

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

ARMS#

12859



0 - FRONT

Triage unit
sequence # **APMS# 12859**

A. Patient information

1. Patient identifier [Redacted]	2. Age at time of event: or Date of birth: 34 yrs.	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight or 102 lbs or 46 kgs
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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 checked="" type="checkbox"/> death 4/23/98 (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: **4/16/98** (mo/day/yr)

4. Date of this report: **4/24/98** (mo/day/yr)

5. Describe event or problem

34 yr. old ♂, otherwise healthy, started a weight loss regimen beginning approx. 3 wks. prior to hospital admission, in preparation for his military "PT." Took 3 products which had been purchased at [Redacted] store: (1) Megaman multivitamins, (2) a protein drink (chocolate flavor) - unknown name, unknown if a powder or liquid, and (3) a product taken as a dietetic with chromium picolinate [this information was obtained from the pt near the time of admission]. All products were begun at the same time. About 3 days prior to admission, stopped eating completely in order to lose more weight. Lost a total of 17 lbs over the 3 preceding weeks. On day of admission, ran 2 miles as part of "PT." Collapsed.

6. Relevant tests/laboratory data, including dates

Pt. seen by [Redacted] found to have atrial flutter. Initially admitted to [Redacted] at [Redacted]. Pt. then transferred to [Redacted]. Initially, pt. had CK of 470 and was hypokalemic. Pt. was conscious. Not known if hyperthermic on admission. No cardiac problem. By next day,

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

developed severe anemia, very prolonged PT (60 sec). Placed on 4/19/98 dialysis. CK continued to increase (800,000). Pt. began to deteriorate with bleeding. Developed compartment syndrome of legs/buttocks, requiring fasciotomy. Continued to deteriorate with bleeding. Died of unknown cause (4/23/98).

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)		3. Therapy dates (if unknown, give duration from/to (or best estimate))	
#1	"Dietetic" with chromium picolinate	#1	~3/30/98 - 4/16/98
#2	Protein "drink"	#2	~3/29/98 - 4/16/98
2. Dose, frequency & route used		4. Diagnosis for use (indication)	
#1	? Oral	#1	Weight loss
#2	? Oral	#2	Weight loss
6. Lot # (if known)		7. Exp. date (if known)	
#1		#1	
#2		#2	
9. NDC # (for product problems only)		5. Event abated after use stopped or dose reduced	
		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
		8. Event reappeared after reintroduction	
		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
10. Concomitant medical products and therapy dates (exclude treatment of event)			
None known			

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)	
* Report taken by telephone from [Redacted] by: Nancy Slifman, M.D. Medical Officer/CERS	

E. Reporter (see confidentiality section on back)

1. Name, address & phone # [Redacted]			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation Pharmacist	
4. Also reported to <input type="checkbox"/> manufacturer <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

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting
by health professionals of adverse
events and product problems

Page 2 of 2

Form Approved OMB No 0910-0291 Expires 12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit
sequence #

ARMS# 12 859

A. Patient information

1. Patient identifier In confidence	2. Age at time of event: or Date of birth:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
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B. Adverse event or product problem

1 <input type="checkbox"/> Adverse event and/or <input type="checkbox"/> 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)	4 Date of this report (mo/day/yr)

5 Describe event or problem

Cont. from pg. 1
Urine tox screen → negative.
No history of other medications. No other medical problems.

Sample of the ^{diverted} products are available. Unfortunately, the pt. kept the product in an Advil bottle. Original container was not found. Pt. unable to remember name of "diverted" product.
No information available from the pharmacist (reporter) regarding the protein "drink" - not known if liquid or powder. Not known if label & labeling for this product is available.

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.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1		#1	
#2		#2	
2. Dose, frequency & route used		5. Event abated after use stopped or dose reduced	
#1		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
4. Diagnosis for use (indication)		8. Event reappeared after reintroduction	
#1		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)	7. Exp. date (if known)	9. NDC # (for product problems only)	
#1	#1	-	
#2	#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
	<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other.
6. model #	5. Expiration date (mo/day/yr)
catalog #	7. If implanted, give date (mo/day/yr)
serial #	8. If explanted, give date (mo/day/yr)
lot #	
other #	
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)	

E. Reporter (see confidentiality section on back)

1. Name, address & phone #			
000002			
2. Health professional?	3. Occupation	4. Also reported to	
<input type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> manufacturer <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

