

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

ARMS#

12933



0 - FRONT

Triage unit sequence #
12933

A. Patient information

1 Patient identifier	2 Age at time of event: or _____ Date of birth: _____	3 Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4 Weight ____ lbs or ____ kgs
----------------------	---	--	--

B. Adverse event or product problem

1 Adverse event and/or Product problem (e.g., defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death _____ (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other _____

3 Date of event (mo/day/yr) **Jan 85**

4 Date of this report (mo/day/yr) **5/18/98**

5 Describe event or problem

Difficulty in urinating progressing to an inability to urinate.

See attached for details.

6 Relevant tests/laboratory data, including dates

7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)

taken by phone in OSH/CIZES

K. Cheeseman

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)

#1 *See Attached. for details*

#2 *#12 product Herbalife program*

2 Dose, frequency & route used

#1 _____

#2 _____

3 Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 _____

#2 _____

4 Diagnosis for use (indication)

#1 _____

#2 _____

5 Event abated after use stopped or dose reduced

#1 yes no doesn't apply

#2 yes no doesn't apply

6 Lot # (if known)

#1 _____

#2 _____

7 Exp. date (if known)

#1 _____

#2 _____

8 Event reappeared after reintroduction

#1 yes no doesn't apply

#2 yes no doesn't apply

9 NDC # (for product problems only)

#1 _____

#2 _____

10 Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1 Brand name

2 Type of device

3 Manufacturer name & address

4 Operator of device

health professional

lay user/patient

other

5 Expiration date (mo/day/yr)

6 model # _____

7 If implanted, give date (mo/day/yr)

8 If explanted, give date (mo/day/yr)

9 Device available for evaluation? (Do not send to FDA)

yes no returned to manufacturer on _____ (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

000001

E. Reporter (see confidentiality section on back)

1 Name, address & phone #

2 Health professional? yes no

3 Occupation

4 Also reported to

manufacturer

user facility

distributor

5 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report **SERIOUS** adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

The public reporting burden for this collection of information has been estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send your comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Reports Clearance Officer, PHS
Hubert H. Humphrey Building,
Room 721-B
200 Independence Avenue, S.W.
Washington, DC 20201
ATTN: PRA

and to:
Office of Management and
Budget
Paperwork Reduction Project
(0910-0230)
Washington, DC 20503

Please do NOT
return this form
to either of these
addresses.

FDA Form 3500-back

Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business

Penalty for Private Use \$300

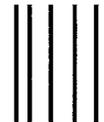
BUSINESS REPLY MAIL

FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH

The FDA Medical Products Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787



NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES
OR APO/FPO



000002



12933

COMPLAINT/INJURY FORM

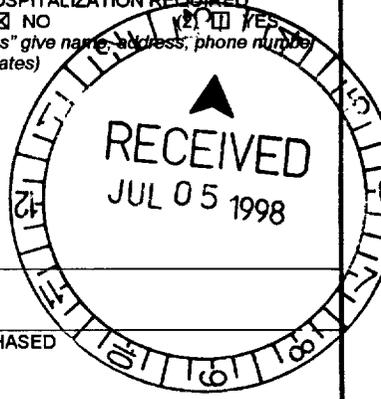
1. COMPLAINT NUMBER
NWJ8-1019
2. DATE OF COMPLAINT (Month/Day/Year)
6-18-98

3. FORM OF COMPLAINT	(1) <input type="checkbox"/> TELEPHONE	4. SOURCE OF COMPLAINT	(1) <input checked="" type="checkbox"/> CONSUMER	(3) <input type="checkbox"/> TRADE SOURCE
	(2) <input checked="" type="checkbox"/> LETTER		(2) <input checked="" type="checkbox"/> GOVERNMENT	(4) <input type="checkbox"/> OTHER
	(3) <input type="checkbox"/> VISIT		<input type="checkbox"/> L <input type="checkbox"/> S <input checked="" 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 Complainant was taking product when he developed a problem with his urinary tract.		
			b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? (1) <input 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-161) NOTIFIED (1) <input type="checkbox"/> NO (2) <input type="checkbox"/> YES DATE	b. TYPE SYMPTOM 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 ? Urination Blockage	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 Herbalife	b. PRODUCT NAME Dietary Supplement
	c. SIZE AND PACKAGE TYPE Various	d. NAME AND LOCATION OF STORE WHERE PURCHASED Local distributor
	e. PACKAGE CODE/SERIAL NUMBER/ETC. Unknown	f. DATE PURCHASED 1-89
	g. PRODUCT USED (If "yes" enter date) 1-89 (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES	h. AMT REMAINING NONE

