

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

ARMS#

12504



0 - FRONT

COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER
EDR-1849 12504

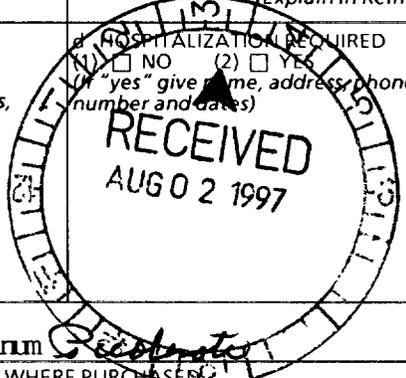
2. DATE OF COMPLAINT (Month/Day/Year)
6/23/97

3. FORM OF COMPLAINT	(1) <input checked="" type="checkbox"/> TELEPHONE	4. SOURCE OF COMPLAINT	(1) <input checked="" type="checkbox"/> CONSUMER	(3) <input type="checkbox"/> TRADE SOURCE
	(2) <input type="checkbox"/> LETTER		(2) <input type="checkbox"/> GOVERNMENT	(4) <input type="checkbox"/> OTHER
		(3) <input type="checkbox"/> VISIT		
		<input type="checkbox"/> L <input type="checkbox"/> S <input type="checkbox"/> F (Indicate in Remarks)		

5. COMPLAINANT IDENTIFICATION	a. NAME AND ADDRESS (Include Zip Code)		b. AREA CODE AND TELEPHONE NUMBER	
	[REDACTED]		HOME ([REDACTED])	WORK ()

6. COMPLAINT OR INJURY	a. DESCRIPTION OF COMPLAINT/INJURY		b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES (Explain in Remarks)
	Took according to directions - 2 caps in AM and one before lunch. Felt shaky, heart pounding, chills, scalp tingling - lasted 25 hours. Makes all kinds of drug claims claims - contains ma huang, kola nut, picolinate, etc.		

7. INJURY OR ILLNESS RESULTED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES (If "yes" complete items a through d)	a. EIB (HFC-161) NOTIFIED (1) <input type="checkbox"/> NO (2) <input type="checkbox"/> YES DATE	b. TYPE SYMPTOMS ONSET (HR.)	c. ATTENDING HEALTH PROFESSIONAL (1) <input type="checkbox"/> NO (2) <input type="checkbox"/> YES (If "yes" give name, address, and phone number)	d. HOSPITALIZATION REQUIRED (1) <input type="checkbox"/> NO (2) <input type="checkbox"/> YES (If "yes" give name, address, phone number and dates)
		1. <input type="checkbox"/> VOMITING _____ 2. <input type="checkbox"/> NAUSEA _____ 3. <input type="checkbox"/> DIARRHEA _____ 4. <input type="checkbox"/> FEVER _____ 5. <input type="checkbox"/> SKIN/EYE IRR. _____ 6. <input type="checkbox"/> HEADACHE _____ 7. <input checked="" type="checkbox"/> OTHER _____ see 6a		



8. PRODUCT AND LABELING	a. BRAND NAME Magic Herb	b. PRODUCT NAME Diet Plus Formula Chromium Picolinate
	c. SIZE AND PACKAGE TYPE 10/capsule gel cap	d. NAME AND LOCATION OF STORE WHERE PURCHASED Mail Order
	e. PACKAGE CODE/SERIAL NUMBER/ETC. none	f. DATE PURCHASED 6/19/97
EXP/USE BY DATE:		g. PRODUCT USED (if "yes" enter date) (1) <input type="checkbox"/> NO (2) <input type="checkbox"/> YES
		h. AMT REMAINING

9. MANUFACTURER/DISTRIBUTOR OF PRODUCT	a. HOME DISTRICT	c. NAME AND LOCATION OF FIRM (Include Zip Code) Magic Herbs 8513 N Rockwell Oklahoma City, OK 73139	d. IMPORT PRODUCT (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES
	b. C. F. NO		

10. EVALUATION AND DISPOSITION	a. PROBLEM KEYWORD (1) CODE ; (2) DESCRIPTION RX ; shakely	c. DISPOSITION (1) <input type="checkbox"/> IMMEDIATE FOLLOW-UP (2) <input type="checkbox"/> F/U NEXT EI (3) <input type="checkbox"/> CLOSED WITHOUT FURTHER INVESTIGATION (4) <input type="checkbox"/> REFERRED TO OTHER FEDERAL AGENCY (Closes File) (5) <input type="checkbox"/> REFERRED TO STATE/LOCAL AGENCY (Closes file) (6) <input type="checkbox"/> REFERRED TO OTHER FDA _____ DISTRICT	11. PRODUCT CODE
	b. EVALUATION (1) <input type="checkbox"/> NOT AN FDA OBLIGATION (2) <input type="checkbox"/> OBLIGATION, NO VIOLATION (3) <input type="checkbox"/> FDA ACTION INDICATED (4) <input type="checkbox"/> INSUFFICIENT INFORMATION UNABLE TO EVALUATE		12. INFORMATION COPIES TO, <input type="checkbox"/> HFB-100 <input type="checkbox"/> HFZ-343 <input type="checkbox"/> HFD-730 <input type="checkbox"/> HFC-161 <input type="checkbox"/> HFV-236 <input type="checkbox"/> _____

REMARKS: Has some product remaining and promotional material if FDA is interested, (CONTINUED) IF PROGRAM IS STILL IN EFFECT ALL CONSUMERS AND SEE IF CONSUMER PORTION IS STILL AVAILABLE FOR SAMPLING. COMPLAINT FORM SAYS CONSUMER DOES NOT EXPECT FDA CONTACT.

