What's all the BUZZ about?

A Survey of Popular Energy Drinks Finds Inconsistent Labeling, Questionable Ingredients and Targeted Marketing to Adolescents

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A report written by the staff of Congressman Edward J. Markey (D-MA) in coordination with the staff of Senators Richard J. Durbin (D-IL) and Richard Blumenthal (D-CT)

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Executive Summary

The term "energy drinks" generally represents a class of products in liquid form that contains high levels of caffeine frequently combined with other stimulants and specialty ingredients. The spike in the number of energy drinks in the marketplace and the frequency in which these products are marketed to children and teens raises serious questions, both about the safety of this class of products and whether they fulfill their claims to consumers.

Recently, the Food and Drug Administration (FDA) released a series of adverse event reports of illness, injury and death allegedly linked to the consumption of products marketed as energy drinks. The FDA also is currently investigating energy drinks. The Department of Health and Human Services recently issued a report that emergency room visits related to energy drinks doubled from 10,000 to 20,000 visits between 2007 and 2011.

To address growing concerns over energy drinks, the marketing of these products to children and provide more information about the ingredients used in these products, Representative Edward J. Markey (D-MA) and Senators Richard J. Durbin (D-IL) and Richard Blumenthal (D-CT) launched an investigation into the practices of fourteen commonly sold energy drink brands. This report presents the information gathered in response to this investigation and places it in the context of the current regulatory structure for energy drink products.

Findings in Brief:

- Various marketing, labeling and ingredient disclosure requirements are applied to energy drinks, sometimes inconsistently. As a result, nearly identical energy drinks can be marketed and represented to consumers differently, leading to consumer confusion and a lack of transparency.
    - Four out of the 14 companies surveyed classify and market one or more of its products as dietary supplements, as opposed to conventional beverages.
    - The beverage company Arizona produces several energy drink products, but although the products come in similar sizes and caffeine concentrations, half of the products disclose caffeine concentrations on the label, while the other half do not.
    - Both Monster Beverage Corporation and Rockstar Inc., recently switched classification of their energy drinks from dietary supplements to beverages, resulting in some products being marketed, represented, regulated and labeled as dietary supplements and some as conventional beverages despite their identical compositions.

- Energy products come in a range of sizes, with various amounts of caffeine that exceed what has been previously recognized as safe by the FDA for soda beverages (approximately 71 milligrams of caffeine per 12 ounces). Despite these elevated levels, concentrations of caffeine are not uniformly represented on the label of the brands evaluated.

- Of the 14 companies, Coca-Cola's NOS energy drink product contains the most caffeine at 260 milligrams per 16 ounce can, while Target's Archer Farms energy drink contains just 70 milligrams in 16 ounces.
- Monster's Worx Energy shot contains 200 milligrams of caffeine in just 2 ounces, but the level of caffeine is not disclosed on the label. In contrast, Arizona Energy Fast shot contains 113 milligrams of caffeine in 2 ounces and discloses the caffeine on the label.
- Rockstar energy drink contains 240 milligrams of caffeine in 16 ounces, but because the company is undergoing a change in labeling practices, only some cans currently on the market present the amount of caffeine on the label.

- All 14 companies stated that they do not market energy drinks to children. However, there is clear evidence that adolescent consumers are frequent targets for the marketing pitches of energy drink companies. The use of unconventional marketing practices combined with product design and placement on store shelves assists in creating product images that appeal to children and teens.
  - Companies such as Monster Beverage Corporation and Rockstar Inc, focus on youth-oriented social media advertising as well as sponsoring events and athletes that cater to high school-aged students.
  - Monster Beverage Corporation produces a range of products meant to mimic frequently consumed alcoholic beverages and which appear to be intended for audiences that are not old enough to consume alcohol legally.

- Energy drink companies make a range of advertising claims related to the functional benefits of their products that are not generally evaluated or substantiated by the FDA. Some of these claims appear to be targeted to young audiences or student athletes. However, the National Collegiate Athletic Association, National Federation of High Schools, and American Academy of Pediatrics have all warned of the risks these products play, particularly for children and student athletes.
  - PepsiCo's AMP Energy Boost claims that it will help "energize and hydrate the body," while Coca-Cola's NOS promises "50% more focus".
  - Monster energy pledges that its products will provide a "big, bad buzz."
  - Dr. Pepper's Venom highlights its products ability to improve "up to the nanosecond performance."
  - Red Bull claims "increased concentration and reaction speed" and "stimulated metabolism."

- In addition to caffeine, energy drinks contain a myriad of specialty ingredients whose combinations and additive impacts are not thoroughly evaluated or well understood. Companies can and often do self-determine that ingredients are safe for use in energy drinks, and there is no requirement for companies to notify the FDA of this determination or the use of the ingredient. Moreover, much like caffeine, companies can choose whether they want to disclose the amount of these other ingredients on the product label.
  - Nearly all energy drinks surveyed contain taurine, an amino acid that has not been approved as a food additive by the FDA, but has been self-determined by energy drink companies to be safe for inclusion in its products.