9. MANUFACTURER/DISTRIBUTOR OF PRODUCT	a. HOME DISTRICT A	c. NAME AND LOCATION OF FIRM (Include Zip Code) Herbal Life International of America 9800 LaCienega Blvd Los Angeles, CA 90080	d. IMPORT PRODUCT (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES
	b. C.F. NO. 2022908		

10. EVALUATION AND DISPOSITION	a. PROBLEM KEYWORD (1) CODE (2) DESCRIPTION RX URINATION	c. DISPOSITION (1) <input checked="" type="checkbox"/> IMMEDIATE FOLLOW-UP (2) <input type="checkbox"/> F/U NEXT E1 (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 60CBA21
	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		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"/> HFV-236 <input checked="" type="checkbox"/> HFS-635 LOS-DO

REMARKS
Assignment requested by CFSAN. Project #12933. Collect medical records from complainant's Urologist and collect sample for label review only.

98 JUL 15 12:21

NAME AND TITLE Ms. Emma A. Nesbit, CCC	DATE 6/18/1998
---	-------------------

COMPLAINT/INJURY FORM

1. COMPLAINT NUMBER
NWJ8-1019

2. DATE OF COMPLAINT (Month/Day/Year)
6-18-98

3. FORM OF COMPLAINT	(1) <input type="checkbox"/> TELEPHONE (2) <input checked="" type="checkbox"/> LETTER (3) <input type="checkbox"/> VISIT	4. SOURCE OF COMPLAINT	(1) <input checked="" type="checkbox"/> CONSUMER (2) <input checked="" type="checkbox"/> GOVERNMENT (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: ()
--------------------------------------	--	--

6. COMPLAINT OR INJURY	a. DESCRIPTION OF COMPLAINT/INJURY Complainant was taking product when he developed a problem with his urinary tract	b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? (1) <input type="checkbox"/> NO (2) <input type="checkbox"/> YES (Explain in Remarks)
-------------------------------	---	--

7. INJURY OR ILLNESS RESULTED	a. EIB (HFC-161) NOTIFIED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES (If "yes" complete items a through d)	b. TYPE SYMPTOM 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 ? Urination Blockage	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 Herbalife	b. PRODUCT NAME Dietary Supplement		
	c. SIZE AND PACKAGE TYPE Various	d. NAME AND LOCATION OF STORE WHERE PURCHASED Local distributor		
	e. PACKAGE CODE/SERIAL NUMBER/ETC. Unknown EXP/USE BY DATE	f. DATE PURCHASED 1-89	g. PRODUCT USED (If "yes" enter date) 1-89 (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES	h. AMT REMAINING NONE

9. MANUFACTURER/DISTRIBUTOR OF PRODUCT	a. HOME DISTRICT A	c. NAME AND LOCATION OF FIRM (Include Zip Code) Herbal Life International of America 9800 LaCienega Blvd Los Angeles, CA 90080	d. IMPORT PRODUCT (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES
	b. C.F. NO. 2022908		

10. EVALUATION AND DISPOSITION	a. PROBLEM KEYWORD (1) CODE (2) DESCRIPTION RX URINATION	c. DISPOSITION (1) <input checked="" type="checkbox"/> IMMEDIATE FOLLOW-UP (2) <input type="checkbox"/> F/U NEXT E1 (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 60CBA21
	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		12. INFORMATION COPIES TO: <input type="checkbox"/> HFB-100 <input type="checkbox"/> HFC-343 <input type="checkbox"/> HFD-730 <input type="checkbox"/> HFC-161 <input type="checkbox"/> HFV-236 <input checked="" type="checkbox"/> hfs-635, LOS-DO

REMARKS
 Assignment requested by CFSAN. Project #12933. Collect medical records from complainant's Urologist and collect sample for label review only.