COMPLAINT INJURY REPORT

1 COMPLAINT NUMBER BLT 5162

AZM 12859

2 DATE OF COMPLAINT (MONTH/DAY/YEAR)
5/13/98

3. FORM OF COMPLAINT	<input type="radio"/> TELEPHONE <input checked="" type="radio"/> LETTER	4. SOURCE OF COMPLAINT	<input type="radio"/> CONSUMER <input type="radio"/> TRADE SOURCE <input checked="" type="radio"/> GOVERNMENT <input type="radio"/> OTHER A L A S <input checked="" type="radio"/> F (Indicate in Remarks)
5. COMPLAINT 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 Ms. [REDACTED] husband died on 4/22/98 after allegedly using 8 different dietary supplements from 3/26-4/16/98. She will hold the products for FDA collection and analysis.		b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT? (1) NO (2) <input checked="" type="radio"/> YES (Explain in Remarks)
7. INJURY OR ILLNESS RESULTED	a. EIB (HFC-161) NOTIFIED (1) NO (2) <input checked="" type="radio"/> YES DATE: 5/14/98	b. TYPE SYMPTOMS ONSET (HR) 1. VOMITING 2. NAUSEA 3. DIARRHEA 4. FEVER 5. SKIN/EYE IRR. 6. HEADACHE 7. <input checked="" type="radio"/> OTHER hemorrhaging	c. ATTENDING HEALTH PROFESSIONAL (1) NO (2) <input checked="" type="radio"/> YES (If "yes" give name and address, and phone number) [REDACTED]
8. PRODUCT AND LABELING	a. BRAND NAME Herbalife		b. PRODUCT NAME Herbal Tablets Original Green
	c. SIZE AND PACKAGE TYPE 120 tab white plast bottle		d. NAME AND LOCATION OF STORE WHERE PURCHASED Purchased through local distributor, Herbalife- Not available from retail sales
	e. PACKAGE CODE/SERIAL NUMBER/ETC. lot 057006 EXP/USE BY DATE:		f. DATE PURCHASED g. PRODUCT USED (If "yes" enter date) (1) NO (2) <input checked="" type="radio"/> YES:
9. MANUFACTURER/DISTRIBUTOR OF PRODUCT	a. HOME DISTRICT LA	c. NAME AND LOCATION OF FIRM (Include Zip Code) HERBALIFE INTERNATIONAL 9800 LACIENEGA BLVD. INGLEWOOD CA 90080	
	b. C.F. NO. 2022908	d. IMPORT PRODUCT (1) NO (2) <input checked="" type="radio"/> YES	
10. EVALUATION AND DISPOSITION	a. PROBLEM KEYWORD (1) CODE (2) DESCRIPTION		c. DISPOSITION (1) <input checked="" type="radio"/> IMMEDIATE FOLLOW-UP (2) F/U NEXT EI (3) CLOSED WITHOUT FURTHER INVESTIGATN (4) REFERRED TO OTHER FEDERAL AGENCY (Closes File) (5) REFERRED TO STATE/LOCAL AGENCY (Closes File) (6) REFERRED TO OTHER FDA _ DIST.
	b. EVALUATION (1) NOT AN FDA OBLIGATION (2) <input type="radio"/> OBLIGATION, NO VIOLATION (3) <input checked="" type="radio"/> FDA ACTION INDICATED (4) <input type="radio"/> INSUFFICIENT INFORMATION UNABLE TO EVALUATE		11. PRODUCT CODE 54DDA99 12. INFORMATION COPIES TO: <input checked="" type="checkbox"/> HFB-100 HFZ-343 <input checked="" type="checkbox"/> HFD-730 HFC-161 <input checked="" type="checkbox"/> HFV-236 HFC-636
REMARKS: COMPLAINT RECEIVED AS CFSAN MEDWATCH REPORT ON 5/14/98 AS A FOLLOW UP TO ADVERSE EVENT (DEATH) OF COMPLAINANT'S HUSBAND- [REDACTED] -ON 4/22/98.			
NAME AND TITLE STEVEN THURBER, CSO			DATE 5/14/98

FORM FDA 2516 (1/90)

Circle Appropriate Copy

White copy (Original)

Pink Copy

Orange Copy

Green Copy

Yellow Copy

000003

COMPLAINT - JURY FOLLOW-UP

1. COMPLAINT NUMBER BLT-5162

2. ACTION REQUESTED

- INVESTIGATION
- COLLECT SAMPLE
- INSPECTION

a. REMARKS (Additional details)

Visit consumer's wife to obtain product samples, labeling, medical records and questionnaire.

b. REQUESTING OFFICIAL'S NAME AND TITLE
Ronald Roy/CFSAN

c. DATE REQUESTED
5/13/98

d. PRODUCT NAME
Dietary Supplements

3. ASSIGNED TO:
Steven Thurber

a. DUE BY
ASAP

4. ACTION TAKEN
- INVESTIGATION
 - SAMPLE COLLECTED
 - INSPECTION

a. SAMPLE NUMBER(s)
98-788-093/9

b. DESCRIPTION OF ACTION TAKEN

On 5/14/98, I received a CFSAN MedWatch assignment to follow up on an adverse event (death) of Mr. [REDACTED] that occurred on 4/22/98. I completed a Consumer Complaint Report (form FDA 2516) and made contact with the complainant, Ms. [REDACTED], wife of Mr. [REDACTED] on 5/14/98.

