticals, 1831 Main St., Billings, MT 59101
So Cal Supplements, P.O. Box 727, Ramona, CA 92065
d. IMPORT PRODUCT
(1) ☒ NO
(2) ☐ YES

10. EVALUATION AND DISPOSITION
a. PROBLEM KEYWORD
(1) CODE: RX (2) DESCRIPTION: Angina
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: 54FCT09

12. INFORMATION COPIES TO:
☐ HFN - 355 (Biologics) ☐ HFZ - 343
☐ HFZ - 400
☐ HFN - 730 ☐ HFC - 161
☐ HFN - 333 ☒ HFS-635
☐ HFV - 236

REMARKS
BLK 8: Store Manager, [redacted], States, not aware of other Complaints & The product is no longer for sale at their Store, Refer to HQ [redacted] States: Product was pulled from all Stores ~~6/~~ 7/97 & They have not received other complaints. Ms. [redacted] Also stated that the Product was Distributed by So Cal Supplements & Manufactured by All American Pharmaceuticals.

NAME AND TITLE: Allen F. Hall, CSO
DATE: 10/16/97

000005

FORM FDA 2516 (4/95)

COMPLAIN. / INJURY FOLLOW-UP

1. COMPLAINT NUMBER: LOS-3089

2. ACTION REQUESTED
(1) [X] INVESTIGATION
(2) [ ] COLLECT SAMPLE
(3) [ ] INSPECTION
(4) [ ] OTHER

(a) REMARKS (Additional details): Please interview Attending Physician and obtain any associated Medical Records. Since No product Remains with Complainant and Lot Code Unknown, Sample Not Requested.

(b) REQUESTING OFFICIAL'S NAME AND TITLE: Allen F. Hall, CSO

(c) DATE REQUESTED: 10/17/97

(d) PRODUCT NAME: Internal Blast

3. ASSIGNED TO: Catherine Vieweg, CSO

(a) DUE BY: 10/22/97

4. ACTION TAKEN
(1) [X] INVESTIGATION
(2) [ ] SAMPLE COLLECTED
(3) [ ] INSPECTION
(4) [ ] NONE

(a) SAMPLE NUMBER(s): N/A

(b) DESCRIPTION OF ACTION TAKEN

Allen F Hall, CSO has contacted Mr. [redacted] a So Cal distributer who stated that he Knew of no other problems or complaints associated with this product. The complainant faxed to SAD-RP a copy of a flyer displayed with the product at [redacted] where he purchased it. It is attached and contains instructions for use and the declared ingredients. Complainant no longer has any product on hand. Per Dr. [redacted] the patient's described symptoms are consistent with a possible withdrawal syndrome from Ephedra/Caffeine. She thought pt had seen another MD prior to her. Pt had lost 30 lbs while on product and has no signs of permanent sequalea from use of product. Records obtained. Mr [redacted] contacted for info on ADR Questionnaire and he denies seeking medical attention from another doctor. ~~but did go to Emergency Room after accident.~~ error C Vieweg 10/21/97 Mr [redacted] is attempting to recover costs of car accident and medical treatment from manufacturer. Release of Information obtained by Allen F Hall, CSO.

(c) ACTION OFFICIAL'S NAME AND TITLE: Catherine L Vieweg, CSO UFP 10/22/97

(d) ACTION DISTRICT: LOS-DO (A)

(e) DATE COMPLETED: 10/21/97

5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE

(a) HOME DIST.: SEA (H)

(b). CF NO.: 3027901

(C) NAME AND ADDRESS: All American Pharmaceuticals, 1831 Main St, Billings, MT 59101

6. PROGRAM DATA

(a) OPERATION: 13

(b) PAC: 46R801 ~~56R801~~ UFP

(c) PRODUCT CODE: 54FCT09

(d) EMP. HOME DIST.: LOS-DO (A)

(e) EMP. NO.: 237

(f) POS CL.: 2

(g) HOURS: 5

7. EVALUATION
(0) [X] 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.

8. FINAL DISPOSITION
(1) [ ] FOLLOW-UP NEXT E I
(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
[X] HFS-636
[X] HFC-160
[X] Bridgette Wallace Office of Field Programs

REMARKS: Pending notification from CFSAN re disposition of complaint

NAME AND TITLE OF DISPOSITION OFFICIAL: M LaVetere 12/18/97

DISPOSITION:

DISPOSITION DATE:

FORM FDA 2516a (1/90)

★U.S GPO:1991-0-312-206/41637

Attachment to 2516a of LOS-3089
C L Vieweg, CSO 10/21/97

Adverse Reaction Questionnaire

Complaint Number: LOS-3089

Investigator: C Vieweg

Consumer Information

Date of Report: 10/20/97 (MM/DD/YY)

Initial Report Source: ☑ORA Consumer Injury LOS-3089
☑Telephone ☐Correspondence ☐MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted]

Gender: ☐F ☑M

Age: 41

Race: ☑1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other _____ ☐9-Unknown

Information on Adverse Reaction

Date of Adverse Reaction:
Previous Reaction to Product Type: ☐Yes ☑No

Give the site of consumption/ingestion (e.g. home, restaurant, office): Various - taken 4/97 - 6/18/97

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): On 2nd day of use had feeling of extreme chest tightness for approx 15 minutes. Used product for approx 90 days then stopped. He had lost 30 lbs. Approx 6 hours after last dose he had "withdrawal" of nightsweats, severe persistent headache not relieved by aspirin, stomach + muscle cramps, nausea anorexia and sleeplessness.

How long did the symptoms last? 72° and included a "sudden heart attack feeling" resulting in a car accident.

Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.).
1 cap 2x daily once in am + once pm

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:
no other of significance. Denies any other medications or dietary supplements.

Did event abate after use of suspected product stopped or dose reduced: ☑Yes ☐No ☐Unknown after 72° Occasional stomach cramps continue to date.
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☑No ☐Unknown ☑Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☑Not Applicable

Medical Information

Was a health care provider seen?: ☑Yes ☐No

Give health care provider's name, address and telephone number: [redacted] MD [redacted]

Occupation of Health Care Provider: ☑MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☐Other (specify) _____

What medical tests were performed and what were the results? EKG - normal

What was the medical diagnosis? probable adverse Drug Rxn

What treatment(s) was given (e.g., drugs, other)? None

Were there any preexisting condition(s)/treatment(s)? No
(If YES, list them including allergies, and chronic diseases): ☐Yes ☑No

'98 JAN -8 AM:04
RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-452