- In addition to caffeine, energy drinks combine other stimulants such as ginseng, guarana, green tea and, less frequently, methylated xanthine (as in 5-hour Energy), a synthetic stimulant.

Recommendations:

There are a number of steps that energy drink manufacturers should take to improve transparency and representation of this class of products as well as ensure that children and teens are adequately protected from deceptive advertising practices. Energy drink manufactures should immediately:

1. Label products with a clear description of the total amount of caffeine (in milligrams) added to the product from all sources. For products that are packaged in non-resealable containers (such as pop-top cans), the label should include the amount of caffeine from all sources in the entire container, not just one serving.

2. For products that contain caffeine that has been intentionally added to the product at levels above 200 parts per million (approximately 71 milligrams per 12 fluid ounces), the level affirmed as GRAS by the FDA, display a prominent precautionary statement that at a minimum says, “This product is not intended for individuals under 18 years of age, pregnant or nursing women or for those sensitive to caffeine. Consult with your doctor before use if you are taking medication and/or have a medical condition.”

3. Cease marketing of energy drink products to children and teens under the age of 18. Marketing includes use of both traditional media and social media as well as the sponsorship of events, activities and individuals that are intended for an audience comprised primarily of children or teens.

4. Report to the FDA the receipt of any serious adverse events associated with energy drink use. Serious adverse events are defined by the FDA, but reporting is currently only required by the FDA for products that are represented as dietary supplements.

Background

In the past few years, there has been an explosion in the consumption of a class of beverage products, known collectively as energy drinks, which carry a unique set of risks for adolescents. Although the term "energy drink" is not defined by the Food and Drug Administration (FDA), the primary entity responsible for the safety, labeling and ingredients present in the food supply, it generally represents a class of products in liquid form that contains high levels of caffeine and, typically also includes, additional ingredients not found in sodas and juice drinks.

Energy drinks have become a multibillion-dollar business, with steadily increasing sales that rose 16% in 2012 alone, amounting to a US sales market worth more than $12.5 billion.[1] Consumption of energy drinks by children and teens has been a growing trend; a 2012 study of U.S. high school students revealed that energy drinks represented 8.8 % of the sugar-sweetened beverages they consumed.[2] Another U.S. study found that 31 % of 12-17 year olds regularly drink energy drinks, in comparison to 22 percent of 25-35 year-olds.[3]

The proliferation of energy drinks is largely related to the tailored marketing and claims made by these products, which promise outcomes such as improved athletic performance, reaction time and increased attention and alertness. Energy drink companies rely on added sugars and caffeine in the effort to fulfill these promises. However, both the high levels of caffeine and the mixture of other unique ingredients, not typically found in other beverages, call into the question the safety of these products, particularly for youth. Furthermore, the high levels of sugar (typically double the amount of soda) present serious health risks of obesity, diabetes and heart disease.

The increasing consumption of energy drinks by children and teenagers has emerged as a new public health threat for youth. Frequently these products are marketed through youth-oriented media and venues and use packaging and images that appeal to a young audience.[4] The American Academy of Pediatrics (AAP) has stated that "energy drinks have no therapeutic benefit to children" and that the properties of the ingredients of these drinks "may put some children at risk for adverse health events."[5] A recent survey by the US Department of Health and Human Services revealed that emergency room visits related to energy drinks doubled from

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[1] Energy Drinks and Shots: U.S. Market Trends, Packaged Facts, Feb. 11, 2013

[2] Park, S., Blanck, H.M., Sherry, B., Brener, N. and O'Toole, T. (2012) Factors associated with sugar-sweetened beverage intake among united states high school students. Journal of Nutrition 142(2): 306–312

[3] Simon, M. and Mosher, J. (2007) Alcohol, Energy Drinks, and Youth: A Dangerous Mix. California: Marin Institute.

[4] Pomeranz, J.L., Munsell, C.R. and Harris, J.L. (2013) Energy drinks: An emerging public health hazard for youth. Journal of Public Health Policy. Advance online publication 14 March 2013

[5] See Energy Drinks Can Harm Children, Feb. 114, 2011 http://www.aap.org/en-us/about-the-aap/aap-press-room/pages/Energy-Drinks-Can-Harm-Children.aspx

10,000 to 20,000 visits between 2007 and 2011.[6] It has been previously reported that 11 percent of total emergency room visits related to energy drink consumption involved youth aged 12-17 years.[7]

The FDA recently released injury report filings, also known as adverse event reports, that were associated with several popular energy drink brands including, Rockstar, Red Bull, Monster and 5-hour Energy.[8] These reports indicated serious or life threatening injuries such as heart attacks, convulsions and, in a few instances, death. The FDA is currently investigating these reports, as the mere filing of an incident report with the FDA does not mean that a product was responsible for a death or an injury. The FDA has also announced that it intends to form a third party review panel to help determine whether energy drinks pose particular risks to teenagers or people with underlying health problems.