7/16/97 R-945 [B. MUMMAN] GROUP: DJJ
 ATTORNEY IS BACKGROUND ON FILE OF COMPLAINT GROUP: 70417
 IN VOLUNTARY EPHEDRINE DIETARY SUPPLEMENTS. ASSIGN # 7/11/97
 CAR WILLIAM HUMMER / ORINSE TO ASSURE FILE PROGRAM IS STILL IN EFFECT IN 1997 DATE: 7/25/97

NAME AND TITLE: Mark Fow, DEIOI, EMOPS DATE: 6/30/97

COMPLAINT / INJURY FOLLOW-UP				1. COMPLAINT NUMBER EDR-1489	
2.a. ACTION REQUESTED (1) <input checked="" type="checkbox"/> INVESTIGATION (2) <input checked="" type="checkbox"/> COLLECT SAMPLE (3) <input type="checkbox"/> INSPECTION (4) <input type="checkbox"/> OTHER:		2.b. REMARKS (Additional details) Collect literature and sample consumer is holding for FDA.			
2.c. REQUESTING OFFICIAL'S NAME AND TITLE Daniel J. Sitko, S.I./RAL-RP/ATL-DO			2.d. DATE REQUESTED 7/16/97	2.e. PRODUCT NAME Magic Herb Diet Plus Formula	
3.a. ASSIGNED TO: B. Tallman		3.b. DUE BY: 7/25/97	4.a. ACTION TAKEN (1) <input checked="" type="checkbox"/> INVESTIGATION (2) <input checked="" type="checkbox"/> SAMPLE COLLECTED (3) <input type="checkbox"/> INSPECTION (4) <input type="checkbox"/> NONE		4.b. SAMPLE NUMBER(s) for label review only
4.c. DESCRIPTION OF ACTION TAKEN On 7/21, I called the DEN-DO lab and spoke with Ken Miller who said the earlier CFSAN memo requesting Districts to collect consumer samples on all ephedrine containing dietary supplements for analysis by DEN lab, had been recinded, however samples and accompanying literature and IOM Exhibit 910-D should still be sent to CFSAN for label review. On 7/22, I visited the consumer, [REDACTED], presented my credentials and collected a package containing 7 capsules and accompanying literature sent to her beauty salon as free samples (1 cap was lost at the salon) and I issued her a FDA-484. She said she regretted taking this product but had wanted to loose a few pounds. She had spoken with [REDACTED] (EDR) who asked her to hold the sample for us. Ms. [REDACTED] said after taking the 2 caps, she became ill within 2 hours (rapid heart beat, shaking, severe headache, tingling of scalp, chills was extremely hyperactive with some nausea). These symptoms lasted about 24 hours during which time she was only able to eat a few crackers. She said had the symptoms lasted longer, she would have notified her family physician. She said she was lucky that she didn't have pre-existing medical problems such as high blood pressure that may have caused her serious health problems. I advised her of FDA's concern with reported illnesses from dietary supplements, especially ephedrine containing products and that this sample and literature will be sent to CFSAN for label review and possible follow-up at the company if such hadn't already been done, but no analysis would be done on the caps at this time. Ms. [REDACTED] expressed her appreciation for our interest. This complaint, sample, literature with medical claims and Exhibit 910-D will be forwarded to CFSAN's Adverse Reaction Monitor (HFS-653) for review. No further f/u is planned.					
4.d. ACTION OFFICIAL'S NAME AND TITLE Bernadette T. Tallman, CSI			4.e. ACTION DISTRICT ATL	4.f. DATE COMPLETED 7/22/97	
5. MANUFACTURER / DISTRIBUTOR / DEALER RESPONSIBLE			6. PROGRAM DATA		
5.a. HOME DIST. DAL	5.c. NAME AND ADDRESS Magic Herb 8513 N. Rockwell Oklahoma City, OK 73132		6.a. OPERATION 13	6.b. PAC 03R801	6.c. PRODUCT CODE v 54FCH99
5.b. CF NO. none			6.d. EMP. HOME DIST. 1	6.e. EMP. NO. 007	6.f. POS CL. 9
6.g. HOURS 5	7. EVALUATION (0) <input type="checkbox"/> PENDING (1) <input type="checkbox"/> NO ACTION INDICATED (NAI) (2) <input type="checkbox"/> VOLUNTARY ACTION INDICATED (VAI) (3) <input type="checkbox"/> OFFICIAL ACTION INDICATED (OAI) (4) <input type="checkbox"/> NOT AN FDA OBLIGATION (5) <input checked="" type="checkbox"/> REFERRED TO HOME DISTRICT HFS-635 (6) <input type="checkbox"/> INSUFFICIENT INFO. UNABLE TO EVAL. (7) <input type="checkbox"/> REFERRED TO OCI		8. FINAL DISPOSITION (1) <input type="checkbox"/> FOLLOW-UP NEXT E1 (2) <input type="checkbox"/> WARNING LETTER (3) <input type="checkbox"/> CITATION (4) <input type="checkbox"/> SEIZURE [Referred to HFS-635] (5) <input type="checkbox"/> INJUNCTION / PROSECUTION (6) <input type="checkbox"/> REFERRED TO OTHER AGENCY (7) <input type="checkbox"/> RECALL (8) <input type="checkbox"/> NO ACTION (Indicate Agency in Remarks)		9. INFO. COPIES TO: <input type="checkbox"/> HFB-100 <input type="checkbox"/> HFD-730 <input type="checkbox"/> HFV-236 <input type="checkbox"/> HFZ-343 <input type="checkbox"/> HFC-161 <input type="checkbox"/> HFS-635 <input checked="" type="checkbox"/> DAL <input checked="" type="checkbox"/> [REDACTED] <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____
REMARKS					
NAME AND TITLE OF DISPOSITION OFFICIAL Kristen D. Evans, ASI		DISPOSITION Refer to HFS-635		DISPOSITION DATE 7/31/97	

