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

ARMS#

12717

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

Best Quality FDA

COMPLAINT / INJURY REPORT

1. COMPLAINT NUMBER: CIN-7752 12717

2. DATE OF COMPLAINT (Month / Day / Year): 12/22/97

3. FORM OF COMPLAINT

a. (1) [X] TELEPHONE (2) [ ] LETTER (3) [ ] VISIT

4. SOURCE OF COMPLAINT

a. (1) [X] CONSUMER (2) [ ] GOVERNMENT (3) [ ] TRADE SOURCE (4) [ ] OTHER [ ] L [ ] S [ ] F (Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION

a. NAME AND ADDRESS (Include ZIP Code): [redacted]

b. AREA CODE AND TELEPHONE NUMBER: HOME ([redacted]) WORK ( )

6. COMPLAINT OR INJURY

a. DESCRIPTION OF COMPLAINT / INJURY: Mr. [redacted] had been taking 4 caplets/day for ≈ 1 week when his stomach began to hurt. On 12/19/97, he stopped using pdct and is begining to feel better. When Mr. [redacted] explained problem to his supplier, he was told that pdct was all natural and would not hurt him. Mr. [redacted] also stated that he may have an ulcer. (See Rmks

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? (1) [X] NO (2) [ ] YES (If "Yes" Explain in Remarks)

7. INJURY OR ILLNESS RESULTED (1) [ ] NO (2) [X] YES * *(If "yes" complete items a through d)

a. EIB (HFC - 161) NOTIFIED (1) [X] NO (2) [ ] YES DATE:

b. TYPE SYMPTOMS / ONSET (HR.)
(1) [ ] VOMITING
(2) [ ] NAUSEA
(3) [ ] DIARRHEA
(4) [ ] FEVER
(5) [ ] SKIN/EYE IRR.
(6) [ ] HEADACHE
(7) [X] OTHER ≈ 5 days stomach pain

c. ATTENDING HEALTH PROFESSIONAL? (1) [X] NO (2) [ ] YES (If "Yes" give name, address, and phone number)

d. HOSPITALIZATION REQUIRED? (1) [X] NO (2) [ ] YES (If "Yes" give name, address, phone number and dates)

RECEIVED JAN 21 1998

8. PRODUCT AND LABELING

a. BRAND NAME: AMS Advantage Marketing System

b. PRODUCT NAME: AM 300 Natural Herbal Energizer

c. SIZE AND PACKAGE TYPE: 90 Caplet bottle

d. NAME AND LOCATION OF STORE WHERE PURCHASED: [redacted]

e. PACKAGE CODE / SERIAL NUMBER / ETC.: EXP. / USE BY DATE:

f. DATE PURCHASED: o/a 12/1/97

g. PRODUCT USED (If "Yes" enter date) (1) [ ] NO (2) [X] YES Date: o/a 12/1/97

h. AMT. REMAINING: none

9. MANUFACTURER / DISTRIBUTOR OF PRODUCT

a. HOME DISTRICT: Dal

b. C.F. NO.:

c. NAME AND LOCATION OF FIRM (Include ZIP Code): Advantage Marketing System 2601 N.W. Express Suite 1210W Oklahoma City, Ok 1-800-426-4267 Mr. Loney (405) 415-4905

d. IMPORT PRODUCT (1) [X] NO (2) [ ] YES

10. EVALUATION AND DISPOSITION

a. PROBLEM KEY WORD (1) CODE: R (2) DESCRIPTION: Stomach Pain

b. EVALUATION
(1) [ ] NOT AN FDA OBLIGATION
(2) [ ] OBLIGATION, NO VIOLATION
(3) [X] FDA ACTION INDICATED
(4) [ ] INSUFFICIENT INFORMATION UNABLE TO EVALUATE

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) [X] REFERRED TO OTHER FDA DAL DISTRICT
(7) [ ] REFERRED TO OCI

11. PRODUCT CODE: 54FTC09

12. INFORMATION COPIES TO:
[ ] HFM-660 [ ] HFZ-343
[ ] HFD-730 [X] HFC-161
[ ] HFV-210 [X] HFS-635
[X] OTHER DEN

13. REMARKS: Supplement contains ephedra. Literature states that pdct is made in FDA approved laboratories. Mr. [redacted] will send literature. Rec'd o/a 12/31/97. D. Loney (AMS) pdct is mfr'd by Chemins Corp, 1825 E Cheyenne Rd Colorado Springs, Co - CFN: 1717927 (405) 415-4905. The labeling is the responsibility of AMS. They are aware of FDA reference in brochure. New brochures are being printed. Mr. [redacted] was referred to E. Crosby Dal - DO CB re: disposition of remaining brochures w/ FDA reference. Mr. [redacted] also stated that the supplement can cause stomach irritation if taken on an empty stomach due to the ing. cayenne pepper. Occasionally, complaints of this nature are rec'd.

14. NAME AND TITLE OF DISPOSITION OFFICIAL: David C Radle PDM

15. DATE: 1/14/98 1/13/98

FORM FDA 2516 (1/96)

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