

ENERGY DRINK EXPERT CALL

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SEPTEMBER 11, 2013

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ENERGY DRINKS

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DEFINITION

FDA: has no official definition of energy drinks (ED)

Wikipedia: An energy drink is a type of beverage containing stimulant drugs, chiefly caffeine, which is marketed as providing mental or physical stimulation.

Merriam-Webster: a usually carbonated beverage that typically contains caffeine and other ingredients (as taurine and ginseng) intended to increase the drinker's energy

INGREDIENTS IN ED

Lots of sugar and/or artificial sweeteners

Salt

Source of caffeine: caffeine, guarana, coffee

Others: Panax ginseng, taurine, B vitamins, amino acids, I-

carnitine, creatine

WHAT CAN BE ADDED TO ED?

Under the Food Drug and Cosmetic Act, ingredients added to beverages are considered food additives. These food additives must be pre-approved by the FDA unless they are GRAS (Generally Regarded as Safe) ingredients.

If the ED is sold as a supplement the manufacturer can add what they want without preapproval. The manufacturers determine their products safety.

BEVERAGE VS SUPPLEMENT

Supplement (DSHEA ACT)	Beverage
Can add more ingredients	Limited to GRAS ingredients; taurine and Panax Ginseng is not on GRAS list
No limit to caffeine content Do not need to disclose caffeine amount in product	Currently soda is limited to 71 mg in 12 oz; Caffeine is not a nutrient so do not have to list amount
Can not buy with food stamps	Can buy with food stamps
Must report adverse effects	Not required to report death or injuries
Considered a supplement	Considered a conventional food under the FFDCA
Ingredients do not need premarket approval for safety	Ingredients need premarket approval by FDA
More lenient health claims	Limited to strict health claims

HISTORY

- Scotland 1901: Iron Brew
- Japan 1962: Lipovitan- B vitamins and taurine
- UK 1980's Lucozade
- U.S 1985 Jolt Cola "All the sugar and twice the caffeine"
- Austria 1987 Red Bull sold in Austria (made in Hong Kong 1985)
- U.S 1995 Josta from Pepsi: 1st US Energy Drink
- 1997 Red Bull sold in US (in 8.4 oz can, now 20 oz)
- 2001 Rock Star
- 2002 Monster Energy Drink
- 2004 5-Hour Energy shots

A BIG BUSINESS

\$12.5 billion dollar business

31% of 12-17 year olds regularly consume ED

66% of its consumers are between 13 and 35 years

65% of consumers are Male

Sales in 2011 increased 12.5% overall but the leaders, Rock Star and Red Bull sales increased 15-30%

Sales of ED surpasses that of fruit drinks and sports drinks in the United States

CAFFEINE

WHAT IS CAFFEINE

- Caffeine is a stimulant drug (CNS stimulant)
- All tissues in the body absorb it
- Increases heart rate, blood pressure, speech rate, motor activity....
- Concern for children and their developing neurologic and cardiovascular systems

DAILY CAFFEINE INTAKE

U.S average for adults is 250 mg to 300 mg per day per person

Moderate consumption = 1-2 cups of coffee a day (approximately 260 mg caffeine)

Heavy consumption = 5 cups of coffee a day; 500 mg of caffeine per day

Teens should limit to under 100 mg/day

Children should not consume caffeine regularly and limit is 2.5 mg/kg (approximately 45 mg on average)

HOW MUCH CAFFEINE CAN A PERSON HANDLE?

- Depends on current regular intake
- Age: children and those over 70 years are at greater risk for adverse events
- Weight: caffeine's effects on blood pressure changes is greater in overweight individuals
- Gender: males are more susceptible than females for adverse events
- Health conditions: anxiety disorders
- Medications:
 - Antibiotics Cipro and Noroxin
 - Asthma medications- caffeine increases theophylline levels
 - Other stimulants
 - Echinacea

HOW MUCH CAFFEINE IS IN ED?

Average 80 mg/8oz serving (more than double the median caffeine content in 8 oz soda)

Examples:

Jolt (23.5oz) 280 mg

Rockstar Citrus Punched (16 oz) 240mg

5-hr energy (1.9 oz shot) 208 mg

Monster, Venom, NOS, (16 oz) 160 mg

Red Bull (8.4 oz) 80 mg

Range 6mg -242 mg per serving but some are served in 20 and 32 oz non-resealable containers and are consumed as such (Consumer Reports 12/2012)

