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

ARMS#

12630

0 - FRONT

COMPLAINT/INJURY REPORT

12630

LOS-6760

2. DATE OF COMPLAINT (Month/Day/Year): 11/7/97

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
Took X-Rated, Hi Health Brand & Diet Fuel (~~Unk. mfr.~~ Twin Labs) at doses of 330 mg/dose, 2x/day. "Inferno" drink by Amer. Body Building Assoc. Experienced racing heart; found heart murmur. After several months, echocardiogram found heart murmur still there. Highest dose took was 660 mg.

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 11/11/97

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

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)

8. PRODUCT AND LABELING
a. BRAND NAME: Multiple (See descrip.)
b. PRODUCT NAME: Multiple
c. SIZE AND PACKAGE TYPE: N/A
d. NAME AND LOCATION OF STORE WHERE PURCHASED: [redacted]
e. PACKAGE CODE/SERIAL NUMBER/ETC.: N/A
EXP/USE BY DATE:
f. DATE PURCHASED: —
g. PRODUCT USED (If "yes" enter date) (1) ☐ NO (2) ☐ YES
h. AMT REMAINING: —

9. MANUFACTURER/DISTRIBUTOR OF PRODUCT
a. HOME DISTRICT: LOS
b. C.F. NO.: —
c. NAME AND ADDRESS OF FIRM (Include Zip Code): Unknown / [redacted]
d. IMPORT PRODUCT (1) ☒ NO (2) ☐ YES

10. EVALUATION AND DISPOSITION
a. PROBLEM KEYWORD
(1) CODE: RX (2) DESCRIPTION: Adv. Reaction
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: 54FCA09

12. INFORMATION COPIES TO:
☐ HFN - 356 (Biologics) ☐ HFZ - 343
☐ HFZ - 400
☐ HFN - 730 ☐ HFC - 161
☐ HFN - 333 ☐ ____
☐ HFV - 236

REMARKS
Consumer used 3 products over 6 mo. time period. She did not take more than 1 product/day. Woman is body builder who was in excellent physical health prior to taking ephedra products.

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NAME AND TITLE: Patricia A. Gupta, Investigator
DATE: 11/11/97

FORM FDA 2515 (4/96)

Adverse Reaction Questionnaire

Complaint Number: _____ Investigator: Gupta

Consumer Information

Date of Report: 11/7/97 (MM/DD/YY)

Initial Report Source: ☒ORA Consumer Injury ☒Telephone ☐Correspondence ☐MedWatch ☐USP ☐PQRS ☐Poison Control ☐CDC

Name [redacted] Gender: ☒F ☐M Age: 33

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: Sept., 96

Previous Reaction to Product Type: ☐Yes ☐No

Give the site of consumption/ingestion (e.g. home, restaurant, office): Home

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): 6 mos. post → started getting daily migraine headaches. So, she went to Dr. and he found heart murmur during general exam

How long did the symptoms last? 14 months and still have

Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.). Orally, took 1x/day, for 2 wks; then go off for 1 wk & cycle. Occasionally took 2x/day.

Normal dose = 330mg/day Occ. took 660 mg/day.

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: None

Did event abate after use of suspected product stopped or dose reduced: ☒Yes ☒No ☐Unknown

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: Dr [redacted] [redacted]

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

What medical tests were performed and what were the results? EKG detected heart murmur.

What was the medical diagnosis? Heart murmur

What treatment(s) was given (e.g., drugs, other)? None; said to come back in 6 mos.

Now have racing heart & pain

~~Now have racing heart & pain~~

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

Product Category

1. Adverse reaction 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 as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

X-Rated (from Hi Health)
Diet Fuel (~~unknown mfr~~ Twin Labs)
Inferno (from American Body Building ~~Assoc~~ Corp.)

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

All 3 products contained Ephedra.

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

- ☐ Aspartame
- ☐ Monosodium Glutamate
- ☐ Sulfite
- ☒ Other Ephedra
- ☐ 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 Unknown

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