On 5/15/98, I visited Ms. [REDACTED] at [REDACTED] to interview her and obtain product samples. Ms. [REDACTED] stated the death allegedly occurred from the Mr. [REDACTED] use of eight different dietary supplements for three weeks (3/26-4/16/98) to lose weight for a military physical. He reduced food intake on 4/13/98 and collapsed on 4/16/98, while on a two mile run. Mr. [REDACTED] was admitted to [REDACTED] on 4/16/98 and transferred to [REDACTED] later that day. I collected the products, obtained disclosure for release of medical records, and information for the adverse event questionnaire. The death is associated with one of the eight products, Original Green Herbal Tablets, which contains Ma Huang (ephedra). This product is identified as sample #98-788-092, and was sent to SEA-DO laboratory for analysis on 5/19/98. I spoke with the [REDACTED] drug lab director, [REDACTED] and confirmed sample size and products involved.

On 5/19/98, I spoke on the telephone with Dr. Lisa Ginn (202-205-5055) at CFSAN, whom interviewed hospital officials regarding this case. She stated that Mr. [REDACTED] had a very high CK rate (800,000), which is a muscle damage test. He also had a low hypokalemic test

c. ACTION OFFICIAL'S NAME AND TITLE Steven Thurber/CSO

Steven Thurber

d. ACTION DIST
BLT

e. DATE COMPLTD
5/20/98

5. MANUFACTURER/DISTRIBUTOR/DEALER RESPONSIBLE

a. HOME DIST.
LA

c. NAME AND ADDRESS
Herbalife International
9800 LaCienega Blvd.
Inglewood, CA 90080-0210

b. CF NO.
2022908

6. PROGRAM DATA

a. OPERATION
13

b. PAC
03F800

c. PROJ. CODE
54DDA99

d. EMP. HOME DIST
BLT

e. EMP. NO.
818

f. POS. CL. 2
g. HRS 14

7. EVALUATION

- PENDING
- NO ACTION INDICATED (NAI)
- VOLUNTARY ACTION INDICATED (VAI)
- OFFICIAL ACTION INDICATED (OAI)
- NOT AN FDA OBLIGATION
- REFERRED TO HOME DISTRICT

8. FINAL DISPOSITION

- FOLLOW-UP NEXT EI
- WARNING LETTER
- CITATION
- SEIZURE
- INJUNCTION/PROSECUTION
- REFERRED TO OTHER AGENCY
(Indicate Agency in Remarks)
- RECALL
- NO ACTION

9. INFO. COPIES TO

- HFB-100
- HFD-730
- HFV-236
- HFZ-343
- HFC-161
-
-
-

REMARKS

NAME AND TITLE OF DISPOSITION OFFICIAL

DISPOSITION

DISPOSITION DATE

FORM FDA 2516a (1/90)

Circle Appropriate Copy:

White copy (Original)

Pink Copy

Orange Copy

Green Copy

Yellow Copy

000004

COMPLAINT JURY FOLLOW-UP

1. COMPLAINT NUMBER BLT-5162

2. ACTION REQUESTED

- (1) INVESTIGATION
- (2) COLLECT SAMPLE
- (3) INSPECTION

a. REMARKS (Additional details)

Visit consumer's wife to obtain product samples, labeling, medical records and questionnaire.

b. REQUESTING OFFICIAL'S NAME AND TITLE

Ronald Roy/CFSAN

c. DATE REQUESTED

5/13/98

d. PRODUCT NAME

Dietary Supplements

3. ASSIGNED TO:

Steven Thurber

a. DUE BY

ASAP

4. ACTION TAKEN

- (1) INVESTIGATION
- (2) SAMPLE COLLECTED
- (3) INSPECTION

a. SAMPLE NUMBER(s)

98-788-093/9

b. DESCRIPTION OF ACTION TAKEN

Description of action, cont.

(potassium level). In addition, he received blood transfusions and dialysis as treatments. Mr. [REDACTED] died on 4/22/98 from rbdomyolysis (muscle shredding), massive hemorrhaging, and acute hepatic failure.