CAFFEINE IN BEVERAGES/FOOD

Beverage/Food	Amount	Caffeine Content
Coffee Generic Brewed	8 oz	95-200 mg
Espresso	1 oz	40-75 mg
Instant coffee- Generic	8 oz	27-173 mg
Starbucks Latte	16 oz	150 mg
Black Tea	8 oz	14-61 mg
Decaffeinated Black Tea	8 oz	0-12 mg
Green Tea	8 oz	24-40 mg
Ice Tea-Generic	8 oz	26 mg
Coca-Cola	12 oz	30-35 mg
Mountain Dew	12 oz	46-55 mg
Chocolate Chips	1 cup	104 mg
Dark chocolate coated	28 pieces	336 mg
coffee beans		

CAFFEINE IN OTC DRUGS

Actamin Super: 65.4 mg

Anacin Maximum Strength: 32 mg

Anacin Tablets and Caplets: 32 mg

Aspirin-Free Excedrin Caplets: 65 mg

Bayer Select Maximum Strength Headache Pain Relief: 65.4 mg

Dristan Capsules: 16 mg

Excedrin Caplets: 65 mg

Excedrin Extra Strength Caplets and Tablets: 65 mg

Goody's Extra Strength Tablets: 16.25 mg

Goody's Headache Powder: 32.5 mg

Midol Menstrual Maximum Strength Caplets: 60 mg

Midol for Cramps Maximum Strength Caplets: 32.4 mg

NoDoz: 200 mg

Vanquish Caplets: 33 mg

Vivarin: 200 mg

^{*}http://www.webmd.com/migraines-headaches/guide/triggers-caffeine

CAFFEINE IN UNEXPECTED PLACES

- Sumseeds infused with 140 mg caffeine in 1 serving
- Perky Jerky has guarana added to it (150 mg caffeine per 2 oz pack)
- Cracker Jack'd Power Bites 100 mg in cocoa java and vanilla mocha
- Jelly Belly Extreme Sports Beans 50 mg in 1 oz pkg
- Crackheads chocolate covered coffee beans 600mg per package

ENERGY DRINKS

You can not compare the caffeine in coffee to the caffeine in energy drinks.







Plant Beverage	Caffeine Content	Avg. caffeine in a 6 oz beverage*
Guaraná seed (Paullinia cupana)	4–8%	200–400 mg
Coffee beans (Coffea sp)	1–2.5%	100–250 mg
Yerba maté leaves	0.7–2%	50–100 mg
Black tea (Camellia sinensis)	2.5– 4.5%	10–60 mg
Chocolate (Cacao seed)	0.25%	13 mg

THIS IS WHY

- The caffeine in coffee is different than the caffeine in these energy drinks.
 - It metabolizes slower which means it stays in the body longer
- There are a combination of stimulants in many energy drinks that are not found in a cup of coffee
 - Guarana (herbal speed)
 - Theobromine
 - Theophylline
 - Ginseng
 - Yerba Mate
 - Kola Nut
 - Taurine
- The combination of stimulants found in many energy drinks <u>have not</u> <u>been studied</u> for use in children or adults
- Many adverse reports have been reported with energy drinks in the US and abroad including strokes, heart attacks and death

XANTHINES PRESENT

Caffeine Theobromine Theophylline

Coffee

Tea Tea (trace) Tea

Chocolate Chocolate (mostly)

Guarana Guarana (trace) Guarana (trace)

Yerba Mate Yerba Mate Yerba Mate

Asian Ginseng Asian Ginseng Asian Ginseng

AT RISK POPULATIONS

Adults and Children who have:

- Seizures
- Diabetes
- Renal disease
- Cardiac abnormalities (many unknown until their hearts are stressed from aggressive sports or stimulants like caffeine)
- Mood and behavioral disorders
- Those who take certain medications (especially stimulants) like children with ADHD
- Those taking certain antibiotics, asthma medication

DANGER

- There are no re-sealable tops to energy drinks that contain 2 to 3 servings
- Many reports to poison control concerning energy drinks are from children under 6 years of age
- Of the 5448 US caffeine overdoses reported in 2007, 46% occurred in those younger than 19 years
- Health care providers report that they have seen the following effects from the consumption of energy drinks: dehydration, accelerated heart rates, anxiety, seizures, acute mania, and strokes

ADVERSE EVENTS (DAWN REPORT, 2013)

The number of emergency department (ED) visits involving energy drinks doubled from 10,068 visits in 2007 to 20,783 visits in 2011

Among energy drink-related ED visits, there were more male patients than female patients

In each year from 2007 to 2011, there were more patients aged 18 to 39 than patients in other age groups involved in energy drink-related visits

In 2011, more than half of energy drink-related ED visits involved energy drinks only (58 percent), and the remaining 42 percent involved other drugs

"ADVERSE EVENTS" REPORTED TO THE FDA

ADVERSE EVENTS REPORTS ALLEGEDLY RELATED TO RED BULL: shortness of breath, anxiety, chest pain, heart attack, convulsions, mental impairment in (in a 7 year 4 month period)

ADVERSE EVENTS REPORTS ALLEGEDLY RELATED TO MONSTER: 4 heart attacks, 5 deaths, chest pain, tremor, anxiety, psychotic disorder (in an 8 year 10 month period)

EXPERTS SAY "STAY AWAY"

The American Academy of Pediatricians says:

No energy drinks for kids of all ages; greatly limit use of sports drinks

Researchers have linked energy drinks to an increase in heart rate and blood pressure as well as some sleep disturbances and anxiety.

