

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

ARMS#

13266



0 - FRONT

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

I called reporter - product is supplement - bought at health food store on muscle medicine
 For VOLUNTARY reporting by health professionals of adverse events and product problems
 FDA Use Only H Pad
 Triage unit sequence # **94565**
13266

CFSAN

Page **CFSAN** of **CFSAN**

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
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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 type="checkbox"/> death	<input type="checkbox"/> disability
<input checked="" type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" 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) **11-7-98**

4. Date of this report (mo/day/yr) **12-11-98**

5. Describe event or problem

patient presented unresponsive to painful stimuli and with minimal respiratory drive. Unresponsive to naloxone. Relevant labs below.

? diabetic ketoacidosis
 hyponatremia
 renal insufficiency
 unconscious state) No hypoxic encephalopathy

obesity w/ recent wt loss
 upper GI hemorrhage
 ephedrine use
 Bronchospasm
 ? seizure
 pancreatitis -> drug induced?

Patient transferred to different facility

6. Relevant tests/laboratory data, including dates

12/6/97/27	WBC 21.5
4.6 8/23 444	pH 7.04
myoglobin 5834	Bicarb 4
troponin 0.3	

tox screen - negative

amylase 795

1. pape 478

urinalysis
 -> (+) ketones
 (+) protein
 (+) blood
 (+) glucose

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

Ø allergies
 hispanic-american
 Ø smoker
 Ø alcohol use
 Ø illicit drug use
 ml health until this event

C. Suspect medication(s)

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

#1 **Hydroxycut (ephedrine, caffeine)**

#2 **Hydroxycitric acid**

2. Dose, frequency & route used

#1 **unknown**

#2 _____

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

#1 **unknown**

#2 _____

4. Diagnosis for use (indication)

#1 **weight loss - diet aid**

#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 **unknown**

#2 _____

7. Exp. date (if known)

#1 **unknown**

#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)

NONE

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)

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E. Reporter (see confidentiality section on back)

1. Name, address & phone #

2. Health professional? yes no

3. Occupation **Pharmacist**

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

CTU 94565

Adverse Event Questionnaire

Complaint Number: ARMS 13266

Investigator: GJHeidenblut

Consumer Information

Date of Report: 03/05/99
MM/DD/YY

Initial Report Source: ORA Consumer Injury

Telephone Correspondence MedWatch
USP PQRS Poison Control CDC

Name: [REDACTED]

Gender: F M Age: 19

Race: 1-White 2-Black 3-Asian/Pacific Islander 4-Native American 5-Hispanic
8-Other 9-Unknown

Attachment 1/ Page 1 of 2
CFSAN ARMS PROJECT 13266
3/5/99 GJH

Information on Adverse Event

Date of Adverse Event: 11/7/98
Previous Adverse Effects to Product Type:
Yes No

Give the site of consumption/ingestion (e.g. home, restaurant, office):
college residence

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):
Had been on product for about 3 months losing 40 lbs. Complained of polyuria about 1 week before event. Was found unconscious 11/7/98 See att 6 page 3 for hosp. diag. (DKA, coma, etc.)
How long did the symptoms last? realesed from [REDACTED] 12/31/98
Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.): Patient claimed started taking product 3 mos. prior event. Was taking 8 caps/day 7 days/wk. (During interview initially said was taking 4 caps 3X a day-then said only 8/day.

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

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

1. [REDACTED] 2. [REDACTED] 4. [REDACTED] (outpat.)
Was a health care provider seen?: Yes No
Give health care provider's name, address and telephone number (rehab.): [REDACTED]

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

What medical tests were performed and what were the results? Medical records included as att. 5/9.

What was the medical diagnosis? See att. 6 page 3 for initial; final diag: encephalopathy
What treatment(s) was given (e.g., drugs, other)? see medical records

Were there any preexisting condition(s)/treatment(s)?
(If YES, list them including allergies, and chronic diseases): Yes No

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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): _____

Attachment 4 Page 2 of 2
CFSAN ARMS PROJECT 13266
3/5/99 GJH

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):

Hydroxycut Capsules 4 caps/2 x daily before morning and afternoon meals. Do not take more than 5 days per week. Dietary Supplement. Muscletech Research & Development. address not listed

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

Check here if ingredients are unknown

4 caps les contain: Hydroxagen 2,000mg (1000 mg hydroxycitric acid); MaHuang Extract 334mg; / (standardized for 6% ephedra) Guarana Extract 910 mgs (standardized for 22% caffeine); Willow bark extract 100mg (standardized for 15% salacin); L-Carnitine 100 mgs.; Chromium Picolinate 300 mgs.

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

- Aspartame
- Monosodium Glutamate
- Sulfite
- Other _____
- 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: encephalopathy
(If yes, include pertinent medical records)

Death: Yes No

Life-Threatening: Yes No

Hospitalization: Yes No (if YES, indicate if initial or prolonged) prolonged _____

Required intervention to prevent permanent impairment/damage: Yes No

Did the adverse event result in a congenital anomaly: Yes No unknown at this time

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Memorandum

Date 3/5/99

From GJHeidenblut
[REDACTED] HFR-CE4535

Subject CFSAN ARMS Project 13266

To Bridgette Wallace (HFS-636) through
GWCartwright (HFR-CE4530) *GWC 3/18/99*



In response to CIN assignment 147 dated 2/25/99 (DD assignment 99-56), I visited the patient to obtain Adverse Event Questionnaire information, and to obtain signed medical records release (FDA 461). An appointment was made with Mr [REDACTED], on 3/3/99 for a visit the following morning. On 3/4/99 I met [REDACTED] and his son [REDACTED] (age 19) at their residence. [REDACTED] was the subject of the Med Watch report.