For consumers interested in limiting their personal consumption of caffeine or concerned about the ingredients used in energy drinks, labels on the packaging of these products can be confusing or lack necessary information regarding the quantity of caffeine and other ingredients. Manufacturers of energy drinks currently are left to their own discretion in deciding whether a product will be marketed and labeled as a conventional food (beverage) or as a dietary supplement. These two product types have different federal requirements relating to ingredient disclosure, labeling and other FDA responsibilities. As a result, the information that is provided to consumers on a product label is inconsistent within the category of energy drink products depending on whether the product is classified as a beverage or dietary supplement. In 2009, the FDA issued draft guidance to clarify when a liquid energy drink product should be classified as a dietary supplement or a beverage, but the guidance, which is non-binding, has yet to be finalized by the agency.[9]

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[6] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (January 10, 2013). The DAWN Report: Update on Emergency Department Visits Involving Energy Drinks: A Continuing Public Health Concern. Rockville, MD.

[7] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (November 22, 2011). *The DAWN Report: Emergency Department Visits Involving Energy Drinks.* Rockville, MD. Data from between 2004 and 2008.

[8] http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/UCM328270.pdf and http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/UCM328525.pdf

[9] FDA Draft Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods. (December 2009)

Investigation

To address the growing consumer concern over energy drinks, the marketing of these products toward youth and to provide more information about the ingredients used in these products, Representative Edward J. Markey (D-Mass) and Senators Richard J. Durbin (D-IL) and Richard Blumenthal (D-CT) launched an investigation into the practices of fourteen commonly sold energy drink brands (See an example of the letter in Appendix A).[10] Each company was asked to respond to a series of fourteen questions seeking information on:

- how the company determines whether its product should be represented as a dietary supplement or a conventional food;
- the ingredients used in the products;
- the levels of caffeine and serving size of the products;
- the studies performed to back up any claims made about the benefits of the products; and
- the marketing and advertising practices employed by the companies to target youth audiences.

With the exception of Sambazon and 5-hour Energy, all companies responded to the questions posed to them.[11] In instances where companies did not provide complete responses or simply did not respond to a question, supplemental information was gathered from company websites, contacting company consumer representatives through the company's public contact telephone number, or through reviewing other publically available information, including product labels. This report presents the information gathered in response to this investigation.

[10] An example of the letters sent to the companies can be found here: http://markey.house.gov/press-release/markey-durbin-blumenthal-quiz-energy-drink-makers-products

[11] Sambazon and 5-hour energy did not respond to the questions asked. Sambazon requested to be removed from the investigation. 5-hour energy provided a copy of its patent in lieu of responding to specific questions.

Findings

FINDING #1: Various marketing, labeling and ingredient disclosure requirements are applied to energy drinks, sometimes inconsistently. As a result, nearly identical energy drinks can be marketed and represented to consumers differently, leading to consumer confusion and a lack of transparency.

While the FDA does have the authority to regulate both conventional foods, referred to in this report as "beverages," and dietary supplements, the requirements for ingredients, manufacturing processes, reporting of adverse events and labeling, differ depending on whether the product is marketed as a beverage or as a supplement (See Table 1). According to FDA, a manufacturer of a product in liquid form may choose *on its own* whether or not to market its product as a beverage with the required "Nutrition Facts" panel or as a liquid dietary supplement with the required 'Supplement Facts' panel.

Regardless of the category chosen by the manufacturer FDA is responsible for ensuring that the manufacturer complies with the requirements associated with beverages and dietary supplements, including how the product is represented (i.e., marketed) to consumers.

TABLE 1: Key differences between the federal regulation of dietary supplements and beverages

CONVENTIONAL FOOD (BEVERAGE)	DIETARY SUPPLEMENTS
New ingredients must be approved as a food additive by the FDA, unless the ingredient is generally recognized as safe (GRAS)*	Only new ingredients not marketed in dietary supplements in the U.S. prior to October 15, 1994 require FDA preapproval. Otherwise, FDA must determine an ingredient is unsafe under conditions of use to take the product off the market
Any reporting of serious adverse events is completely voluntary	Required by law to report to the FDA any serious adverse events
Includes a "Nutrition Facts" panel on the label, with information on amount of calories, total fat, cholesterol, sodium, carbohydrates, protein, vitamin A, vitamin C, calcium and iron	Includes a "Supplement Facts" panel on the label, with information on quantities of ingredients that exceed standards or that are relevant to a product claim
Listing of ingredients in descending order of predominance is required	List the quantity of each dietary ingredient, unless the ingredient is a part of a 'proprietary blend', in which case quantities are not required
Good Manufacturing Practices (GMP) focus on ensuring safe and sanitary processing conditions	Good Manufacturing Practices (GMP) contain standards of identity to help verify that the product is what it is purported to be

