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

ARMS#

13344

6 - MD NOTES

[redacted]

[redacted]

MICU-[redacted]

HISTORY AND PHYSICAL EXAMINATION

Date: 1/18/99 AH: [redacted]
Res: [redacted]

[redacted]

Please use Addressograph Plate

CC: unresponsiveness

HPI: 22 y/o W ♂, previously healthy, presented to [redacted] ED after a day of "acting funny" and an seizure-like episode, and was combative while on a bus from [redacted] According to family pt had been taking an OTC metabolic enhancer called Hydroxycut for a few weeks (Had taken it before but stoped per family). Pt's family also report No known drug abuse and occassional Etoh use. There is Ø FH seizures or pt h/o seizure. Pt's father says 3 days PTA pt was c/o HA/fatigue and did not come to work but decided to attend ski trip over the weekend. He also c/o not feeling well, "feeling weird" and having shakey hands.

The constituents of the Hydroxycut include caffeine, Mahuang (ephedra) Cevarana (caffeine), hydroxagen, Willow Bark extract, L-carnitine, and Chromium Picolinate.

In ED pt was combative; pupils dilated sedated and intubated, paralyzed and received charcoal, IVF, monitoring LP..

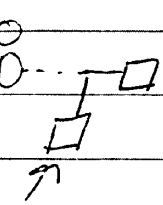
PMH: Ø
broken nose ⊼

PSH: Ø

A: NKDA

M: Hydroxycut (12+ tablets/day
1 Hydroxagen 2000 mg (1000 mg hydroxycitric acid)
2 Ma Huang extract 334 mg (ephedra)
3 Cevarana extract 910 mg (caffeine) 6%
~~4~~ (22% caffeine)
4 Willow Bark extract 100 mg (15% salicin)
5 L-Carnitine 100 mg
6 Chromium Picolinate 300 mg

SH: lives c̄ a friend in [redacted] works for Dad, very active in sports (hockey, ski club president) occ Etoh, Ø IVDA known

FH  Ø SZ
⊕ Heart Disease maternal

ROS - unattainable.

000002

PE

VS - BP - 140/72 P-83 - R-.
SaO2 - 100% 363 - T

gen - sedated, intubated WM
pale apearing

HEENT - NC/AT PERRL (5 mm (B))
NGT in place, ETT in place
Ø TM, Ø LAD, Ø JVD, trachea
midline.

Resp - equal expansion (B)
(+) BS (B), Ø wheeze/ronchi

Abd - flat, (+) BS, Ø HSM
soft.

CV - RRR, Ø m/r/g

Ext - 2+ distal pulses, ØC/C/e
(L) ankle tattoo, erythema
(B) ankles/wrists

Rectal - Guaiac (-), no tone

Neuro - unresponsive to
verbal or painful stimuli.
moves all extremities.

ABS - 143 | 104 | 9 147 | 8.6
(3.2) | 26 | 1.0 | 1.9
(1.8)

AIG - 4.4 CK (324)
TB - 0.7 Osm - 293 Calc 297
AØ - 115 AG - 13
AST - 23 PT/PTT
ALT - 32 19.3/28.2

14.6
6.2 / 41.9 305

Etoh <10, Acet <10, Sal 0
Tox Screen (P)

ABG 7.45/38/558 100% FiO2

CXR ne Ø infiltrate

CSF - gluc 72
prot 56
tube #1 34 RBC, 4 WBC, 4 Seg, 18 Lymphs.
tube #2 1 RBC, 1 WBC.

Head CT - Ø evidence SAH,
Mass

EKG - age apropriate LVH

A/ 22 y/o WM c̄ h/o caffeine/tex in
ingestion who presents
with unresponsiveness and
combativeness and
questionable h/o SZ.
Ø evidence of tacharrythmia,
hypotension, cerebral bleed,
infection (per CSF), pul-edema.
Ø evidence of other ingestions
at this time. Seen by
neurology in ED who did not
recomend emergent EEG

P/
① Resp - cont mech vent, protect airway tonight.
② CV - monitor EKG, VS
③ F/E/N - repeat Kt, Phos
IVF - 1 L bolus followed
by 150 cc/hr D5NS c̄ 20 mg Kt
NPO
④ Neuro - Sedatation - ativan 2 mg/hr
+ seizure prophlaxis.
- follow MS
- consider EEG in am
- tox screen (P)

[redacted]

000003

[redacted]

[redacted]

HISTORY AND PHYSICAL EXAMINATION

Date: 1/18/99

[redacted]

[redacted]

