

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

ARMS#

13009



0 - FRONT

Triage unit sequence # **86162**
13009

A. Patient information

1 Patient identifier	2 Age at time of event: 38 yrs. or Date of birth: [redacted]	3 Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4 Weight 219 lbs or kgs
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B. Adverse event or product problem

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

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

<input type="checkbox"/> death (mo/day/yr)	<input checked="" type="checkbox"/> disability <i>now on cardiac medication to prevent a recurrence</i>
<input checked="" type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other

3 Date of event (mo/day/yr) **01/28/98**

4 Date of this report (mo/day/yr) **06/15/98**

5 Describe event or problem

Inferior Wall Myocardial Infarction

On 1/27/98, I began taking Herbalife Original Green dietary tablets as directed. On 1/28/98, I took the tablets about 9:30 a.m. I took 2 Sudafed about 10 am for nasal congestion. At 3 pm I took 2 more Sudafed, I did not have the afternoon dose of Herbalife. At 4 pm I suffered an IwMI while working in a physician's office. I was hospitalized at [redacted] in CCU for 5 days and in progressive care an additional 2 days. My heart attack was caused by a heart spasm, in which the stimulants I took most likely caused. There were no warnings on either bottle stating these were stimulants.

6 Relevant tests/laboratory data, including dates

EKG showed IwMI (1/28/98).
Lab tests positive for stimulants. (1/28/98)

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

none
no family history
low cholesterol
non-smoker

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)	original Green	
#1	Herbalife Herbal Tablets Dietary Supp.	
#2	Sudafed 30mg ; Warner Wellcome	
2 Dose, frequency & route used	3 Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1 11 tabs p.o. in am & p.m.	#1	
#2 11 tabs p.o. q 4-6 hrs	#2	
4 Diagnosis for use (indication)	5 Event abated after use stopped or dose reduced	
#1 Appetite Suppressant	#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 Decongest for sinuses	#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6 Lot # (if known)	7 Exp. date (if known)	
#1 057230	#1 N/A	
#2 4W1861A	#2 11/98	
9 NDC # (for product problems only)	8 Event reappeared after reintroduction	
	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	

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

98 & REF. CLIN

D. Suspect medical device

1 Brand name	2 Type of device	3 Manufacturer name & address	4 Operator of device
			<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> 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)			
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (mo/day/yr)			

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

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E. Reporter (see confidentiality section on back)

1 Name, address & phone #	I am a health professional, but also the patient.		
[redacted]	2 Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3 Occupation Certified med. Assistant Bachelors	4 Also reported to
			<input checked="" type="checkbox"/> manufacturer Sudafed <input type="checkbox"/> user facility <input type="checkbox"/> distributor
5 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>			



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

or FAX to:
1-800-FDA-0178

86162

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

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& REVIEW/OSN HFS-452
98 JUL 21 17:53

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

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Adverse Event Questionnaire

Complaint Number: 13009Investigator: CHERYL F. JHS

Consumer Information	
Date of Report: <u>06/15/98</u> MM/DD/YY	Initial Report Source: <input type="checkbox"/> ORA Consumer Injury <input type="checkbox"/> Telephone <input type="checkbox"/> Correspondence <input checked="" 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>38</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>01/26/98</u> Previous Adverse Effects to Product Type: <input type="checkbox"/> Yes <input type="checkbox"/> No <u>NA</u>	Give the site of consumption/ingestion (e.g. home, restaurant office): <u>OFFICE (OR'S)</u>
The following information relates to the consumers' use of the product.	
Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): <u>HEART ATTACK - PRODUCT WAS TAKEN AT 9:00AM</u> <u>- HEART ATTACK OCCURRED AT 4:00 PM</u>	
How long did the symptoms last? <u>HOSPITALIZED FOR 7 DAYS</u>	
Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.): <u>1/27/98 - 1 TABLET OF "BEIGE" HERBALIFE TAKEN AT 9:00AM;</u> <u>2 TABLETS OF "ORIGINAL GREEN" HERBALIFE TAKEN AT 9:00AM & 2 TABLETS</u> <u>TAKEN AT 3:00PM. 01/28/98 - 1 BEIGE TABLET + 2 GREEN TABLETS AT 9:00AM.</u>	
List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: <u>1/28/98 - 2/30mg EA, TABLETS SWOAFED TAKEN AT 10:00AM; FEW SIPS OF COFFEE</u>	
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 <u>3:30PM</u>	
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 <u>CONTINUED: 2/30mg EA, SWOAFED AT 2:30 PM.</u>	
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? What was the medical diagnosis? What treatment(s) was given (e.g., drugs, other)?	
Were there any preexisting condition(s)/treatment(s)? (If YES, list them including allergies, and chronic diseases): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No - <u>GASTROESOPHAGEAL REFLUX DISEASE</u> <u>IRRITABLE BOWEL SYNDROME</u>	

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#13009

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):

HERBALIFE INTERNATIONAL, LOS ANGELES, CA 90080 - NO INDICATIONS
 BEIGE - ONE TABLET W/ 1 TO 3 GREEN TABLETS 2X/DAY @ 10:00AM & 3:00PM
 ORIG, GREEN - 1 TO 3 TABLETS W/ 1 BEIGE TABLET 2X/DAY @ 10:00AM & 3:00PM

