

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

ARMS#

12842



0 - FRONT

To: Janet Rowe@DEIO@FDAORAHQ
 Cc: Pete Cook@DEIO@FDAORAHQ, Mark Fow@DEIO@FDAORAHQ, Rebecca Hackett@DEIO@FDAORAHQ
 From: Ellen Morrison@DEIO@FDAORAHQ
 Certify: N
 Subject: fwd: report of suspected illness from d/s product
 Date: Wednesday, February 11, 1998 at 1:13:32 pm EST
 Attached: None
 Forwarded By: Ellen Morrison@DEIO@FDAORAHQ

Comments By: Ellen Morrison@DEIO@FDAORAHQ
 Originally To: Ellen Morrison@DEIO@FDAORAHQ
 Originally Cc: Ronald Roy@OFF@FDA.CFSAN
 Originally From: Lilyan Goossens@OCO@FDA.CFSAN
 Original Date: 2/10/98 3:26 PM
 Comments:

2384

Janet - would you please follow-up on this report as a complaint from Mr. [REDACTED] - this report has no specifics, however if Mr. [REDACTED] is selling products that he knows are causing serious side effects, we need to follow-up and get details.

Thanks - Ellen

-----[Original Message]-----

February 9, 1998 I received a call from:
 Mr. [REDACTED]
 Phone: [REDACTED]

Mr. [REDACTED] sold a dietary supplement products and related that 8 or 38 people became ill. A Mrs. [REDACTED] "had serious side effects". Heart flutters, and "it runs you wild-crazy". The natural herb product is for weight loss and contains MaHung and gurana:

I had difficulty understand the man but I believe the product is: Sport Trim, by Turbo Dietary, a Turbo Weight loss product made by: Surtron, McKenny, TX

My concern was the number of people who may be involved in this adverse reaction event.
 Lilyan Goossens
 via HappyMail!

Happy Mail

COMPLAINT/INJURY REPORT

12842

1. COMPLAINT NUMBER
 EDR-2394

2. DATE
 02/11/98

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

4. SOURCE OF COMPLAINT
 (1) CONSUMER
 (2) TRADE SOURCE
 (3) GOVERNMENT
 (4) OTHER
 L S P

5. COMPLAINANT IDENTIFICATION

a. NAME AND ADDRESS (Include Zip Code)
 Mr. [REDACTED]

b. AREA CODE AND TELEPHONE NUMBER
 HOME [REDACTED]
 WORK [REDACTED]

6. COMPLAINT OR INJURY

a. DESCRIPTION OF COMPLAINT/INJURY
 Mr. [REDACTED] calls this supplement and related that he knows of a number of people who have become ill. One customer reported serious side effects of heart flutters and the feeling that "it runs you wild-crazy". He stated that product is a natural herb for weight loss and that it contains MaHuang and ginseng.

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 b through d)

a. HHS (EPC-161) NOTIFIED
 (1) NO
 (2) YES
 DATE:

b. TYPE SYMPTOMS (Check all that apply)
 1. VOMITING
 2. NAUSEA
 3. DIARRHEA
 4. FEVER
 5. SKIN/EYE IRR.
 6. HEADACHE
 7. OTHER

c. ATTENDING HEALTH PROFESSIONAL
 (1) NO (2) YES
(If "Yes" give name, address & phone number)

d. HOSPITALIZATION REQUIRED
 (1) NO (2) YES
(If "Yes" give name, address, phone number & date)

8. PRODUCT AND LABELING

a. BRAND NAME
 Turbo Dietary

b. PRODUCT NAME
 Sport Trim Natural Dietary

c. SIZE AND PACKAGE TYPE

d. NAME AND LOCATION OF STORE WHERE PURCHASED

e. PACKAGE CODE/SERIAL NUMBER/etc

f. DATE PURCHASED

g. PRODUCT USED (If "Yes" complete date)
 (1) NO (2) YES

h. AMT. LEFT

EXP/USE BY DATE:

