

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

ARMS#

13041



0 - FRONT

COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER
MIN-922913041
2. DATE OF COMPLAINT (Month/Day/Year)
8/4/98

3. FORM OF COMPLAINT (1) <input checked="" type="checkbox"/> TELEPHONE (2) <input type="checkbox"/> LETTER (3) <input type="checkbox"/> VISIT	4. SOURCE OF COMPLAINT (1) <input checked="" type="checkbox"/> CONSUMER (2) <input type="checkbox"/> GOVERNMENT <input type="checkbox"/> L <input type="checkbox"/> S <input type="checkbox"/> F		(3) <input type="checkbox"/> TRADE SOURCE (4) <input type="checkbox"/> OTHER (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 The complainant took a dietary supplement for about 1 month because she heard that it would promote weight loss. During the one month period, her ankles and face began to swell. Her ankles became very swollen and her face (see remarks) b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES (Explain in Remarks)		
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-167) NOTIFIED (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES DATE	b. TYPE SYMPTOMS ONSET (HR.) 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 Swollen face and ankles 2 wks	c. ATTENDING HEALTH PROFESSIONAL (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES (If "yes" give name, address, and phone number) [REDACTED] d. HOSPITALIZATION REQUIRED (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES (If "yes" give name, address, phone number and dates)
8. PRODUCT AND LABELING a. BRAND NAME Natural Herbs Metabolife c. SIZE AND PACKAGE TYPE 90 caplet bottle e. PACKAGE CODE/SERIAL NUMBER/ETC. EXP/USE BY DATE:		b. PRODUCT NAME Dietary Supplement 356 - An herbal formula to enhance your diet and provide energy. d. NAME AND LOCATION OF STORE WHERE PURCHASED by mail order from Metabolife International Inc. 5070 Santa Fe St San Diego, CA 92109 f. DATE PURCHASED June 16 1997 g. PRODUCT USED (if "yes" enter date) (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES h. AMT REMAINING 1 open and 1 full bottle	
9. MANUFACTURER/DISTRIBUTOR OF PRODUCT a. HOME DISTRICT b. C.F. NO.		c. NAME AND LOCATION OF FIRM (Include Zip Code) Metabolife International, Inc. 5070 Santa Fe St San Diego, CA 92109 d. IMPORT PRODUCT (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES	
10. EVALUATION AND DISPOSITION a. PROBLEM KEYWORD (1) CODE (2) DESCRIPTION RX swollen ankles b. EVALUATION (1) <input type="checkbox"/> NOT AN FDA OBLIGATION (2) <input type="checkbox"/> OBLIGATION, NO VIOLATION (3) <input checked="" type="checkbox"/> FDA ACTION INDICATED (4) <input type="checkbox"/> INSUFFICIENT INFORMATION UNABLE TO EVALUATE		c. DISPOSITION (1) <input type="checkbox"/> IMMEDIATE FOLLOW-UP (2) <input type="checkbox"/> F/U NEXT EI (3) <input checked="" type="checkbox"/> CLOSED WITHOUT FURTHER INVESTIGATION (4) <input type="checkbox"/> REFERRED TO OTHER FEDERAL AGENCY (Close File) (5) <input type="checkbox"/> REFERRED TO STATE/LOCAL AGENCY (Close File) (6) <input type="checkbox"/> REFERRED TO OTHER FDA _____ DISTRICT	
		11. PRODUCT CODE S4FCA09	
		12. INFORMATION COPIES TO: <input type="checkbox"/> HFB-100 <input type="checkbox"/> HFC-343 <input type="checkbox"/> HFD-730 <input checked="" type="checkbox"/> HFC-161 <input type="checkbox"/> HFD-236 <input checked="" type="checkbox"/> HES-635	

REMARKS (6a (continued) became abnormally round with swelling. The complainant went to her physician to have him check the swelling. The complainant's physician advised her to discontinue taking the dietary supplement and said that it might be causing her symptoms. One week after the complainant stopped taking the dietary supplement the swelling in her face and ankles disappeared. The dietary supplement she took contained guarana supplying 40 mg. of caffeine and Matanga providing 12 mg. of ephedrine. It also contained about 10 other herbs including ginseng and salvia. The label also...

NAME AND TITLE
Dirk J. Mowry Recall and
Complaint Coordinator
8/4/98

COMPLAINT JURY FOLLOW-UP

1. COMPLAINT NUMBER
MIN-9229

2. ACTION REQUESTED (1) <input checked="" type="checkbox"/> INVESTIGATION (2) <input type="checkbox"/> COLLECT SAMPLE (3) <input type="checkbox"/> INSPECTION (4) <input type="checkbox"/> OTHER	(a). REMARKS (Additional details) Conduct investigation per instructions from HFS-636
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(b) REQUESTING OFFICIAL'S NAME AND TITLE Dirk J. Mouw, Recall and Complaint Coordinator	(c) DATE REQUESTED 9/17/98	(d) PRODUCT NAME Metabolife Dietary Supplement
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3. ASSIGNED TO: Greg A. Abel	(a) DUE BY 10-14-98	4. ACTION TAKEN (1) <input checked="" type="checkbox"/> INVESTIGATION (2) <input type="checkbox"/> SAMPLE COLLECTED (3) <input type="checkbox"/> INSPECTION (4) <input type="checkbox"/> NONE	(a) SAMPLE NUMBER(s) N/A
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(b) DESCRIPTION OF ACTION TAKEN

Follow-up investigation conducted 9/23/98. Sample of the product label was collect and an Adverse Event Questionnaire (IOM exhibit 910-0) was completed per CFSAN, ~~DOED~~ ^{DOED (9M)} direction. Medical records were also obtained. See attached memo, dated 10/16/98