* Manufacturers of a product are permitted to self-determine that an ingredient is generally recognized as safe (GRAS) without FDA affirmation

In 2009, FDA attempted to clarify the agency's views on the distinction between liquid dietary supplements and beverages by issuing a guidance document that outlines some of the factors that may cause a product to be represented as a beverage, instead of as a dietary

supplement.[12] These items include the volume in which the product is intended to be consumed, the labeling of the product, the recommended conditions of use, and the packaging in bottles or cans that are similar to packaging found in other beverages like soda and bottled water. This guidance has yet to be finalized by the FDA, but the agency has indicated that it hopes that once completed the guidance will more clearly demarcate the line between beverages and liquid dietary supplements.

TABLE 2: Energy drinks, even those produced by the same company, are represented inconsistently in the market as both dietary supplements and regular beverages

PARENT COMPANY	BRAND NAME	PRODUCT NAME	MARKETED AS DIETARY SUPPLEMENT OR CONVENTIONAL FOOD (BEVERAGE)
Living Essentials	5-hour Energy	5-hour Energy	Dietary Supplement
Celsius	Celsius	Celsius	Dietary Supplement
Monster Beverage Corporation	Worx Energy	Worx Energy	Dietary Supplement
Monster Beverage Corporation	Monster	Monster Energy, Blue Energy, Hansen's Energy	Conventional Food (since March 2013)
Rockstar Inc.	Rockstar Energy Drink	Rockstar	Conventional Food (since January 2013)
PepsiCo	AMP Energy Boost	AMP	Conventional Food (since 2012)
Dr. Pepper Snapple Group	Venom	Venom Energy	Conventional Food
Clif Bar and Company	Clif Shot	Clif Shot Gel	Conventional Food
Red Bull	Red Bull	Red Bull	Conventional Food
Coca Cola	Full Throttle	Fuze	Conventional Food
Coca Cola	NOS	Nos	Conventional Food
Nestlé USA (until November 2012)	Jamba	Jamba Energy	Conventional Food
Sambazon	Sambazon	Sambazon	Conventional Food
Target Corp. made by third party	Archer Farms	Archer Farms Energy Drinks	Conventional Food
AriZona Beverages	Arizona	AZ Energy, RX Energy Fast Shot	Dietary Supplement
AriZona Beverages	Arizona	Caution, Joltin Joe, Rx Energy Herbal	Conventional Food

[12] FDA Draft Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods. (December 2009)

The FDA has stated that energy drinks can be lawfully marketed as either dietary supplements or as beverages as long as they satisfy the requirements for the product category which they represent. Responses from energy drink companies indicate that four of the fourteen responding companies classify and market one or more of its products as dietary supplements (See Table 2). These products include Celsius, Monster's Worx, 5-hour Energy and approximately 50 percent of the Arizona brand energy drinks (representing 5 products).

In addition, three energy drink brands, AMP Energy (owned by PepsiCo), Rockstar and Monster energy drinks have only within the last year shifted from marketing their products in the category of dietary supplements to marketing and labeling their products as beverages.[13] Until this market transition is complete, which in the case of Rockstar may take a year, consumers can expect to find identical products by Rockstar Inc., and Monster labeled with both Supplement Facts (as in dietary supplements) and Nutrition Facts (as in beverages). According to Monster Beverage Corporation, this decision was made for business purposes as well as to avoid criticism that the company was marketing their products as dietary supplements to avoid FDA oversight.

When the companies were asked to explain how they determine whether a product should be marketed as a beverage or dietary supplement, the responses indicated that the companies routinely review FDA laws and regulations and in some instances cited warning letters issued by the FDA to other companies. The companies indicated that the decisions are made on a case-by-case basis dependent on the intention of the product. For instance if the product is intended to primarily quench thirst, the company markets it as a beverage, but if the product is intended to be a supplement to the diet they would treat the product as a dietary supplement.

Interestingly, Monster indicated in its response that it views its products as intended to specifically supplement the diet with dietary ingredients and "not merely to be consumed ad libitum to provide refreshment and good taste." Despite this declaration, the company still transitioned its products (with the exception of Worx Energy) from dietary supplements into the beverages category. Furthermore, Arizona beverages produces several remarkably similarly packaged and sized energy drink products with comparable claims and ingredients and the company appears to arbitrarily select whether a product is classified as a dietary supplement or beverage. The blurred distinction between supplements and beverages is a source of confusion for consumers. The FDA should expeditiously ensure that energy drink manufacturers utilize a consistent approach to categorize their products.

