CFSAN 159451

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

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Form Approved: OMB No. 0910-0291. Expires: 10/31/08
See OMB Statement on reverse.

FDA USE ONLY
Triage unit sequence #: 494807

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
In confidence	15 Years	☐ Female ☑ Male	140 lb or ___ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☑ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
☐ Death: ___ (mm/dd/yyyy) ☐ Disability or Permanent Damage
☐ Life-threatening ☐ Congenital Anomaly/Birth Defect
☐ Hospitalization - Initial or prolonged ☑ Other Serious (Important Medical Events)
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
10/29/2012	11/19/2012

5. Describe Event, Problem or Product Use Error

My son was given a preworkout product called Craze. WHen I found him unconscious and unresponsive, I had no idea what had happen. He was taken by EMS to the hospital and after CAT scans and many tests. It turned out that the product he drank tested positive to amphetamine and his diagnosis was, syncope, dehydration and amphetamine reaction.

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6. Relevant Tests/Laboratory Data, Including Dates

amphetamine -posiive

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7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

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C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)
☐ Yes ☑ No ☐ Returned to Manufacturer on: ___ (mm/dd/yyyy)

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer (from product label)
#1 craze preworkout
#2

2. Dose or Amount	Frequency	Route
#1		
#2		

3. Dates of Use (if unknown, give duration) from/to (or best estimate)	5. Event Abated After Use Stopped or Dose Reduced?
#1 --	#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 --	#2 ☐ Yes ☐ No ☐ Doesn't Apply

4. Diagnosis or Reason for Use (Indication)	8. Event Reappeared After Reintroduction?
#1 helps with endurance, focus	#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2	#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot #	7. Expiration Date	9. NDC # or Unique ID
#1	#1	
#2	#2	

E. SUSPECT MEDICAL DEVICE

1. Brand Name: craze preworkout
2. Common Device Name
3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date (mm/dd/yyyy)	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date (mm/dd/yyyy)	7. If Explanted, Give Date (mm/dd/yyyy)

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☑ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (exclude treatment of event)

Craze preworkout-oct 25, 2012

More

G. REPORTER (See confidentiality section on back)

1. Name and Address

Phone # E-mail

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☑ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☑

FORM FDA 3500 (8/05) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.