HPI: Pt is a 22 y.o. WM c̄ ø PMH who presented p̄ becoming unresponsive p̄ a ski trip. Pt had been feeling poorly 3d PTA c̄ tremors, Nausea → went skiing + on the bus on the way home p/c unresponsive s̄ tonic/clonic movements but c̄ loss of bladder continence + foaming at the mouth. ? duration. When [redacted] got there he was combative c̄ dilated but reactive pupils. In ED intubated for airway protection. ø known drug ingestion x̄ "Muscle Tech-Hydroxycut Formula" which contains ephedrine + caffeine. ø "lo sz, DM, drug abuse. Denies F/C/N/V/D/C/CP/SOB by friends c̄ him → hadn't been himself today, but nothing specific

PMH
ø

NKDA

Meds
Hydroxycut - 12 tabs qd
Hydroxagen 2000mg
- ? antioxidant
Mahuang - 334mg
- ephedrine
Cevarana 910mg
- caffeine
22% Caffeine
Willow Bark 100mg
- ? salicylate
L-Carnitine 100mg
Chromium Picolinate 300mg

SH - Lives in [redacted] works for father. Very athletic. ø tob, drugs. Very occ ETOH. Big baseball, hockey player

FH - heart dz

ROS - unattainable other than HPI.

000004

VE - T 36° BP 174/72 P83 RIC
Sat 100%
Gen - Intubated, sedated.
Purposeful movements c̄
touch.
HEENT - NCAT. Pupils dilated
+ minimally responsive
NG in place.
Neck - supple ŠLA
Lungs - CTA (B)
Heart - RRR c̄ NL S1 S2
ØM/R/G
Abd - soft, NT, ND, (+) BS,
(-) HSM
Ext - (-) C/C/E. DP/PT 2+ (B)
Neuro - Nonfocal

Labs

143	104	9	147	8.6
3.2	26	1.0		1.9
				1.8

CK 324 ALT 32
Alb 4.4 SOsm 293
TB 0.7 EtOH <10
AØ 115 Acet <10
AST 23 Sal 0

ABG 7.45/38/558
14.6
6.2 305
419
PT/PTT 14.3/28.2
UA - 5.0, 1+ prot, gluc (-)

EKG - NSR, QTc NL
CSF -

Tube 1	Tube 4
RBC 34	1
WBC 4	1
Gluc 72, Prot 56	

CXR - ØACPD

CT head - ØBleed or any
Abnormality

HP - 22 y.o. WM c̄
unresponsive episode
now intubated, sedated.
Most likely 2° to drug
ingestion (probably
Muscle Tech formula)
but drug screen (B)
Ø AG acidosis, so will
initiate supportive care
c̄ IVF, ventilatory
support (only for
airway protection)
- Drug Screen
- Monitor hemodynamics
- Reassess need for
ETT tomorrow
- Given drip for
sedation + SQ
prophylaxis
- Neuro consult

[redacted]

000005

[redacted]

[redacted]

HISTORY AND PHYSICAL EXAMINATION

Date:

Please use Addressograph Plate

(I have seen, [illegible], I agree: [illegible] [redacted]

1/19/99 Pt [illegible] Δ 22 yr. [illegible] over the [illegible] meds. He [illegible] [illegible] after [illegible]. Cm to [illegible] c̄ ↓ cors, [illegible], [illegible] [illegible].

- New [illegible]
- Reports very little ([illegible], [illegible])
- [illegible] [illegible] [illegible]
- [illegible] [illegible] [illegible]
- [illegible] [illegible]

(Ag) - Certainly, [illegible] [redacted]
- Agree: New [illegible] -
- [illegible] [illegible]
- [illegible] [illegible] [illegible]
  [illegible] [illegible] [illegible]

[redacted]

000006

[redacted]

PATIENT IDENTIFICATION

[redacted]

DATE	TIME	
1/19/99	02:30	Respiratory Care Note
		P6 arrived in [redacted] cu intubated c #8 ETT taped 22 cm
		@ lip. He was placed on 900E Servo @ 30% /PSV 6/+5
		V_T 500-800cc RR 18-20 (when quiet) Sats 100%. B/S CTA
		(B). Plan is to evaluate for extubation in am, maintain
		support overnight, contact HO of Δ's
		[redacted]
1/19/99	925	MICU [redacted]
		s/ overnight remained sedated, agitated when stimulated.
		Father visited, Spiked F (ox sent)
		O/VS- BP= 100-177 / 50-93 HR-113-124 RR-8-18 Tm 38.5 SaO2 100
		Tc 37.5
		sent - PS 6 FiO2 30% TV 527-818 PEEP-5
		I/O q 8° 2170/900 + 1200
		gen- sedated/intubated
		HEENT- PERRL 4 mm
		CV - RRR, ø m/r
		Resp - CTA (B)
		Abd - soft, (P) BS
		Ext - 2+ pulses, ø edema
		neuro - responds to painful stimuli semi-purposefully
		↓ plantar reflexes; 12+ 2+ 3+ 3+
		000007
		LABS -
		141 | 108 | 7 (135) | 7.5 → corr. 8.68
		3.8 | 27 | 0.9 | 1.6 / 2.0
		CPK - 713 (324)
		10.2 | 12.2 | 292 / 35