KIDS & ENERGY DRINKS

KIDS AND ED

Based on stats from 2011, children (<12), adolescents (12-18), and young adults (19-25) make up <u>half</u> the energy drink market

The AAP outlines potential problems of energy drinks among children and adolescents including possible negative effects on: cardiovascular health, ADHD, eating disorders, caloric intake and diabetes, and bone mineralization

ARE KIDS BEING TARGETED

- Energy drinks are sold in places children frequent, even young children
- Energy drink companies sponsor many sporting and extreme sporting events that children, especially tweens frequent
- Energy drinks are being sold to young children- 4 and 5 year olds can and do buy them on their own
- The tween/teen market is a target for energy drink sales
- College campuses are visited by Verve energy drink reps, a multi level marketing company, and for hundreds of dollars students can buy in and then sell these drinks to their friends

WHAT DO KIDS THINK?

The majority of Kindergarteners think energy drinks are healthy for them and should be consumed often (Kennedy 2013 unpublished)

Many teens and tweens do not understand the difference between energy drinks and sports drinks and many use them interchangeably

Energy drinks are consumed by 30% to 50% of adolescents and young adults

Based on stats from 2011, children (<12), adolescents (12-18), and young adults (19-25) make up half the energy drink market

SUSPICIOUS DEATHS AND ENERGY DRINKS

No one has proven that the following deaths were caused by energy drinks but these are the stories their families tell..... You decide!

Brian, 15y: reportedly given a free sample of red bull. Died of a heart arrhythmia later that day. (spoke with father, Canada)

Anais, 14y: Drank 1 monster energy drink 2 days in a row. Went into coma & died 5 days later. Had underlying heart condition. (in touch with mother)

SUSPICIOUS DEATHS

Drew, 19: 1st time reported drinking monster nitrous energy drink (1/2 can). ½ hour later had seizure and died soon after. (spoke with mother)

Sara, 16y: mixed alcohol and 3 Pulses: she died later that night. (in touch with mother, Australia)

Sailor, 17y: had a seizure and was hospitalized for five days last year after drinking two large Nos energy drinks

Alex, 19y: Drank at least 2 energy drinks the day before his death

LEGAL ISSUES

TIME LINE

In 2008, scientists and physicians wrote to the FDA requesting increased regulation of energy drinks

2004-2008: France, Denmark, and Norway attempted to ban Red Bull but the European Court of Justice found it to be an improper trade restriction

2011 AAP position paper "energy drinks have no place in the diet of children and adolescents"

2011 Canada imposes stricter regulations on ED

10/2012: FDA investigating 5 deaths and 1 non fatal heart attack related to Monster ED

10/2012 Wrongful death suit Anais against Monster ED

9/2012 Blumenthal and Durbin write letter to FDA asking for increased regulation of ED

3/2013 Doctors write letter to FDA asking for limit of caffeine in ED

6/2013 Wrongful death suit Alex Morris against Monster ED

6/2013: AMA Recommends banning marketing of ED to those under 18 years

RECENT ACTIVITIES

March 2013 Suffolk County bans sales of ED to minors at county parks and beaches

2013: 74% of parents interviewed by Rudd Center said ED should not be sold to children or adolescents

August 2013 Workshop on Potential Health Hazards
Associated with Consumption of Caffeine in Food and
Dietary Supplements

On July 31, 2013, the U.S. Senate Committee on Commerce, Science, and Transportation held a hearing entitled "Energy Drinks: Exploring Concerns about Marketing to Youth.

LEGAL RECOURSE

JOURNAL OF PUBLIC HEALTH POLICY. 2013, POMERANZ ET AL

States

 Can prohibit sale of ED in their district to certain age groups or prescribe placement of product

FDA: Can require that ED be considered as beverages

- Can reconsider GRAS status for sugar, caffeine and guarana and limit amount to be used for each
- Require caffeine disclosure on label, create DRV for caffeine and added sugar
- Add warning labels

Manufacturers and ABA: stop marketing to kids

*Both state and local authorities should enforce the regulations

PREDICTIONS

Manufacturers will stop marketing to kids under 12

Will never give up the tween and teen market

Will disclose caffeine content

All will call them beverages; except for the shots

FDA will create new regulations for GRAS, especially in regards to guarana and caffeine

THANK YOU

For questions to be answered on this call please submit them to QA@hedgeye.com.