The following is a general summary of events:

[REDACTED] age 19, is a sophomore at [REDACTED]. His residence there is [REDACTED]. According to [REDACTED] he had begun a diet approximately 3 months prior to the 11/7/98 incident. He had read about "Hydroxycut" in a muscle building magazine. He purchased the supply of product from [REDACTED]. He used the product for about 3 months and had lost about 40 lbs. During the interview he initially said he took 4 tablets three times a day (12), but latter said he took 8 tablets total daily. I asked him how many days a week he took the product and he said DAILY. Label directions say not over 8 tablets a day, with a maximum of 5 days a week. On about 11/4/98 he began feeling poorly. His mother had set up a doctor's appointment at the family doctor the following Monday, 11/9/98.

[REDACTED] said prior to the event he had become extremely thirsty and was consuming a large amount of soft drinks the week of the event. He said he was frequently urinating and had a fruity taste in his mouth. He felt worse as the week progressed. On the evening of 11/7/98 he was found unconscious on the bathroom floor of his residence in [REDACTED]. He was taken to [REDACTED] and was subsequently life-flighted to [REDACTED] on 11/8/98. Records show he was [REDACTED] from 11/8-12/9/98. His assessment at [REDACTED] on 11/8 was 1. Diabetic ketoacidosis; 2. Altered mental status, coma; 3. Pancreatitis; 4. Hepatitis; 5. Acute renal failure insufficiency; 6. Rhabdomyolysis; 7. Upper GI bleeding; 8. Hypokalemia; 9. Mediastinal free air. According to [REDACTED] father he was in a coma for 10 days.

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On 12/9/98 he was transferred to [REDACTED] for rehabilitation. He remained there until 12/31/98. His discharge summary listed: 1. Hypoxic encephalopathy; 2. Rhabdomyolysis; 3. Pancreatitis; 4. Improved activities of daily living, mobility, and cognitive level.

[REDACTED] is currently going to [REDACTED] for outpatient rehabilitation. Additionally he sees his family doctor, [REDACTED] as needed. His current diagnosis is encephalopathy.

[REDACTED] hopes to return to [REDACTED] this summer.

Signed FDA-461's were obtained from [REDACTED] and the following locations were visited for medical records:

1. [REDACTED]
2. [REDACTED]
3. [REDACTED]
4. [REDACTED]
5. [REDACTED]

The consumer sample was to be collected, however [REDACTED] said he had dumped out the contents. The empty bottle was provided to obtain a copy of the label. It is to be returned to Mr. [REDACTED] Bridgette Wallace (HFS-636) was called on 3/4/99 and advised a sample was not available from the complainant.

Attachments:

1. Assignment 147 dated 2/25/99 with MedWatch report.
2. Assignment update 3/2/99 assigned log number 99-56.
3. Labeling
4. Adverse Event Questionnaire.
5. [REDACTED] Documents.
6. [REDACTED] Documents
7. [REDACTED] Documents
8. [REDACTED] Documents
9. [REDACTED] MD. Documents
10. Signed FDA-461.


Gilbert J. Heidenblut

Distribution: O: HFS-636 w/att; CIN w/att; [REDACTED] w/att; [REDACTED] w/o att; R/F w/o att.

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TO: Lori Love, M.D., Ph.D.

FROM: Constance J. Hardy



DATE: 7/8/99

SUBJECT: AER13266

This memo is being written to document an attempt to clarify usage of the product Hydroxycut by Mr. [REDACTED] (AER 13266—unresponsive to painful stimuli and minimal respiratory drive). I was able to contact his mother Mrs. [REDACTED] who told me that her son was continuing to have residual physical and psychological problems since being released from a rehabilitation center; this has resulted in her contacting appropriate specialists for additional evaluations. Mr. [REDACTED] was not at home but his mother will relay my message and be able to tell me tomorrow as to when he will be home so that I can contact him.

File: c [REDACTED]

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TO: Lori Love, M.D., Ph.D.

FROM: Constance J. Hardy



DATE: 7/14/99

SUBJECT: AER 13266

I spoke via the telephone to Mrs. [REDACTED] the mother of the patient [REDACTED] on 7/13/99 as to her recollection of her son making two different statements concerning his use of the product Hydroxycut. She stated she remembered that her son had been interviewed by Gilbert J. Heidenblut, FDA investigator, but at the time, [REDACTED] was still in rehabilitation and sometimes was confused and did not always respond consistently to questioning. She stated that after talking to me on 7/8/99, she had talked to her son about his usage of the product and he had stated that he had consumed 4 capsules two times per day, once in the morning and once in the afternoon. I then spoke to [REDACTED] and he confirmed his mother's statement in that he had followed the directions and took 4 capsules, two times per day, once in the morning and once in the afternoon, for a total of 8 capsules per day.

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