

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

ARMS#

12832



0 - FRONT

# COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER  
 BUF-7639 / 12832  
 2. DATE OF COMPLAINT (Month/Day/Year)  
 3/2/98

3. FORM OF COMPLAINT  
 (1)  TELEPHONE (3)  VISIT  
 (2)  LETTER  
 4. SOURCE OF COMPLAINT  
 (1)  CONSUMER (3)  TRADE SOURCE  
 (2)  GOVERNMENT (4)  OTHER  
(Indicate in Remarks)  
 L  S  F

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 one cap at 10 am on 2/25/98. At 11:30 am had a itchy head, sweats and nausea. Drank milk to settle stomach. Lunch 12:15 pm (cottage cheese). One cap at 3 pm. No reaction. At 7 pm - cramps (1/2 to 1 hr.) and chest pains. Chest pains continued and were current (3/2/98). Nausea also set in on 3/2/98. No medication. Normal diet. Plans to see doctor and call back with info. Discarded product.  
 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 3/9  
 Rowe  
 b. TYPE SYMPTOMS ONSET (HR.)  
 1  VOMITING \_\_\_\_\_  
 2  NAUSEA \_\_\_\_\_  
 3  DIARRHEA \_\_\_\_\_  
 4  FEVER \_\_\_\_\_  
 5  SKIN/EYE IRR. \_\_\_\_\_  
 6  HEADACHE \_\_\_\_\_  
 7  OTHER \_\_\_\_\_  
 see above  
 c. ATTENDING HEALTH PROFESSIONAL  
 (1)  NO (2)  YES (If "yes" give name, address, and phone no.)  
 Unknown. Never received call back. Attempted to contact by phone on 3/9/98.  
 d. HOSPITALIZATION REQUIRED  
 (1)  NO (2)  YES (If "yes" give name, address, phone no. and dates)

8. PRODUCT AND LABELING  
 a. BRAND NAME: Health Works  
 b. PRODUCT NAME: Contains caffeine + ephedra "Truckers Love-It" Dietary Supplement (95)  
 c. SIZE AND PACKAGE TYPE: 30 caps/btl.  
 d. NAME AND LOCATION OF STORE WHERE PURCHASED: [REDACTED]  
 e. PACKAGE CODE/SERIAL NUMBER/ETC.: unknown  
 f. DATE PURCHASED: 2/25/98  
 g. PRODUCT USED (If "yes" enter date): (1)  NO (2)  YES  
 h. AMT REMAINING: none

9. MANUFACTURER/DISTRIBUTOR OF PRODUCT  
 a. HOME DISTRICT: NOL  
 b. C.F. NO.:  
 c. NAME AND ADDRESS OF FIRM (Include Zip Code): Health Works Int'l. 204 Fair Ave., Winnsboro, LA 71295  
 d. IMPORT PRODUCT: (1)  NO (2)  YES

10. EVALUATION AND DISPOSITION  
 a. PROBLEM KEYWORD  
 (1) CODE: AR (2) DESCRIPTION: chest pains  
 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: 54YBC99  
 12. INFORMATION COPIES TO:  
 HFN - 355 (Biologics)  HFZ - 343  HFC-151  
 HFN - 730  HFZ - 400  
 HFN - 333  HFC - 161  
 HFV - 236  HFS-635 (95)

REMARKS

NAME AND TITLE: William P. Chilton, CSC *Wm. Chilton* DATE: 3/2/98 000001

**COMPLAINT / INJURY FOLLOW-UP**

1. COMPLAINT NUMBER  
Buf-7639

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

(a) REMARKS (Additional details)

(b) REQUESTING OFFICIAL'S NAME AND TITLE  
Raymond D. Kent, TL

(c) DATE REQUESTED  
3/9/98

(d) PRODUCT NAME  
Truckers Luv-It

3. ASSIGNED TO:  
William P. Chilton

(a) DUE BY  
3/10/98

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

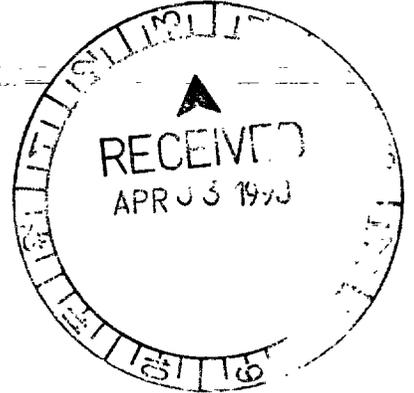
(a) SAMPLE NUMBER(s)  
none

(b) DESCRIPTION OF ACTION TAKEN

On 3/9/98, I called the retailer and spoke to [REDACTED], Manager. He said they have not received complaints about this product. They've been selling the product since Dec. 97.

On the same day I visited the retailer and id myself to [REDACTED], Assist. Mgr. He provided me with information. He verified what Mr. [REDACTED] had said. Stock consisted of 38 btls./30 caps. Lot number - 5981 EXP 12/99. Photographs of product labeling are attached.

Attachments: Photographs



(c) ACTION OFFICIAL'S NAME AND TITLE  
William P. Chilton, CSO *W P Chilton*

(d) ACTION DISTRICT  
Buf-Do

(e) DATE COMPLETED  
3/13/98

5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE

(a) HOME DIST. NOL  
(b) CF NO. No CFN  
(c) NAME AND ADDRESS  
Health Works International  
204 Fair Ave. (possible  
Winnsboro, LA 71295 new firm)

6. PROGRAM DATA

(a) OPERATION 13  
(b) PAC 03R801  
(c) PRODUCT CODE 54YBG99  
(d) EMP. HOME DIST. Buf-Do  
(e) EMP. NO. 228  
(f) POS CL. 2  
(g) HOURS 2

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 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
- HFF-343
- HFC-161
- HFS-635
- HFC-151

REMARKS

NAME AND TITLE OF DISPOSITION OFFICIAL

DISPOSITION

DISPOSITION DATE