Alb - 3.4 (4.4)	Thyroid (P)
TB - 0.5	Tox Screen (P)
CB - 0	UCx (P)
AØ - 81	Umgb (P)
AST - 27	
ALT - 67	UA - 1025, 6.0
	small blood, 9 RBC's ⊖

[redacted]

PATIENT'S PROGRESS NOTES

[redacted]

DATE	TIME	
1/19/99		MICU PN cont -
		Labs cont:
		PT/INR/PTT
		13.1/1.2/27.6
		A/ 22 y/o WM c̄ h/o toxic ingestion and acute psychosis/delirium c̄ psychomotor agitation. Has remained hemodynamically stable and sedated.
		P/ ① Resp - c̄ ↑MS d/c mech. vent.
		② CV - cont monitoring
		③ GI - sorbitol to ↑ BM (clearance)
		④ F/E/N - repeat Ca^{2+}, Phos
		IVF - ~~½L~~ bolus followed by 200 cc/hr saline
		will follow UO; ~~goal 2-4 ml/kg/hr~~
		⑤ Renal - ✓ UMg6; CK↑ may be 2° SZ vs activity (R/O rhabdomyolysis); will follow
		⑥ Neuro - follow MS; cont restraints
		- get additional h/o @ wkd activity/behavior/co-ingestions
		- neuro consult M. SSG, etc.
		- mean sedation; Δ to PRN ativan.
		[redacted]
		000008

PATIENT'S PROGRESS NOTES

[redacted]

PATIENT IDENTIFICATION [redacted]

DATE	TIME	
19 Jun 99	Neuro Staff 1025	See consult sheet
		Healthy ♂, body builder, with acute encephalopathy 5 focal / lat signs. CT nl, CSF c̄ mild ↑ protein, no lat abnl.
		My exam today, just being weaned from sedation. Looks asleep, follows no commands resists all manipulation, fighting restraints. Reflexes brisk, crossed adductors, toes ↓↓.
		Imp: Encephalopathy ? etiol.
		1) drugs – his "herbs," androgenic steroids (either from use or withdrawal), caffeine, illicit drugs.
		Would also vigorously pursue use of "cold" remedies or weight loss drugs containing phenyl propanolamine that can cause CNS vasculitis.
		2) seizure – perhaps frontal lobe, but not likely
		3) encephalitis.
		EEG, MRI MRA + further Hx would be valuable.
		Will follow with you [redacted]
1/19/99	17:30	Social work Note
		[redacted] introduced self to pt + family, pt asleep at present. Discussed family plans to stay in [redacted] motel close to hospital. Offered support. MSW will f/u as needed [redacted]

000009

[redacted]

PATIENT'S PROGRESS NOTES

DATE	TIME	
1/19/99	0730	[redacted] ICU Nursing Note Pt to URI / MRA @ 1900 sedated c̄ propofol, results sending. Sorbitol, Mg citrate, Bisacodyl, MOM resulting in very large liquid stool. Pt. Ex. M_6V_T not appropriately on PS ventilation. Please see CCPS and assessment for details.
1/20/99	0915	MSPN MICU-

S: Overnight pt remained quite sedated (on propofol for MRA, Ativan dc'd 1/19 am) but this am awakened to command. Pt had large BM. Of note - additional hx pt had also been taking several cold medicines (OTC - Advil cold + sinus, etc) for cold sx.
Also, pt has had surgery (yrs ago) a nasal septum repair for which his family states took him an unusually long time to recover from anesthesia.

O: VS- P 60-85 BP- 100-117 / 34-58 T-37' R-6-18 SaO_2 98-100%
I/O q 8° 1880/1743 q 24° 8967/7220 wt 88.3
Vent: overnight: F_1O_2 30% IMV/PS PEEP 5 PS 10
PE:
gen: awake, responsive (pt now extubated, sleeping)
CV: tachycardic, Ø m/r/g
Resp: CTA (B), Ø wheeze
Abd: flat, soft, nt, (+) BS
Ext: 2+ distal pulses, Ø edema
Neuro: pupils equal, RL, ~4 mm (B)
moves all ext
follows commands, responds to family/jokes/etc.