[13] Monster Beverage Corp. indicated in its response that all products, with the exception of Worx Energy would be transitioned to beverages and labeled with a nutrition facts panel.

<u>FINDING #2:</u> Energy products come in a range of sizes, with various amounts of caffeine that exceed what has been previously recognized as safe by the FDA for soda beverages (approximately 71 milligrams of caffeine per 12 ounces). Despite these elevated levels, concentrations of caffeine are not uniformly represented on the label of the brands evaluated.

The fourteen companies surveyed produce different types of energy drink products (See Table 3). In the case of Clif Shot, the product is an energy gel packaged in small squeezable packet and intended to be consumed by athletes during endurance activities. Clif Shot is marketed as a conventional food. Another product, Celsius, which is sold as a single serving packet of powder to mix with water as well as ready to drink cans and is marketed as the "ultimate fitness partner" is classified as a dietary supplement. In the case of Celsius, the product is intended to be consumed pre-exercise to help reduce body fat and improve endurance. These two companies have remarkably similar uses, but two different designations.

The remaining twelve companies produce two main energy product types, which they refer to as "drinks" and "shots" (See Table 3). The energy shots come in 2-ounce single serve containers. The energy drinks are commonly sold in 8-32 ounce packaging, many of which are packaged in large, non-resealable cans, despite the number of servings listed on the container. For example, Monster Energy and Arizona AZ Energy both produce a 24 fluid ounce canned product that contains 240 mg and 306 mg of caffeine, respectively, and more than 75 grams of sugar per container. Both companies claim that the can represents 3 servings of the product, yet the carbonated beverage is provided in a non-resealable can similar to a soda can, encouraging the product to be consumed in one sitting. For comparison, this is 7-9 times more caffeine and approximately twice as much sugar as a can of Coca-Cola Classic. Monster produces a 32 ounce non-resealable can with approximately 108 grams of sugar and 320 mg of caffeine.

The caffeine content varies widely between the energy products surveyed, and in many cases is not disclosed on the product label. In cases where it is disclosed, companies vary in the way they present this information, sometimes impairing consumers' ability to make informed decisions about caffeine levels in the products they are purchasing. For example, some products only present the amount of caffeine per recommended serving size rather than in the entire container. For products packaged in large 24 or 32 ounce non-resealable containers that are typically consumed all at once, this practice could mislead consumers about the total amount caffeine and other ingredients they are ingesting, as they may presume that there is no distinction between the recommended serving size and the serving in the container itself. While some companies provide caffeine concentration in milligrams, other companies, including 5-hour Energy and some of the Arizona energy drink products, disclose caffeine only in comparison to other products, stating on the label that the product contains "caffeine equivalent to 2 cups of coffee" or "contains caffeine comparable to a cup of the leading premium coffee." The inconsistent ways in which caffeine concentration is presented on the label may further confuse consumers.

TABLE 3: Energy drinks contain a varied amount of caffeine that is inconsistently represented on the label

PRODUCT NAME	PRODUCT TYPE	CONTAINER SIZE (fl.oz.)	TOTAL CAFFEINE PER CONTAINER FROM ALL SOURCES (mg)	CAFFEINE AMOUNT DECLARED ON THE LABEL
Rockstar	Drink	24	360 or 240*	Transitioning to labeling caffeine on all products
Arizona AZ Energy Half&Half Iced Tea Lemonade	Drink	23	265	Yes
NOS	Drink	16	260	Yes
Rockstar	Drink	16	240 or 160*	Transitioning to labeling caffeine on all products
Monster Energy	Drink	24	240	Transitioning to labeling caffeine on all products
Worx Energy	Shot	2	200	No
Celsius	Drink, Powder	12	200	Yes
Full Throttle Fuze	Drink	16	200	Yes
Java Monster	Drink	16	200	Yes
Arizona AZ Energy	Drink	15	195	Yes
Venom	Drink	16	160	Yes
Monster Energy	Drink	16	160	Transitioning to labeling caffeine on all products
Arizona Caution	Drink	11.5	144	Yes
AMP Energy Boost	Drink	16	142	Yes
Red Bull	Drink	12	114	Yes
Arizona Rx Energy Fast Shot	Shot	2	113	No
Jamba	Drink	8.4	80	Yes
Sambazon	Drink	10.5	80	Yes
Target Archer Farms	Drink	12	70	Yes
Clif Shot	Gel	34 grams	0, 25 mg, 50 mg, or 100	Yes
5-hour Energy	Shot	2	did not answer	No