On 5/19/98, I spoke with Mr. Ronald Roy, CFSAN, (202-205-4771) whom confirmed analysis and routing of the additional dietary supplement samples. The seven other dietary supplement products obtained from the complainant were identified as samples #98-788-092 through 099. Mr. Roy stated he would review the labels on the seven samples for ephedra substances. I sent the samples to Mr. Roy at CFSAN for label review on 5/20/98. Medical reports are being forwarded to CFSAN, for additional review. Ms. [REDACTED] would like the return of the samples, following label review and analysis.

000005

Adverse Event Questionnaire

Complaint Number: BLT-5162

Investigator: Steven Thurber

Consumer Information

Date of Report: <u>5/15/98</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 type="checkbox"/> F <input checked="" type="checkbox"/> M Age: <u>33</u>
Race: <input type="checkbox"/> 1-White <input checked="" 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>4/22/98</u> Previous Adverse Effects to Product Type: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Give the site of consumption/ingestion (e.g. home, restaurant, office): <u>home</u>
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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):
Healthy patient took dietary supplements for 3 weeks (3/26-4/16/98) to lose weight. Patient reduced food intake on 4/13/98. on 4/16/98 the patient ran 2 miles, collapsed, and was admitted to hospital.

How long did the symptoms last? 6 days (4/16-22/98)
Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.).

Patient took eight different dietary supplements from 3/26-4/16/98

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:
Same as above

Did event abate after use of suspected product stopped or dose reduced: Yes No Unknown

Did symptoms reoccur after reintroduction of suspected product: Yes No Unknown Not Applicable

Did symptoms reoccur after using other products with the same ingredients: Yes No Unknown Not Applicable

Medical Information

Was a health care provider seen?: Yes No

Give health care provider's name, address and telephone number:

Occupation of Health Care Provider: MD Osteopath Naturopath Nurse Pharmacist
Other (specify) _____

What medical tests were performed and what were the results?
CK test (muscle level damage) - 800,000 (very high), Hypokalemic test (potassium level)

What was the medical diagnosis? *rab domyolysis (muscle shredding), acute hepatic failure*

What treatment(s) was given (e.g., drugs, other)? *blood transfusions, dialysis given*

Were there any preexisting condition(s)/treatment(s)? No

(If YES, list them including allergies, and chronic diseases): Yes No

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):

*Herbal Tablets, Original Green, Herbalife International Inc
Take 1-3 tablets 2X per day*

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

Check here if ingredients are unknown

*Chinese Ma Huang (ephedra), Bladderwrack, yerba mate,
Valerian Root, Purple Willow, Fumitory Herb, Papain and
coating color: FD + C Blue No. 1 lake.*

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

Aspartame

Monosodium Glutamate

Sulfite

Other *ephedra*

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

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

To: Nancy Slifman@OSN@FDA.CFSAN
From: <LAL@FDA.CFSAN>
Certify: N
Subject: NO SUBJECT
Date: Thursday, April 23, 1998 at 3:33:26 pm EDT
Attached:None

Would you please handle/triage this call. Thanks

*** Forwarding note from SMTP --BFD 04/23/98 12:39 ***

Received: from vm.cfsan.fda.gov by VM.CFSAN.FDA.GOV (IBM VM SMTP V2R2)
with BSMTP id 4670; Thu, 23 Apr 98 12:39:15 EDT

Message-Id: <19980423.123915.srb@cfsan.fda.gov>

Date: 23 Apr 1998 12:39:15 EDT

From: Shirley Blakely <srb@cfsan.fda.gov>

To: <EAY@BFD>,
<LAL@BFD>

Subject:

To: CCR --BFD AMR --BFD
EAY@BFD
LAL@BFD
cc: SRB --BFD

From: Shirley Blakely

Subject:

I'm not entirely clear on how CFSAN handles reports of adverse events related to dietary supplements. This telephone call came in to me and I referred the person to a phone number (OSN) which she called and got voice mail. She was uncomfortable leaving the message on voice mail so she called me back. Here is the gist of her report:

Source of report: [REDACTED]

Patient with Adverse Event: male, 34 years old, had been trying to lose weight for about one month. He had been taking tablets which he obtained from [REDACTED] He told the pharmacist that the tablets contained CrPicolate and a diuretic. [REDACTED] indicated she still has some of the tablets). The patient after having collapsed. He indicated to the doctor that he had run about 2 miles before he collapsed. He reported with severe dehydration, severe compartment syndrome, and "rhabdomyolysis." The patient never recovered from this event and has died.

Please have the appropriate persons contact Ms. [REDACTED] for further details. Thanks.