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

Check here if ingredients are unknown
 ORIGINAL GREEN: CHINESE MA HUANG, BLADDERWRACK, YERBA MATE,
 VALERIAN ROOT, PURPLE WILLOW, FUMITORY HERB, PAPAINE AND COATING
 COLOR: FD+C (REST NOT LEGIBLE)
 BEIGE: HAWTHORN, BERRY, ALEAFA, PARSLEY, MARSHMALLOW ROOT, UVA URSI
 CORNSILK, MAGNOLIA BARK, FENNEL SEED, ASTRAGALUS (BAI CHI), PFAFFIA PANICULATA

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

- Aspartame Color Additive (please specify) _____
- Monosodium Glutamate
- Sulfite
- Other EPHEORINE ALKALOIDS (MA HUANG)
- Unknown

PAO D'ARCO,
 GOLDEN ROOT,
 AND LICORICE

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

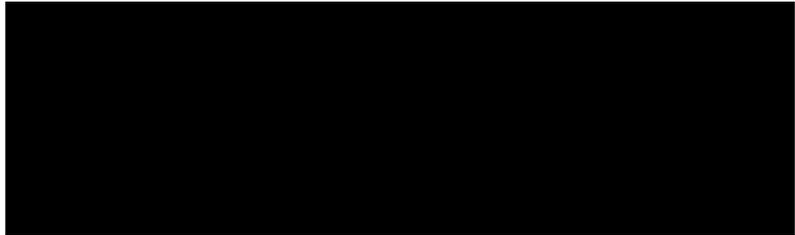
Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records)

- Death: Yes No
- Life-Threatening: Yes No
- Hospitalization: Yes No (if YES, indicate if initial or prolonged) 01/28 - 02/03/98
- Required intervention to prevent permanent impairment/damage: Yes No
- Did the adverse event result in a congenital anomaly: Yes No

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FOOD AND DRUG ADMINISTRATION



Date: 08/07/98

From: Cheryl Fuhs, Investigator, DET-DO, [REDACTED] RP

Subject: Project #13009-Herbalife, DOEP Request for F/U



To: File

Contact was made with a consumer in response to an assignment from CFSAN, DOEP, dated 07/28/98, project number 13009. MED WATCH report #86162 was submitted by the consumer on 06/15/98.

I visited [REDACTED] of [REDACTED] on 08/04/98. She stated that she suffered a heart attack on 01/28/98; one day after initial consumption of Herbalife tablets. On 01/27/98, the consumer took 2 tablets of "original green" and 1 tablet of "beige" at 9:00am. 2 tablets of "original green" were taken again at 3:00pm. On 01/28/98, 2 "original green" tablets and 1 "beige" tablet were taken at 9:00am. 2/30mg tablets of Sudafed were taken at 10:00am and again at 2:30pm. A few sips of coffee were also consumed on this day at approximately 3:30pm. The heart attack occurred at approximately 4:00pm.

Samples of the "original green" and "beige" Herbalife products were collected from [REDACTED] at [REDACTED]. The consumer wanted to retain the bottles that contained the product, therefore, only copies of the labels were obtained. Label information is contained in Exhibit A for the "original green" product and Exhibit B for the "beige" product.

When the consumer felt as though she were having a heart attack, she was immediately monitored by an EKG machine since she was in a physician's office. The consumer gave me a copy of this EKG print-out, and one from a routine EKG conducted on her in 1992 (see Exhibit C and D, respectively).

The consumer signed a medical release form and medical records were obtained from [REDACTED] (see Exhibit D). The consumer was hospitalized at this facility from 01/28-02/03/98.

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& REVIEW/OSN HFS-452
AUG 11 1998

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The sample of "original green" was assigned sample number INVz528 and shipped to SEA-DO Laboratory on 08/06, for ephedrine alkaloid analysis. The label of the "beige" product did not list ma huang as an ingredient and was not shipped to the Lab, per instructions of Bridgette Wallace, ARMS Monitor, on 08/06/98.

ATTACHMENTS:

Assignment dated 07/28/98 from DOEP
Adverse Event Questionnaire

EXHIBITS:

- Exhibit A-Label content of "original green", 4 pgs.
- Exhibit B-Label content of "beige", 6 pgs.
- Exhibit C-EKG during heart attack, 01/28/98, 2 pgs.
- Exhibit D-EKG from 11/03/92, 2 pgs.
- Exhibit E-Medical Records from [REDACTED] 45 pgs.

Cheryl A. Fuhs

Cheryl A. Fuhs
Investigator, DET-DO, [REDACTED]/RP

O: CFSAN ARMS Monitor, Bridgette Wallace HFS-636

CC: DET-DO, [REDACTED]/RP

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The sample of "original green" was assigned sample number INV2528 and shipped to SEA-DO Laboratory on 08/06, for ephedrine alkaloid analysis. The label of the "beige" product did not list ma huang as an ingredient and was not shipped to the Lab, per instructions of Bridgette Wallace, ARMS Monitor, on 08/06/98.

ATTACHMENTS:

Assignment dated 07/28/98 from DOEP
Adverse Event Questionnaire

EXHIBITS:

Exhibit A-Label content of "original green", 4 pgs.

Exhibit B-Label content of "beige", 6 pgs.

Exhibit C-EKG during heart attack, 01/28/98, 2 pgs.

Exhibit D-EKG from 11/03/92, 2 pgs.

Exhibit E-Medical Records from [REDACTED] 45 pgs.

Cheryl A. Fuhs

Cheryl A. Fuhs

Investigator, DET-DO, [REDACTED] RP

O: CFSAN ARMS Monitor, Bridgette Wallace HFS-636

CC: DET-DO, [REDACTED]/RP

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