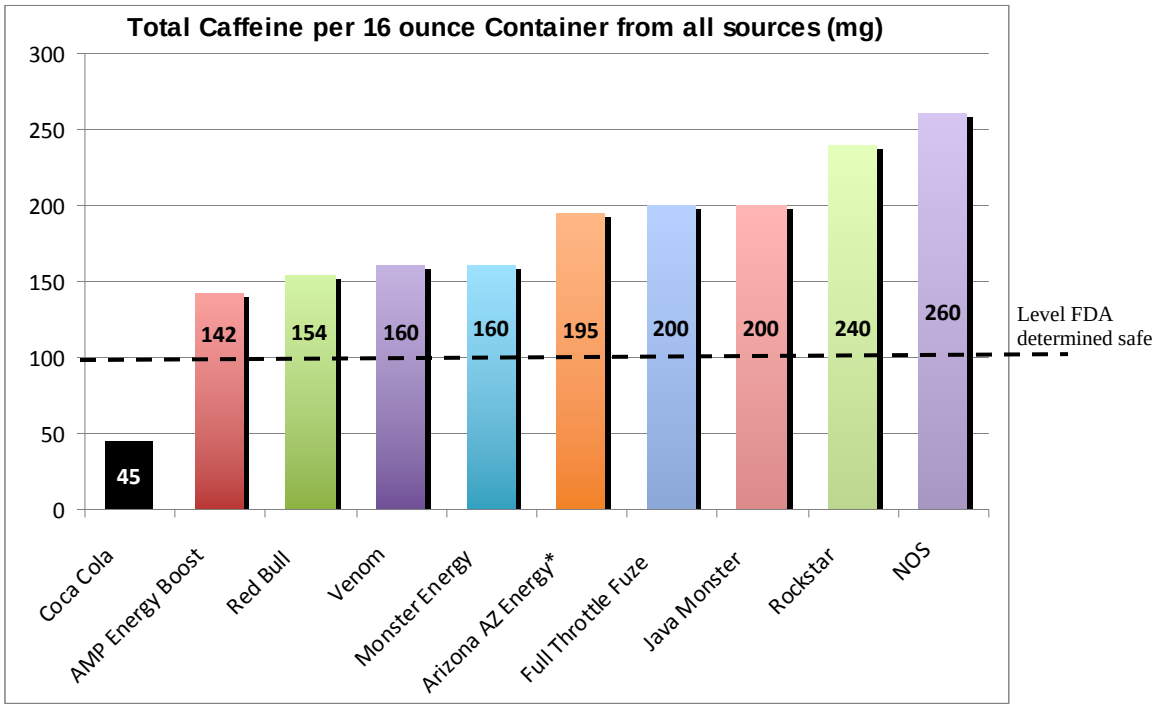
* Caffeine amount depends on specific product.

Although FDA does not require caffeine disclosure for either beverages or supplements, the American Beverage Association (ABA), the trade association that represents the non-alcoholic beverage industry in the U.S., recommends that all such energy products clearly label their products with the amount of caffeine from all sources in the product. However, not all energy products, abide by these voluntary guidelines. For example, Arizona has several energy drink products with labels that either do not disclose the level of caffeine at all or provide a level of caffeine that is not representative of the actual caffeine content from all sources. Living Essentials 5-hour Energy, not a member of the ABA and marketed as a dietary supplement energy shot, also does not provide the amount of caffeine on the label of its product. Monster and

Rockstar energy products are transitioning to labels that disclose caffeine content from all sources, in compliance with ABA's voluntary guidelines. Most caffeinated sodas also disclose the concentration of caffeine present in the container from all sources.

In general the caffeine concentration of the energy products surveyed is much higher than that of sodas for which the FDA has generally recognized as safe (GRAS) at a level of 200 parts per million of caffeine (approximately 71 mg per 12 fl oz serving). In contrast, popular energy drinks, such as NOS and Rockstar contain between 240 and 260 milligrams of caffeine per 16 ounce can and popular energy shots, such as 5-hour energy and Worx contain between 200- 242 milligrams of caffeine[14] per 2 ounce bottle (See Figure 1). For 5-hour Energy and Worx, because these products are marketed as dietary supplements, there is no requirement or voluntary guidance that the amount of caffeine be listed on the product label or disclosed to the consumer in any way

<u>FIGURE 1</u>: Comparison of similar sized energy drink caffeine concentrations



*Container size 15 fluids ounces

Caffeine toxicity is a concern, especially for children and adolescents, who are the frequently targeted demographic for energy drink companies. According to the American Academy of Pediatrics (AAP) "caffeine can produce harmful health effects in adolescents, including cardiovascular problems, anxiety, insomnia, digestive problems, dehydration, and

[14] Information for 5 hour Energy provided by Consumer Report Magazine (December 2012). The buzz on energy-drink caffeine.

others."[15] The American Academy of Pediatrics' Committee on Nutrition and the Council on Sports Medicine and Fitness recently concluded that, "rigorous review and analysis of the literature reveal that caffeine and other stimulant substances contained in energy drinks have no place in the diet of children and adolescents.[16]"

Children and teens who consume energy drinks for the promise of increased physical performance, before, during, or after physical activity are exposed to a high dose of caffeine and other ingredients in a short window of time. According to a recent study[17], "cardiovascular effects as a result of heavy caffeine use can be a significant source of morbidity in athletes," and "given the unknown levels of caffeine and other poorly studied additives, there is significant risk associated with energy drink consumption that may outweigh the benefits in the adolescent consumer."