Adverse Reaction Questionnaire

Complaint Number: EDR-1849

Investigator: Bernadette Tallman
 [Redacted] ATL-DO

Consumer Information	
Date of Report: <u>6/23/97</u> MM/DD/YY	Initial Report Source: <input 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: 33
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 Reaction	
Date of Adverse Reaction: <u>6/20/97</u>	Give the site of consumption/ingestion (e.g. home, restaurant, office): <u>Home, taken by mouth</u>
Previous Reaction to Product Type: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
<p>The following information relates to the consumers' use of the product.</p> <p>Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): Took 2 capsules early am (8-9) with water and a piece of toast. By noon same day, experienced "very rapid heart beat, shaking, headache, tingling of scalp, chills, hyperactive". No diarrhea or vomiting. How long did the symptoms last? <u>24 hours</u> Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.): Took 2 caps with water and toast in am on 6/20. No other caps taken.</p> <p>List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used <u>at the time</u> of the event: No meds, no allergies, no other diet supplements. Generally "excellent health".</p> <p>Did event abate after use of suspected product stopped or dose reduced: <input checked="" type="checkbox"/>Yes <input type="checkbox"/>No <input type="checkbox"/>Unknown Did symptoms reoccur after reintroduction of suspected product: <input type="checkbox"/>Yes <input type="checkbox"/>No <input type="checkbox"/>Unknown <input checked="" type="checkbox"/>Not Applicable Did symptoms reoccur after using other products with the same ingredients: <input type="checkbox"/>Yes <input type="checkbox"/>No <input type="checkbox"/>Unknown <input checked="" type="checkbox"/>Not Applicable</p>	
Medical Information	
Was a health care provider seen?: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Give health care provider's name, address and telephone number:	
Occupation of Health Care Provider: <input type="checkbox"/> MD <input type="checkbox"/> Osteopath <input type="checkbox"/> Naturopath <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other (specify) <u>ND</u>	
What medical tests were performed and what were the results? <u>N/A</u>	
What was the medical diagnosis? <u>N/A</u> What treatment(s) was given (e.g., drugs, other)? <u>Self prescribed bed rest and liquids.</u>	
Were there any preexisting condition(s)/treatment(s)? (If YES, list them including allergies, and chronic diseases): <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

EDR-1849
6/23/97

000003

Product Category

1. Adverse reaction to:

Medical Food (under medical supervision) Infant Formula

Dietary Supplement (a vitamin; an essential mineral; a protein; a herb or similar nutritional substance 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, succinic 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 as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

Magic Herb Diet Plus Formula With Chromium Picolinate

Director for use: Take up to 3 capsules daily: Two in the morning, one at lunch time:

As with any dietary food supplements, consult your doctor before taking any herbal

products. No recommended duration of use is mentioned on the package or accompanying

literature. Literature reads in part: "Fat Binder, curbs appetite, reduced sugar craving,

energy booster".

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

Check here if ingredients are unknown

Ma Huang Chromium Picolinate Cola Nut Camellia Sinensis Fo Ti Guarana

Kelp Licorice Ashwaganda Siberian Ginseng Sparulina White Willow Bark

listed on the package and accompanying brochures.

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

Aspartame

Color Additive (please specify) _____

Monosodium Glutamate

Sulfite

Other _____

Unknown

Is the product label available, if yes submit a quality copy along with this questionnaire: Yes No Unknown

Product Sample Available: Yes No Unknown

Attached

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 reaction result in a congenital anomaly: Yes No

EDR-1849
6/23/97