HFS-019, 200 C St., SW, Washington, DC. (202)205-8409
Internet: SRB@cfsan.fda.gov

12859

000008

Notes on Telephone Conversation
Clinical Research and Review Staff

ARMS# 12859

Date	4/27/98	Phone No.	[REDACTED]
Name	[REDACTED]	Fax No.	[REDACTED]
Affiliation	[REDACTED]		
Address	[REDACTED]		
FDA Representatives	Nancy Slifman		
Question/Subject			

Discussion	<p>Spoke with Ms. [REDACTED] about certain aspects of the case. Explained that without at least the name of the "diuretic" product the pt. was consuming, laboratory analysis would not be useful. Also explained that ephedra is contained in some protein drink powders, so that if the label & labeling of this product were available, a sample could be analyzed for ephedrine alkaloids. Asked Ms. [REDACTED] if she thought the pt's wife would be agreeable to providing this information. Ms. [REDACTED] had not had contact with the pt's wife & decided to ask the [REDACTED] head nurse (Major [REDACTED]). According to voice mail message from Ms. [REDACTED] Major [REDACTED] said "the wife did not give any indication that she would be willing to help." Major [REDACTED] unwilling to release the pt's wife's name or telephone number.</p>
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Follow up	<p>Will try to contact Major [REDACTED] to clarify our need to speak with the pt's wife as well as to obtain her permission for release of medical records. Will try to determine if Major [REDACTED] spoke with the pt's wife and conveyed our request.</p>
-----------	--

Signed:

N. Slifman

Date: 4/27/98

000009

Notes on Telephone Conversation
Clinical Research and Review Staff

Date	May 6, 1998	Phone No.	[REDACTED]
Name	Mrs. [REDACTED]	Fax No.	N/A
Affiliation	Consumer's next of kin/wife		
Address			
FDA Representatives	Lisa Han, MD CRRS / OSN		
Question/Subject	Mrs. [REDACTED] was contacted to request permission/ assistance in obtaining field follow-up on ARMS # 12859. This AER involves her husband who expired on 4/23/98.		

Discussion	<p>Mrs. [REDACTED] was very willing to speak to me regarding this case. Although she was not able to clarify details of husband's hospital course, she confirmed that her husband had had no significant past medical history and had undergone a military physical 2/yr the past 24 months during which he was determined to be in "excellent health."</p> <p>Since her husband's death, consumer has found 6 products in original containers & attached labels in their home. She states that her husband is presumed to have used this products for an unknown period of time. In addition, wife indicates that she discarded 2 additional products (GNC-Vitamin C,</p>
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Follow up	GNC-Ultra Mega Men & Liquid Energy) plus to our conversation today.
<p>Field assignment will be issued as wife is willing to provide FDA & the following: (1) medical records (2) product label (3) product sample for analysis (4) adverse event questionnaire.</p>	

Signed: Lisa R. Han Date: 126 5/6/98 **000010**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to:

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone (410) 957-4040

Date May 27, 1998

From: Steven J. Thurber/CSO/[REDACTED]

Thru: Michael C. Rogers/Team Leader/[REDACTED] MR

Subj.: Follow-up on Adverse Event (ARMS#12859)/Medical Records

To Brigette M. Wallace/CFSAN ARMS Monitor



On 5-20-98, I visited [REDACTED] to obtain medical records for Mr. [REDACTED] Mrs. [REDACTED], Record Department Head, stated that Mr. [REDACTED] was not admitted to the hospital as an in-patient. He was brought to [REDACTED] emergency room and transferred to [REDACTED] with his records, on 4/16/98.

On 5-21-98, I visited [REDACTED] and obtained the patient's death certificate, medical board summary, progress notes, and laboratory tests. These records were obtained from Ms. [REDACTED] Record Department Head. The Mortuary Affairs Head, [REDACTED] stated that Mr. [REDACTED] family decided against an autopsy, therefore, no medical examiner was involved. The Records Release Assistant, Ms. [REDACTED] stated no summary had been dictated regarding the doctor's narrative/physician order, however, she is attempting to reach Dr. [REDACTED] to finish the dictation and will contact me when completed

On 5-27-98, I sent the medical records that were currently available from [REDACTED] and will forward the physician summary when it is completed.

Steven J. Thurber
Steven J. Thurber, CSO

Attach: Assignment Request CFSAN ARMS #12859, Adverse Event Questionnaire, labeling copy, Consumer Complaint Form 2516, Consumer Complaint F/U Form 2516a, death certificate, medical records.

O. HFS-636 / cc: BLT-DO [REDACTED]

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