On average the U.S. population consumes approximately 300 milligrams of caffeine per day.[18] For healthy adults, the FDA has noted that consumption of 400 milligrams of caffeine (considered an upper limit) in a day is not associated with adverse health effects. However, the standard of 'healthy adults' does not take into account varying sensitivities to caffeine and varying capabilities of younger consumers to metabolize this stimulant.[19] Furthermore, statements made by energy drinks such as "chug it down" and "pound down"[20] encourage consumers to drink large quantities of these products rapidly, which can decrease the clearance of caffeine from the body and result in elevated caffeine blood concentrations for a sustained period of time.[21] This is especially risky for children and teen consumers, as well as consumers who have pre-existing health conditions or who are taking medications that may interfere or interact with caffeine metabolism. As the FDA has stated, smaller individuals (adolescents) are typically more sensitive to caffeine consumption. The FDA has also warned that while caffeine and other stimulants may make one feel more awake, "judgment and reaction time can still be impaired."[22]

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[15] AAP, Energy Drinks Pose Health Risks to Adolescents Feb. 1, 2013.
[16] Committee on Nutrition and the Council on Sports Medicine and Fitness. Sports drinks and energy drinks for children and adolescents: Are they appropriate? *Pediatrics.* 2011;127(6):1182-1189.
[17] Blankson, K., et al. *Pediatrics in Review* Vol. 34 *No. 2* February 1, 2013 pp. 55 -62
[18] Caffeine Intake by the U.S. Population, September 2009, revd. August 2010, by Laszlo P. Somogyi, Ph.D.
[19] Letter from City Attorney of San Francisco Dennis Herrera to FDA Commissioner Margaret Hamburg (March 19, 2013)
[20] See for example: http://www.monsterenergy.com/ph/en/products/ and http://originalcapsultimate.blogspot.com/2012/08/where-should-buy-8-pack-monster-energy.html
[21] Letter from City Attorney of San Francisco Dennis Herrera to FDA Commissioner Margaret Hamburg (March 19, 2013)
[22] http://www.fda.gov/Food/NewsEvents/ucm328536.htm

FINIDNG #3: Adolescent consumers are frequent targets for the marketing pitches of energy drink companies. The use of unconventional marketing practices combined with product design and placement on store shelves assists in creating product images that appeal to children and teens.

In the course of this investigation, companies were asked whether they market energy drink products to children or teenagers. Unsurprisingly, all companies indicate that their products were not directed toward children, and several products including Venom and Red Bull, indicated that they follow the American Beverage Association (ABA) voluntary guidance for the responsible labeling and Marketing of Energy Drinks (See Table 4).[23] Monster Beverage Corp. and Rockstar indicated that the companies have recently joined the ABA. These ABA guidelines indicate that energy drinks should be labeled with the quantity of caffeine from all sources contained in the beverage, should not promote mixing with alcohol, should not be marketed as sport drinks, should contain an advisory statement[24] and should not be advertised to an audience that is comprised predominantly of children less than 12 years of age.

Not all energy drink companies adhere to ABA guidance. Furthermore, while children 12 years of age and younger may not be targeted by some companies, adolescents who are between the ages of 13 and 17 are frequently the focus for energy drink marketing practices and this population is also at risk for the detrimental impacts of energy drink consumption. For example, Monster Energy and Rockstar Energy both indicate that their target audience is young adults and as a result, these companies frequently sponsor young athletes, such as Mitchie Brusco, a skateboarder who has been sponsored by Rockstar since he was at least 14 years old. Monster also has a practice of awarding outstanding high school student athletes with the "*Monster Energy Drink Player of the Game*." As a part of this honor, photos of these teen student athletes are taken with a package of Monster Energy in each hand and other Monster paraphernalia.[25] Red Bull also engages in the sponsorship of high school sport events, including the "Red Bull Game Breakers" and "Red Bull Rookies Cup" which includes adolescents as young as 13 years old. While Monster Energy indicated in its response that it does not conduct traditional advertising through traditional media, the company, along with Rockstar Energy products, relies heavily on an organized social media presence and the sponsorship of music and sports events that target young audiences. As Rockstar indicated in its response, teenagers do attend and participate in these marketing initiatives.

