

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

ARMS#

13381



0 - FRONT

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION
COMPLAINT / INJURY REPORT

*Rec'd 2/26/99
by DOEP*

1. COMPLAINT NUMBER
MIN-9344 1338/

2. DATE OF COMPLAINT (Month / Day / Year)
2/3/99

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)

b. AREA CODE AND TELEPHONE NUMBER
HOME ()
WORK ()

6. COMPLAINT OR INJURY

a. DESCRIPTION OF COMPLAINT / INJURY
After taking tablets of ^{The} Natural Trim Thermogenic Weight Management System for 3 1/2 weeks, the complainant had a dangerously low level of platelets and experienced hemorrhages all over her body in the form of bruises and blood blisters. Her platelet count was 2000 while a normal platelet count would be (see remarks)

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) NO (2) YES
(If "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: 2/4/99

b. TYPE SYMPTOMS ONSET (HR.)

- (1) VOMITING
- (2) NAUSEA
- (3) DIARRHEA
- (4) FEVER
- (5) SKIN/EYE IRR.
- (6) HEADACHE
- (7) OTHER 3 1/2 wks low platelet count/hemorrhages

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)

8. PRODUCT AND LABELING

a. BRAND NAME: Natural Trim Thermogenic Weight Management System table.

b. PRODUCT NAME

c. SIZE AND PACKAGE TYPE: 120 tablet bottle.

d. NAME AND LOCATION OF STORE WHERE PURCHASED: The product was purchased from a dealer in multi-level distribution system of Starlight International, Monterey, CA

e. PACKAGE CODE / SERIAL NUMBER / ETC.: M00262

f. DATE PURCHASED: middle of Dec. 1998

g. PRODUCT USED (1) NO (2) YES
Date: Started use 1/4/99

h. AMT. REMAINING: 2/3 bott

EXP / USE BY DATE: 10 2000

9. MANUFACTURER / DISTRIBUTOR OF PRODUCT

a. HOME DISTRICT: SAU-DO

b. CF. NO

c. NAME AND LOCATION OF FIRM (Include ZIP Code): Starlight International, 80 Garden Court, Monterey, CA 93940

d. IMPORT PRODUCT (1) NO (2) YES

10. EVALUATION AND DISPOSITION

a. PROBLEM KEY WORD (1) CODE: RX (2) DESCRIPTION: low platelet et.

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 DISTRICT
- (7) REFERRED TO OCI

b. EVALUATION

- (1) NOT AN FDA OBLIGATION
- (2) OBLIGATION, NO VIOLATION
- (3) FDA ACTION INDICATED
- (4) INSUFFICIENT INFORMATION UNABLE TO EVALUATE

between

11. PRODUCT CODE: 54 FCA99

12. INFORMATION COPIES TO:

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

13. REMARKS (a (continued)) 150,000 and 300,000. The complainant was treated by a physician who said that he thought the low platelet count was drug-induced. The complainant does not routinely take any drugs, and OTC pain medications taken occasionally were reportedly ruled out as

14. NAME AND TITLE OF DISPOSITION OFFICIAL possible causes of the low platelet count the dietary supplement was suspected to be the likely cause. When the complainant stopped taking the dietary supplement, her platelet count rose to 10,000 and then prescribed prednisone brought it

up to 37,000. The dietary supplement was taken from about 1/4/99 to 1/28/99. Only the regular tablets were taken. The "Booster" compound in 30-tablet bottle was not taken. The regular tablets appeared and about 15 other herbs

COMPLAINT/INJURY FOLLOW-UP

1 COMPLAINT NUMBER
MIN-9344 - 13381

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

(a) REMARKS (Additional Details)

(b) REQUESTING OFFICIAL'S NAME AND TITLE
Dirk J. Mouw, R & C Coordinator

(c) DATE REQUESTED
04/02/99

(d) PRODUCT NAME
Natural Trim Tablets

3 ASSIGNED TO:
Kathy A. C-Girolamo,
Investigator

(a) DUE BY

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

(a) SAMPLE NUMBER(s)

(b) DESCRIPTION OF ACTION TAKEN

(Continued from page 1)

Mrs. [REDACTED] provided an empty bottle and box labeling for the product, "Natural Trim Thermogenic Herbal Complex Capsules" (Labeling attached as Exhibits 1 & 2 (2 pages)). The box contained not only the bottle of the "Thermogenic Herbal Complex" product, but also an unused bottle of "Active Booster Compound that she never tried. According to the bottle labeling, one of the ingredients is "*** Ephedra Sinica,***". Mrs. [REDACTED] had discarded the remaining pills sometime ago. Mrs. [REDACTED] also signed two copies of the Medical Release Form in case more than one location was needed to be visited for records (one copy remaining attached as Attachment # 1). An Affidavit was read and signed by Mrs. [REDACTED] for providing the empty bottle and box labeling, and information pertaining to the complaint (See Attachment # 2).