Read 2/14/98
 S (DOEP)

NAME AND TITLE Ms Emma A Nesbit, CCC	DATE 6/18/1998
---	-------------------

COMPLAINANT INJURY FOLLOW-UP

1. COMPLAINT NUMBER
NWJ8-1019

2.a. ACTION REQUESTED

- (1) INVESTIGATION
- (2) COLLECT SAMPLE
- (3) INSPECTION
- (4) OTHER:

2.b. REMARKS (Additional Details)

Visit complaint collect sample for label review only Complete Medical Records Disclosure Form Collect medical records from Urologist Send to CFSAN, HFS-635

2.c. REQUESTING OFFICIAL'S NAME AND TITLE

Ms Emma A. Nesbit, CCC

2.d. DATE REQUESTED

6-18-98

2.e. PRODUCT NAME

Herbalife

3.a. ASSIGNED TO:

Ms. Emma A Nesbit

3.b. DUE BY:

4.a. ACTION TAKEN

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

4.b. SAMPLE NUMBER(s)

N/A

4.c. DESCRIPTION OF ACTION TAKEN

On 6-19-98, I visited the home of Mr. [REDACTED] located at [REDACTED] Upon presenting my credentials, I asked Mr. [REDACTED] to explain the problem he had with Herbalife

Mr. [REDACTED] stated that o/a 12/97 he purchased a complete package of Herbalife, consisting of approximately 11 products He began the diet in January 1998. After approximately one month, he noticed a decrease in weight and purchased another package. However, he also noticed a problem in urinating. In the beginning the problem was minor but as each day increased it became worst. he did not connect the use of the product with his problem He finally went to the doctor who suggested that he see a Urologist.

Upon visiting the Urologist, Dr [REDACTED] he explained that he was on a diet, however, the doctor did not initially connect the diet to his problem. After speaking with a friend who knows "a lot" about herbs, he was advised not to take the product containing the "Ma Huang" His problem ceased when he stop taking the product

Mr [REDACTED] signed Medical Records Disclosure Forms and presented me with the empty bottles and canister of each product for label review I left Mr [REDACTED] and went to the office of Dr [REDACTED] located at [REDACTED] The office was closed.

On 6-22-98, I telephoned the Doctor's office to request copies of the medical records I asked [REDACTED] of the Business Office if I could fax the form to her office and later send her a hard copy of the form She stated that would be find The copies of the records arrived on 7-1-98

(Continue on next page)

4.d. ACTION OFFICIAL'S NAME AND TITLE

Ms. Emma A. Nesbit, CCC

4.e. ACTION DISTRICT

T

4.f. DATE COMPLETED

7-8-98

5. MANUFACTURER/DISTRIBUTOR/DEALER RESPONSIBLE

5.a. HOME DIST. A
5.c. NAME AND ADDRESS Herbalife International of America
9800 LaCienega Blvd
Los Angles, CA 90080

6. PROGRAM DATA

6.a. OPERATION 13
6.b. PAC 46R801
6.c. PRODUCT CODE 60CBA21
6.d. EMP. HOME DIST. T
6.e. EMP. NO. 274
6.f. POS CL. 2
6.g. HOURS 8 h

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.
- (7) REFERRED TO OCI

8. FINAL DISPOSITION

- (1) FOLLOW-UP NEXT E1
- (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
- HFZ-343
- HFC-161
- HFS-635
- LOS-DO
-
-
-
-
-

REMARKS

Labels and Medical Records collected for review as per CFSAN request No further follow-up is warranted at this time.

NAME AND TITLE OF DISPOSITION OFFICIAL

Ms Emma A. Nesbit, CCC

DISPOSITION

CLOSED-NAI

DISPOSITION DATE

7-8-98

NWJ8-1019 Continuation

The following product labels were collected:

Product Name	Lot #
1. Thermojetics Formula 1 Weight Control Protein Drink Mix Wild Berry	N/A
2. Thermojetics Formula 2 Multivitamin-Mineral Tablets	097429
3. Thermojetics Formula 3 Cell Activator	067231
4. Thermojetics Aminogen	057145
5. Thermojetics Cell-U-Loss	047150
6. Thermojetics Herbal Concentrate	06302
7. Thermojetics N-R-G (Nature's Raw Guarana)	017044
8. Thermojetics Thermo-Bond	097419
9. Thermojetics Yellow	097157
10. Thermojetics Beige	047211
11. Thermojetics Original Green	107068

On each product label, Mr. [REDACTED] wrote the daily dosage and the time of day in which each dose was administered.

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-452
98 JUL 15 PM 2:21

000006

Memorandum of Record

TO: Lori Love, M.D.
FROM: Constance J. Hardy, M.S., R.D. *gjh*
DATE: February 24, 1999
SUBJECT: AER 12933 Follow-up

I talked to the consumer on 1/24/99 at approximately 10:00 a.m.. He began taking the product Herbalife Thermojetics Original Green just after the first of the year (1998). He began taking two tablets two times per day the first month. Within the first 2nd or 3rd week he began to experience problems in urinating (slow flow, inability to empty the bladder). After the first month, he was told by the salesperson he had bought the product from to increase his intake of the product to 3 tablets three times per day, since his weight loss had tapered off. He mentioned to the salesperson about his urination problem and was told that the product could not have caused the difficulty in urinating problem. The salesperson did tell the consumer that there was another product Herbalife Thermojetics Green which did not contain ma huang and was for persons who had health conditions for which Thermojetics Original Green would be contraindicated; these health conditions did not include a difficult in urinating..