(c) ACTION OFFICIAL'S NAME AND TITLE Greg Abel Investigator	(d) ACTION DISTRICT MIN-DO	(e) DATE COMPLETED 10-16-98
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5. MANUFACTURER (DISTRIBUTOR) / DEALER RESPONSIBLE		6. PROGRAM DATA		
(a) HOME DIST. MIN-DO	(c) NAME AND ADDRESS Metabolife International Inc 5070 Santa Fe St. SAN DIEGO, CA 92109	(a) OPERATION 13	(b) PAC 03R801	(c) PRODUCT CODE 54FCA09
(b) CF NO. 1717927		(d) EMP. HOME DIST. MIN-DO	(e) EMP. NO. 737	(f) POS CL. 2
				(g) HOURS 10.5

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 (6) <input type="checkbox"/> INSUFFICIENT INFO. UNABLE TO EVAL.	8. FINAL DISPOSITION (1) <input type="checkbox"/> FOLLOW-UP NEXT E I (5) <input type="checkbox"/> INJUNCTION/PROSECUTION (2) <input type="checkbox"/> WARNING LETTER (6) <input type="checkbox"/> REFERRED TO OTHER AGENCY (3) <input type="checkbox"/> CITATION (7) <input type="checkbox"/> RECALL (4) <input type="checkbox"/> SEIZURE (8) <input type="checkbox"/> NO ACTION	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"/> _____ <input type="checkbox"/> _____ <input type="checkbox"/> _____
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REMARKS

NAME AND TITLE OF DISPOSITION OFFICIAL	DISPOSITION	DISPOSITION DATE
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Adverse Event Questionnaire

Complaint Number: MIN-9229 / CFSAN Project # 13041

Investigator: Greg A. Abel

Consumer Information	
Date of Report: <u>09/23/98</u> MM/DD/YY	Initial Report Source: <input type="checkbox"/> DORA 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: <u>62</u>
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 Event	
Date of Adverse Event: <u>7/13/98</u> Previous Adverse Effects to Product Type: <u>Period</u> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <u>6/28-7/28</u>	Give the site of consumption/ingestion (e.g. home, restaurant, office): <u>home</u>
<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): <u>Started using product on 6/28/98; approx. 2 weeks after started experiencing symptoms of swollen face & ankles plus an 8 lb. weight gain. Symptoms subsided approx. 2 weeks after use. Product no longer used after 7/28/98 per doctor's advice.</u> How long did the symptoms last? <u>(1 month)</u> Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). <u>2 capsules 2 times per day taken approx. 1 hr prior to lunch & dinner.</u></p> <p>List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: <u>SEE Addendum attached.</u></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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Give health care provider's name, address and telephone number: [REDACTED]	
Occupation of Health Care Provider: <input checked="" type="checkbox"/> MD <input type="checkbox"/> Osteopath <input type="checkbox"/> Naturopath <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other (specify) _____	
What medical tests were performed and what were the results? <u>Urinalysis, EKG, blood lab work (refer to med. records)</u>	
What was the medical diagnosis? <u>in regard to swollen face & ankles, stop taking Metabolife 356.</u>	
What treatment(s) was given (e.g., drugs, other)? <u>Doctor advised Ms. [REDACTED] to stop taking the dietary supplement because of the Ephedrine in the product.</u>	
Were there any preexisting condition(s)/treatment(s)? <u>Allergies to Augmentin, Codeine, EES</u> (If YES, list them including allergies, and chronic diseases): <input type="checkbox"/> Yes <input type="checkbox"/> No <u>irritable bowel, high blood pressure</u>	

When talking with Dr. [REDACTED] he stated he had made no mention of Ms. [REDACTED] swollen ankles & face in his report.

Product Category

1. Adverse event attributed to:

Medical Food (under medical supervision) Infant Formula

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

*Metabolife Dietary Supplement 356, Metabolife International Inc.
1, 2 ~~tablets~~ caplets 2-3 times / day or every 4 hrs do not exceed 8 caplets per day*

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

Check here if ingredients are unknown

*GUARANA CONC. MA HUANG CONC. (12mg naturally-occurring ephedrines) Bee Pollen, Ginseng,
Lacithin, Bovine Complex, Damiana leaf, Sarcaparilla root, Golden Seal, Nettles
Gotu Kola, Spirulina Algae, Royal Jelly, Magnesium, Zinc Chromium, Vit. E.*

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

Aspartame

Monosodium Glutamate

Sulfite

Other *ephedrine*

Unknown

Color Additive (please specify) _____

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

Unknown Product Sample Available: Yes No Unknown *Ms [redacted] maintains one open bottle.*

per complainant Metabolife Internal Inc maintains a sales booth at

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records) [redacted]

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 event result in a congenital anomaly: Yes No

Addendum to Adverse Event Questionnaire, with regard to the list of medications, dietary supplements and vitamins used:

Reglan 10 mg (prescription drug) 4 tablets 3 times per day for irritable bowel syndrome, has been using this product for the past 15 to 20 years.

Elavil 75 mg (prescription drug), 1 tablet per day for migraine headaches

Tenormin 25mg per day (prescription drug) beta blocker for high blood pressure, has been using this product for past 9 to 10 years. **Note:** after doctor visit on 7/28/98 prescription of Tenormin was increased to 50 mg per day.

Premarin, 0.625 mg per day (prescription drug) for osteoporosis and menopause

GNC brand women's multiple vitamin and mineral tablet taken 2 times per day for the past 4 years.

Spring Valley brand Vitamin E and C tablets taken daily for the past 8 years.

Citracal Plus D (calcium supplement) taken daily for osteoporosis for the past 4 years.

Ms. [REDACTED] claims she has been maintaining a low cholesterol diet for the past year.