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

ARMS#

13332

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

COMPLAINT / INJURY REPORT

COMPLAINT NUMBER: MIN-9314 13332

2. DATE OF COMPLAINT (Month / Day / Year): 12/8/98

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 [redacted]

6. COMPLAINT OR INJURY

a. DESCRIPTION OF COMPLAINT / INJURY: 2601 Complainant alleged a reaction to Herbal Life products regimen. Complainant took 32 pills from 9 bottles of pills + 2 meal replacement drinks per day for 14 days of ~~2 wk~~ 15 days. Products were taken at break fast, mid-morning, lunch, mid-afternoon, pre-dinner, dinner, + post dinner. Cont'd #13 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] YES (2) [X] NO DATE:

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

c. ATTENDING HEALTH PROFESSIONAL? (1) [ ] NO (2) [X] YES (If "Yes" give name, address, and phone number) W/ call his phipican on 12/8/98.

d. HOSPITALIZATION REQUIRED? (1) [ ] NO (2) [ ] YES (If "Yes" give name, address, phone number and dates) Not sure.

RECEIVED FEB 08 1999

8. PRODUCT AND LABELING

a. BRAND NAME: Herbal Life

b. PRODUCT NAME: See attached

c. SIZE AND PACKAGE TYPE: See attached

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

e. PACKAGE CODE / SERIAL NUMBER / ETC. EXP. / USE BY DATE: None.

f. DATE PURCHASED: Mid-late Nov, 1998.

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

h. AMT. REMAINING: Slightly over 1/2 in ea bottle

9. MANUFACTURER / DISTRIBUTOR OF PRODUCT

a. HOME DISTRICT: LOS-DO

b. C.F. NO.: 2022908

c. NAME AND LOCATION OF FIRM (Include ZIP Code): See remarks. Herbal Life is the distributor. There are several different mfgrers. Complaint is referred to Home District.

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

10. EVALUATION AND DISPOSITION

a. PROBLEM KEY WORD (1) CODE: RX (2) DESCRIPTION: Reaction

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 LOS DISTRICT
(7) [ ] REFERRED TO OCI

11. PRODUCT CODE: 41EEE99

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

13. REMARKS: 9C. Herbal Life International of America, Los Angeles, CA 90080-0210. 6a. For 1st 2-3 days, Complainant had diarrhea; then Complainant was fine for 7 days. Last 4-5 days, Complainant was constipated. On day 14, Complainant stopped using regimen. On day ~~14~~ 15 Complainant had to use an Enema, + on 12/8/98 Call his phipician. See attached.

14. NAME AND TITLE OF DISPOSITION OFFICIAL: Acty R&C Coordinator, Linda V. Weyer, Consumer Safety Officer

15. DATE: 12/8/98

FORM FDA 2516 (5/94) *U.S. GPO 1994-301-026/20416 85

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[redacted] Complaint No. MIN-9314

Complainant [redacted] called re: Reaction to Herbal Life.

Herbal Life Dietary Supplement regimen - Complainant Took 32 pills per day & 2 meal replacement drinks per day.
- Complainant got Diarrhea and later Constipated.
The Complainant used the Herbal Life Dietary Supplement regimen for 2 weeks. Complainant took 9 bottles of pills & 2 meal replacement drinks daily.
Meal Repl. Drinks no exp date on meal drink repl.
1) Herbal Life Thermojetics, Formula 1, Dutch Chocolat Exclusive Weight mgmt Protein Drink Mix, In Cardboard can, lb. 3.4 oz, On bottom of can - metal Lot Ozero, OP8J021 B.
2) Herbal Life Thermojetics Formula 1, French Vanilla In, same, wt, same cdb can w/ metal top & bottom, plastic lid, Lot # Serc OP8H044 H.

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Some pills are taken

(2)

No exp date on pills.

9-Bottles of Pills, Herbal Life Brand.

1) Plastic bottles, Herbal Life, Thermojetics, Herbal Concentrate, Original powder, Mix w/ ~~lemonade~~ hot water! (Mix [redacted] drink mix + drink it like a tea, net wt 3.53 oz. On side of bottle, Lot # OP8G054.

2) Plastic bottles, Herbal Life Brand, ~~Brand~~, all in Thermojetics, Original Green, Herbal Tablets dietary supplement, 120 tablets. on side of bottle, Lot # DF8H245.

3). plastic Bottle, Herbal Life Thermojetics formula 3, Cell activator, advanced micro nutrition w/ botanical factors dietary supplement, 120 capsules, on bottom of bottle Lot # DF8J246.

4) Plastic Bottle. Herbal Life Thermojetics, Formula 2, multi-vitamin mineral + Herbal. dietary supplement, 90 tablets, on bottom of bottle Lot # DF8J203.

5) Plastic Bottle Herbal Life Thermojetics, Thermobond 90 tablets Fiber Tablets dietary supplement. On side of bottle, Lot # DF8J047.

6) plastic Bottle, Herbal Life Thermojetics, Herbal Tablets, dietary supplement, beige, 60 tablets, on bottom of bottle, Lot # DF8J(zero) 79.

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7) plastic bottle, Herbal Life Thermojetics, Vitamin mineral, Herbal Tablets, dietary

supplement, cell-u-loss, 90 tablets.
On bottom of bottle, Lot# DF8J162
8) plastic bottle, Herbal Life Thermojetics dietary supplement, Aminogen, 60 tablets, on side of bottle, Lot# DF8H219.

9) plastic bottle, Herbal Life Thermojetics, Garcinia and G.T.F., Chromium Supplement, dietary supplement, Yellow 3, 60 tablets, on side of bottle, Lot# DF8H185

Ultimate Program:
Complainant took products for 2 weeks (14 days - missed one day)

Breakfast 2 level tablespoons Formula 1 H mixed with 100% fruit juice, water, or see following recipes. Complainant mixed it w/ Dole ~~Apple~~ Pineapple/Orange/Banana 100% fruit juice. Also take 1 of the Formula 2 multi-vitamins. Take two formula 35 cell activator + 2 cell-u-loss

Mid-Morning 9:30 am) Complainant took 3 green, 1-beige, & 1 yellow.

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For lunch, Complainant took product, same as breakfast.

For 1 mid-afternoon, 3:00 PM, Complainant took product same as mid morning

For pre-dinner, 1/2 hr before meals take 2-3 Thermo-bombs, depending upon fat content of meal.

For dinner, complainant ate regular meal & then took the following:
One Formula 2 multi-vitamin.
Two Formula 3 cell-activators.
Two cell-u-loss.
One or two of the aminogen, depending upon protein content of meal.

1/2 hr after dinner or post dinner, take two of the yellow tablets.

First 2-3 days into taking this product regimen Complainant had diarrhea. After that Complainant was fine for about 1 wk (7 days). Last 3-4 days Complainant became constipated. On 12/7/98 (approx day 15) Complainant had to use an enema. (on 12/6/98) Complainant stopped taking the Herbal Life product regimen. Complainant wasn't expecting the constipation. He stated he plans to call his physician & get advice, tell the phys. what he was taking & the resultant constipation & need to use an enema condition.

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