Approximately one week after stopping the product, the consumer's symptoms ceased.

The consumer does not have any remaining product because he coincidentally finished the product just about the time he reached his goal weight.

File Name: C:\CONNIE\EPHEDFU\FU12933

000007

Adverse Event Questionnaire

Complaint Number: 12933

Investigator: V. Chandra
OSN/CRS

Consumer Information	
Date of Report: <u>5/18/98</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"/> Male Age: 54
Race: <input 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: Jan 98 Previous Adverse Effects to Product Type: <input type="checkbox"/> No	Give the site of consumption/ingestion (e.g. home, restaurant, office): home
<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): Difficulty in urinating progressing to an inability to urinate</p> <p>Before starting product had a complete physical including a stress test. Starting having problems urinating in Jan after starting product which got worse as time went by. Did not suspect the product at the time, assumed the problem was because he was a 54 year old man. Saw the urologist on March 10, 98 about the difficulty/inability to urinate. Told Dr. [REDACTED] about the herbal diet, doctor did not feel that was a factor. On March 10, it was documented that Mr. [REDACTED] had urine retention and flow problems. Mr. [REDACTED] was scheduled for a "scope" exam later in the month. About the time of the exam, Mr. [REDACTED] finished the diet. Then his urinary problems began to get better. Within one week of exam, he was almost normal. A friend told him that ma-huang / ephedrine can cause urinary problems. Called Dr. [REDACTED] to confirm. Dr. [REDACTED] confirmed that ephedrine could and probably did cause his problem and canceled his "scope" test.</p> <p>How long did the symptoms last? 2.5 months</p> <p>Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.). The first month took 3 tablets twice a day (7 mg ephedra/tablet) and lost 14 pounds. Stopped losing weight so increased amount to a total of 9 tablets per day. Took a total of 360 tablets over two months.</p> <p>List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used <u>at the time</u> of the event: Pravacol for cholesterol</p> <p>Did event abate after use of suspected product stopped or dose reduced: <input type="checkbox"/> Yes Did symptoms reoccur after reintroduction of suspected product: <input type="checkbox"/> Not Applicable Did symptoms reoccur after using other products with the same ingredients: <input type="checkbox"/> Not Applicable</p>	
Medical Information	
Was a health care provider seen?: <input type="checkbox"/> Yes Give health care provider's name, address and telephone number: Dr. [REDACTED] Urologist, [REDACTED] [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 checked="" type="checkbox"/> Other (specify) <u>Urologist</u>	
What medical tests were performed and what were the results? What was the medical diagnosis? What treatment(s) was given (e.g., drugs, other)? Discontinued the product.	000008
Were there any preexisting condition(s)/treatment(s)? (If YES, list them including allergies, and chronic diseases): <input type="checkbox"/> Yes high cholesterol	

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):

Using the 12 product Herbalife diet plan The List of products are:

Thermojetics Original Green - ma-huang, bladderwrack, yerba mate, valerian root, purple willow, fumitory herb, papain, FD&C

Blue No. 1 Lake

(take 1-3 tablets twice a day for a max of 6 tablets per day; distributor told him to increase the amount to 9 tablets per day)

Formula One Protein Drink **Mix**

Formula Two

Formula Three

Thermo-bond - fiber blend

Aminogen

Cell-U-Loss

Herbal Concentrate - camellia sinensis (tea), malto-dextrin, fructose, malva sylvestris extract, cardamom extract, hibiscus extract, lemon peel extract

Thermojetics Beige - hawthorn berry, alfalfa, parsley, marshmallow root, uva ursi, cornsilk, magnolia bark, fennel seed, astragalus (bai-chi), paffia paniculata, pau d'arco, goldenrod, licorice

Thermojetics Yellow - garcinia cambogia extract, GTF chromium (chromium polynicotinate)

NRG Drink - guarana

If a particular ingredient is suspected of contributing to the adverse event, please indicate: **ma-huang/ephedra**

Is the product label available, if yes submit a quality copy along with this questionnaire: Yes

Product Sample Available: No

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 event result in a congenital anomaly: Yes No

000009