

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

ARMS#

13344



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MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

MEDWATCH Form

APPENDIX

Appendix

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

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

FDA Use Only (AHFS)

Trace unit sequence #

96878

Y13344

Page 1 of 2

CFSAN

CFSAN

A. Patient information

1. Patient Identifier [Redacted] In confidence	2. Age at time of event: or Date of birth: [Redacted]	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight [Redacted] lbs or 60 kgs
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B. Adverse event or product problem

1. <input checked="" 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 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) 01/18/99	4. Date of this report (mo/day/yr) 01/20/99

5. Describe event or problem

51 year old male admitted to hospital comatose but unresponsive after having seizure-like activity. Patient reports "feeling funny" and having shaky hands on admission, pupils were reactive but dilated. Patient reports taking Hydralazine* 12+ tablets daily for the past few weeks. Required intubation and 2 day stay in intensive care unit.

6. Relevant tests/laboratory data, including dates

normal CSF on lumbar puncture
alcohol = 10
acetylaminophen 110
salicylate = 0
drugs of abuse screen all negative
ABG 7.45/38/558 on 100% FIO2
no arion gap; no osmolar gap

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

previously healthy
Ø medications
Ø allergies

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 Hydralazine, Muscle Tech	
#2	
2. Dose, frequency & route used	
#1 12 tablets/day	
#2	
3. Therapy dates (if unknown, give duration) (month for best estimate)	
#1 "a few weeks"	
#2	
4. Diagnosis for use (indication)	
#1 muscle building	
#2	
5. Event abated after use stopped or dose reduced	
#1 <input checked="" 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	
6. Lot # (if known)	
#1 not known	
#2	
7. Exp. date (if known)	
#1 not known	
#2	
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 type="checkbox"/> 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	
REC'D. FEB 03 1999	
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 # MEDWATCH CTU	
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)	

E. Reporter (see confidentiality section on back)

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

Severe adverse effects



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

OR FAX to:
1-800-FDA-0178

FDA Form 3500 (8/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

000001

CTU 96878

Hydroxycut by Muscle Tech contains

1. hydroxagen 2000mg (hydroxy citric acid 1000mg)
2. mahuang extract 334mg (6% ephedra)
3. guarana extract 910mg (22% caffeine)
4. willow bark extract 100mg (15% salicin)
5. L-carnitine 100mg
6. chromium picolinate 300mg

99 FEB 22 A8:52

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& REVIEW/OSM FFS-11

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8:18:18

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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



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

FDA Use Only

Triage unit sequence # 97236 133A
13354

Page ___ of ___

CFSAN

A. Patient information

1 Patient identifier  2 Age at time of event: 21 or Date of birth:  3 Sex female male 4 Weight 170 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)

death (mo/day/yr) disability congenital anomaly required intervention to prevent permanent impairment/damage life-threatening hospitalization - initial or prolonged other

3 Date of event (mo/day/yr) 1-18-99 4 Date of this report (mo/day/yr) 2-1-99

5 Describe event or problem

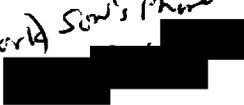
As a result of taking "HYDROXYCUT" the son went into Toxic Shock/Toxic Ingestion. As a result he went into a seizure and became unconscious and very combative. Because he was so combative, he was placed in a medically induced coma until all drugs associated with this product were out of his body. He remained unconscious for 2 1/2 days! Upon consciousness, he suffered severe headaches for approx 9 days & short term memory has not completely returned as of this date. If not with people, could have resulted in a life threatening situation!

6 Relevant tests/laboratory data, including dates

All CAT scans, MRI, blood tests, spinal tests were negative.

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

NONE

(Work) Son's phone 

CTU 97236

C. Suspect medication(s)

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

#1 HYDROXYCUT (thermogenic Formula)

#2

2 Dose, frequency & route used

#1 8 capsules per day

#2

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

#1

#2

4 Diagnosis for use (indication)

#1 Used to build muscle & reduce body fat

#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 37745

#2

7 Exp. date (if known)

#1 04/00

#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)

thera-flu was taken approx. 4 days prior to incident.

D. Suspect medical device

1 Brand name

Advanced Thermogenic Formula

2 Type of device

Muscle Building Product

3 Manufacturer name & address

MuscleTech Research & Development Inc.
1-905-678-3114

4 Operator of device

health professional lay user/patient other

5 Expiration date (mo/day/yr)

04-00

6 model # REC'D.

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)

000003

E. Reporter (see confidentiality section on back)

1 Name, address & phone #



2 Health professional? yes no

3 Occupation Computer Specialist

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

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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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CLINICAL RESEARCH
& REVIEW/GEN. HES. B.



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

000004

TO: Lori Love, M.D., Ph.D
FROM: Constance J. Hardy *CJH*
DATE: 6/9/99
SUBJECT: ARMS 13344—additional consultation with the patient

On June 9, 1999 I spoke to [REDACTED] the patient reported in ARMS 13344, to clarify his usage of the product Hydroxycut. [REDACTED] stated he had been taking the product for about 6 months and usually took 4 capsules in the morning and then 4 in the afternoon. He verified that he had a cold just prior to the event and that he had been taking Theraflu but had stopped taking it on Friday, 1/15/99. He could not remember whether he had taken Advil as noted in the medical record, but he stated that if he had, the intake of the Advil was not on a consistent basis. He stated he remembered this distinctly because he only used the product while at work. He stated he "was not thinking properly" during the weekend of the skiing trip/event (1/16/99-1/17/99) but he did not feel that it could be described as a headache.

File name:c:\connie\ephedrafu\fu13344.doc

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