Labs: ESR 10
T_4 (3.4) ↓
TSH 0.92
T_3U (45%) ↑

138 | 104 | (4) (170)
4.5 | 27 | 0.7

(P) 5.9 | 13.7 / 277 / 38.9

(P) 1.7 / 1.9 / (2.2)

AG - 80
ALT - 27
AST - 33
A10 - 4.0
TB - 0.8 CB - 0.0

000010

PATIENT'S PROGRESS NOTES

[redacted]

PATIENT IDENTIFICATION

[redacted]

DATE	TIME	
1/19/99		MICU cont –
		HSV, PCR CSF (P)
		Cx – Urine / CSF / Blood all negative
		Studies:
		1/19/99 EEG – Ø focal findings, Ø evidence of seizure activity; global slowing consistant c̄ sleep / BDZ, awakens c̄ stim
		1/19/99 MRI – formal reading (P) ⇒ normal preliminary Ø acute processes
		A/ 22 y/o WM hosp day #3 for toxic ingestion caffeine / ephedra c̄ question of CNS vasculitis (Rx'd overnight c̄ one dose of methylprednisolone.) However, pt's responsiveness this am combined c̄ nonconclusive MRI as well as hx of pt's slow clearance of BDZ lead us to ↓ suspicion of vasculitis. (Will not pursue A-gram)
		P/ Continue supportive care
		D/C IVF when pt taking PO
		cont pepcid, ~~sorbi~~
		will follow MS today
		plan D/C to floor or home tomorrow
		[redacted]
		000011

[redacted]

PATIENT'S PROGRESS NOTES

[redacted]

PATIENT IDENTIFICATION

[redacted]

DATE	TIME	
		1/20/99 S: Nurse sees [redacted] pt S: Pt's Mr. [redacted] [redacted] Pt new ventilator, asleep but was cooperative & [illegible] Lungs clear to ausc - CV [illegible] - Abd soft - Ext - no edema but reports to feeles painful B/S observed [redacted]
1/20/99	1130	Respiratory Care Pt extubated this am from [illegible] 30. BIL b. Nasal. Pt extubated & distress on placed on RA. O2 Sat - 96% - 98%. Pt c̄ strong nonproductive cough. Pt able to vocalize well. will follow.
		[redacted]

000012

[redacted]

PATIENT'S PROGRESS NOTES

DATE	TIME	Nursing Tx note [redacted] ICW
1/20/99	1200	Mr. [redacted] is a 21 yr old who had seizure like
		episode on 1/18. Taking OTC Metabolic enhancers.
		Ø allergies. Ø PMH. Pt extubated this am @ 0800
		Sats 99%. Ø O_2 on Pt. RR 14-16 CTA. Pt hard to arouse
		@ this time. did squeeze fingers. Mumbled a few words.
		[redacted]. Unable to check pupils - Pt not allowing RN to
		open eyes. Pt continued this way until 7130 Pt awake
		to speech. Was carrying on full conversation with
		neuro consult team. Confused about happenings
		of previous days. Pt tried to sit up c/o feeling light
		headed and dizzy. Pt remained in bed.
		VSS. afebrile. HR 80's. BP 95-110. (+) pulses. w/D. Ø edema.
		(L) PIV C/F. (R) PIV w .45 NS 20kcl @ 150cc/hr. Titrate as
		Pt ↑ fluid intake. to normalize for Pt to go home —
		Am Lab Phos ↓. Service aware. Can eat @ tolerated.
		Pt swallowing liquids w/o difficulty. foley draining
		over 200cc q 1-2°. Clear yellow. Derm intact.
		family - mom, dad, stepmom - all at bedside.
		Supportive. May request addictions consult for
		Pt today - or before d/c. Plan. Resp monitoring
		Post extubation. Tx to floor. [redacted]
	*	family states Pt hard to arouse from sleep normally.
		Has 2-3 alarm clocks and still oversleeps [redacted]

000013

PATIENT'S PROGRESS NOTES

[redacted]

PATIENT IDENTIFICATION

[redacted]