9. MANUFACTURER/DISTRIBUTOR OF PRODUCT

a. HOME DISTRICT
 Dallas

b. C. E. NUMBER
 1645935

c. NAME AND LOCATION OF FIRM (Include Zip Code)
 Manufacturer: Sportion International
 1249 Commerce Drive
 Richardson, TX 75081

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

10. EVALUATION AND DISPOSITION

a. PROBLEM KEYWORD

(1) CODE RX

(2) DESCRIPTION REACTION

b. DISPOSITION
 (1) IMMEDIATE FOLLOW-UP
 (2) F/U NEXT E.L.
 (3) CLOSED WITHOUT FURTHER INVESTIGATION
 (4) REFERRED TO OTHER FEDERAL AGENCY
 (5) REFERRED TO STATE/LOCAL AGENCY
 (6) REFERRED TO OTHER FDA DISTRICT
 (7) REFERRED TO OOI

c. EVALUATION
 (1) NOT AN FDA OBLIGATION
 (2) OBLIGATION, NO VIOL.
 (3) FDA ACTION INDICATED
 (4) INSUFFICIENT INFOR./ UNABLE TO EVALUATE

11. PRODUCT CODE
 547CE09

12. INFORMATION COPIES TO:
 HRM-660 HFZ-343
 HFD-730 REC-134
 HFV-236 REC-151

REMARKS

NAME AND TITLE Janet Rowe, CCC, EMOPS

DATE 02/12/98

COMPLAINT / INJURY FOLLOW-UP

1. COMPLAINT NUMBER
KDR52384

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

2.b. REMARKS (Additional details)

2.c. REQUESTING OFFICIAL'S NAME AND TITLE
Pauline Mills/CCC

2.d. DATE REQUESTED
2/11/98

2.e. PRODUCT NAME
Sport Trim Natural Dietary

3.a. ASSIGNED TO:
Pauline Mills

3.b. DUE BY:

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

4.b. SAMPLE NUMBER(s)
None

4.c. DESCRIPTION OF ACTION TAKEN

On 2/18/98, I spoke with the consumer. He informed me he have stopped selling this product, and that he only sold it for 2 months, and during those 2 months approximately 13 people complained of side effects they suffered from using this product. I told Mr. [redacted] that in the future if he decides to sell it again, we encouraged him to have the people call the FDA if they experience any side effects. He said he would never sell this product again, because he is afraid someone is going to get seriously ill. Also his phone rings day and night; people are always wanting more and more, without being concern about how much or how long they are consuming this product, and he really feels none of them are under Doctor's care while they are taking this Dietary Supplement.

4.d. ACTION OFFICIAL'S NAME AND TITLE
Pauline Mills/CCC

4.e. ACTION DISTRICT
ATL-DO

4.f. DATE COMPLETED
2/20/98

5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE

6. PROGRAM DATA

5.a. HOME DIST.
Dallas

5.c. NAME AND ADDRESS
Sportron International
1249 Commerce Drive
Richardson, TX 75081

6.a. OPERATION
13

6.b. PAC
G3R801

6.c. PRODUCT CODE
54FCB09

5.b. CF NO.
1645935

6.d. EMP. HOME DIST.
ATL

6.e. EMP. NO.
396

6.f. POS CL
2

6.g. HOURS
1

7. EVALUATION

8. FINAL DISPOSITION

9. INFO.

- (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.
- (7) REFERRED TO OCI

- (1) FOLLOW-UP NEXT ET
- (2) WARNING LETTER
- (3) CITATION
- (4) SEIZURE
- (5) INJUNCTION / PROSECUTION
- (6) REFERRED TO OTHER AGENCY
(Indicate Agency in Remarks)
- (7) RECALL
- (8) NO ACTION

- COPIES TO:
- HFB-100
 - HFD-730
 - HPV-230
 - HFZ-343
 - HFC-161
 - HPS-630
 - _____
 - _____
 - _____
 - _____
 - _____
 - _____

REMARKS

NAME AND TITLE OF DISPOSITION OFFICIAL

DISPOSITION

DISPOSITION DATE