Later that day, this Investigator visited the [REDACTED] to request [REDACTED] pertinent medical records from her attending physician, Dr. [REDACTED]. One signed Medical Release form was left at the [REDACTED] with instruction to call when copies of the records would be available for this Investigator to pick-up. On 4-27, this Investigator returned to the [REDACTED] to pick-up the records (11 pages attached as Exhibits 3-13).

(c) ACTION OFFICIAL'S NAME AND TITLE
Kathy A. C-Girolamo, Investigator *Kathy A. C-Girolamo*

(d) ACTION DISTRICT
MIN-DO

(e) DATE COMPLETED
04/27/99

5. MANUFACTURER/DISTRIBUTOR/DEALER RESPONSIBLE

6. PROGRAM DATA

(a) HOME DIST.
SAN-DO

(c) NAME AND ADDRESS
Starlight International
80 Garden Court
Monterey, CA 93940

(a) OPERATION
13

(b) PAC
04R801

(c) PRODUCT CODE
54FCA99

(b) CF NO.

(d) EMP HOME DIST.
MIN-DO

(e) EMP. NO.
742

(f) POS CL.
2

(g) HOURS
8.00

- 7 EVALUATION
- (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

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
 - _____
 - _____
 - _____

REMARKS

000003

NAME AND TITLE OF DISPOSITION OFFICIAL

DISPOSITION

DISPOSITION DATE

Adverse Event Questionnaire

Complaint Number: MIN-9344 - 13381

Investigator: KATHY A. C. GIROLAMO

Consumer Information

Date of Report: <u>04/27/99</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 checked="" type="checkbox"/> F <input type="checkbox"/> M	Age: <u>41</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 Event

Date of Adverse Event: <u>2-29-99</u>	Give the site of consumption/ingestion (e.g. home, restaurant, office): <u>Home</u>
Previous Adverse Effects to Product Type: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <u>1st time use</u>	

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):
Low platelet count & petechial type rash over hands, face & lips & upper back

How long did the symptoms last?
3 1/2 weeks of use of product. Platelet count was @ 2000 on 1-29-99.

Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.):
Natural Trim "diet pill" taken per label directions for 3 1/2 weeks. Stopped taking when symptoms developed on ~ 1-29-99.

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:
Natural Trim "diet pills", Multi-Vitamin, Aspirin last taken on 1-18-99 for cramps

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: [REDACTED]

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

What medical tests were performed and what were the results? Blood tests 1-29-99 platelet count @ 2000

What was the medical diagnosis? Thrombocytopenia, ie ITP 2-01-99 platelet count @ 10,000 & very rare platelets

What treatment(s) was given (e.g., drugs, other)? Prednisone 12mg/kg

Were there any preexisting condition(s)/treatment(s)? No

(If YES, list them including allergies, and chronic diseases): Yes No

000004

Product Category

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

STARLIGHT INTERNATIONAL Dietary Supplement Thermogenic Herbal Complex Natural TRIM - marketed by: Starlight International, Monterey CA 93940. One capsule 4 x's / day

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

Check here if ingredients are unknown

Bladderwrack, Goldenrod Leaf, Parsley Leaf, Uva Ursi Leaf, Ephedra Sinica, Corn Silk Pistils, Hawthorn Berries, Fumitory Herb, Cascara Sagrada Bark, Licorice Root, Marshmallow root, Magnesium Gluconate, calcium gluconate, Apple Pectin, Chromium Picolinate (50 mcg. per capsule)

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

- Aspartame
 - Monosodium Glutamate
 - Sulfite
 - Other _____
 - 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

Hospitalization: Yes No (if YES, indicate if initial or prolonged) _____

Required intervention to prevent permanent impairment/damage: Yes No

Did the adverse event result in a congenital anomaly: Yes No