DATE	TIME	
		1/21/99 Attending
		I have examined pt
		I Agree to [redacted] ; [illegible]
		& [illegible] [redacted] [illegible]
		- Pt feels well.
		- Realizes that short term memory is [illegible]
		[illegible]
		[illegible]
		- [illegible]
		Pls ① [illegible]
		② NO MEDS
		③ Pls [illegible] DL [redacted]
		[redacted] [illegible] short term memory
		[illegible] it will clear
		[illegible] NUGOS [illegible]
		[redacted]

000014

[redacted]

PATIENT'S PROGRESS NOTES

[redacted]

PATIENT IDENTIFICATION

[redacted]

DATE	TIME	
1/19/99	925	Discharge Summary —
		Admit Date: 1/18/99
		Admit Diagnosis: Unresponsiveness
		D/C Date: 1/21/99
		D/C Diagnosis: Toxic Ingestion
		Admit Service: MICU
		AH: [redacted] Res: [redacted] [redacted]
		Presenting illness: See admit H&P for additional details. Briefly, this 22y/o previously healthy WM was brought to [redacted] ED after "acting weird" x 1 day, questionable seizure activity, confusion and unresponsiveness. Pt has h/o ingesting Hydroxycut x 2 wks, a metabolic enhancer product containing caffeine, ephedra, L-carnitine, chromium picolinate, hydroxycut, and salicin as well as some OTC cold medicines 3 days prior to adm and ~~stop~~ been feeling unwell c̄ sx of nausea/HA/tremulousness. At [redacted] pt was sedated, intubated for airway protection and was ~~not~~ hemodynamically ~~unstable~~. Pt was transferred to MICU after head CT, LP performed
		Hospital course - Pt was monitored, received IVF, sedation with ~~Ativan~~ drip, mechanical ventilation, sorbitol and pepcid. On the am of 1st hospital day pt was not arousable and mechanical vent was continued and EEG and MRI were performed (CT was performed in ED.) EEG did not show seizure activity MRI

[redacted]

D/C Sum cont

DATE	TIME	
1/21/99		showed no abnormalities. One dose of methylprednisolone was administered that pm in case of CNS vasculitis. This was dc'd in am when pt became arousable. On third hosp day pt remained on minimal vent settings and followed commands and was subsequently extubated. Pt became fully awake and conversant two hrs later with Ø c/o pain and no memory of previous days event. The afternoon of third hosp day pt was transfered to the floor. Pt was stable overnight, complaining only of sore throat, cough, weakness.
		Consults: neurology, addictions
		Summary of Studies/Labs:
		1/18/99 Head CT WNL CXR WNL, EKG LVH, NSR
		1/19/99 EEG Ø abnormalities
		1/19/99 MRI Ø abnormalities.
		On adm -
	1/18.	143 | 104 | 9 147 | 8.6 1.9 (3.2) | 26 | 1.0 | (1.8) — CSF gluc 72 prot 56 tube #1 34 RBC, 4 WBC tube #4 1 RBC, 1 WBC
		A16-4.4 TB-0.7 AØ-115
		AST/ALT 23/32 — Tox Screen - negative
		AG-13
		Osm-293 — ESR-10
		PT/PTT 14.3/28.2 6.2 14.6 41.9 305 UCx, BCx, CSF Cx (-)
		D/C PE -
		VS - T-365 p 77 R 24 BP 120/74 SaO_2 99% RA
		gen - well developed WM in NAD, awake.
		HEENT - NC/AT, PERRLA, ØLAD, ØTM
		Resp - CTA (B) Ø wheeze
		CV - RRR Ø M/r/g
		Abd - soft, (+) BS, nt
		Ext - 2+ distal pulses Ø edema/cyanosis
		Neuro - A&O x 3, ne strength throughout
		DTR's 2+ throughout, ↓ plantar reflexes.

000016

PATIENT'S PROGRESS NOTES

[redacted]

PATIENT IDENTIFICATION

[redacted]

DATE	TIME	D/C Summ Cont -
		D/C Labs - 138 | 104 | (4) 170 | 8.7 | 1.9 | (2.2) 5.9 | 13.7 | 277 | 38.9
		4.5 | 27 | 0.7
		AP - 80 A16 - 4.0 TSH 0.92
		ALT - 27 TB - 0.8 T4 (3.4)
		AST - 33 CB - 0.0 T3U (45%)
		HSV 1 PCR (P) (send-out)
		D/C Meds - none
		D/C Instructions - F/U c̄ PCP Dr [redacted] x1wk
		Return c̄ Δ MS/severe HA
		Resume Reg diet.
		Avoid cont. stimulant ingestion
		D/C to home.
		[redacted]

PROGRESS NOTES

000017

[redacted]

PATIENT'S PROGRESS NOTES