Recently both the National Collegiate Athletic Association (NCAA) and the National Federation of State High School Associations (NFHS) have stated that energy drinks may pose a health and safety risk for student-athletes and are particularly worrisome if consumed before or during strenuous exercise. These organizations are making a concerted effort to warn their student athletes of the risk of energy drink consumption and in the case of NCAA to also restrict the marketing advertising of these products to their athletes.

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[23] See: http://www.ameribev.org/files/339_Energy%20Drink%20Guidelines%20%28final%29.pdf

[24] According to ABA voluntary guidelines, labels of energy drinks should include the statement "Not (intended/recommended) for children, pregnant or nursing women,(and/or persons/those) sensitive to caffeine"

[25] Monster energy has indicated through conversations with staff that were unaware of the routine awarding "Monster Energy Player of the Game" and are investigating this practice.

TABLE 4: Company responses on marketing practices and warning labels included on energy drink products

COMPANY NAME	MARKETING PRACTICES RELATING TO KIDS	PRECAUTIONARY STATEMENTS
5-hour Energy	Marketed and intended for adults	Do not take if you are pregnant or nursing, or under 12 years of age. If you are taking medication and/or have a medical condition, consult your doctor before use.
AMP Energy	Target demographic is the male consumer between the ages of 25 and 35	Not recommended for children, pregnant women or people sensitive to caffeine
Arizona	Company does little marketing	Recommended limits and precautionary statements are provided on 7 out of 11 of the company's energy products
Celsius	Follows American Academy of Pediatrics guidelines for marketing dietary supplements and does market to children or teens. Target demographic is 25-54	Not recommended for people who are caffeine sensitive, children under 12 or women pregnant or nursing
Clif Shot	Product is marketed to adult athletes. Company is aware that high schools occasionally offer caffeinated products to teenage athletes	Not recommended for children, pregnant or nursing women, or people sensitive to caffeine
Full Throttle Fuze	Company policy is to market only to consumers over 18 years of age and buy advertising only when 65% of audience is above 18 years of age.	Not recommended for individuals under 18 years of age, pregnant or nursing women or for those sensitive to caffeine. Daily caffeine consumption should be limited to 400 mg per day from all sources, this package contains 200
Jamba	Does not market to children or teenagers. The intended audience is 26-34.	Not recommended for pregnant women, children or people sensitive to caffeine
Monster Energy	Target demographic is young adults (primarily males). Brand initiatives and brand image are directed toward this population.	Not recommended for children, people sensitive to caffeine, pregnant women or women who are nursing.
NOS	Company policy is to market only to consumers over 18 years of age and buy advertising only when 65% of audience is above 18 years of age.	Not recommended for individuals under 18 years of age, pregnant or nursing women or for those sensitive to caffeine. Daily caffeine consumption should be limited to 400 mg per day from all sources, this package contains 260
Red Bull	Company follows American Beverage Association voluntary guidance	Not recommended for children, pregnant or nursing women, or people sensitive to caffeine
Rockstar	Messaging is designed to be aspirational for young adults. Some teenagers do participate in marketing initiatives or view them on TV or the internet	Not recommended for children, pregnant or nursing women, or people sensitive to caffeine
Sambazon	Not conventionally marketed to any groups (particularly teens and children)	None
Target Archer Farms	Not intended or marketed to children or teens. Product is designed to appeal to adults with an active lifestyle as an alternative to soda.	None
Venom	Not marketed to children or teens. Follows American Beverage voluntary guidance	Not recommended for children, pregnant or nursing women, or people sensitive to caffeine

The combination of energy drinks with alcohol is a well-recognized public health hazard, particularly for youth. In the past FDA has taken enforcement action against caffeine containing

alcoholic beverages, because drinking them was considered to create risky, "hazardous and life-threatening situations."[26] While caffeine containing alcoholic beverages are no longer popularly sold, some energy drink companies have sought to fill this market void by marketing products that represent themselves similarly to commonly consumed alcoholic beverages. For example, Monster Energy produces a product known as Cuba Lima, which is compared on its website to the popular alcoholic beverage Cuba-Libre.[27] The company also makes a product with a special "brewing process" and packaged in a bottle made to look similar to a beer bottle. Monster additionally markets a product compared to the alcohol infused whipped cream called 'Whip-it' and for which the company proudly states "it will whip you good."[28] It appears that these products and their advertising and packaging practices are intended to attract young audiences that are not of legal age to consume alcohol.

With the exception of Sambazon, Target's Archer Farms Energy Drinks and some of the Arizona brand energy drink products, the remaining companies surveyed all include a precautionary statement in line with ABA voluntary guidance, that the product is not recommended for children, pregnant women or people who are sensitive to caffeine. Coca-Cola's Nos and Full Throttle Fuze brand products include an additional statement that the product is not recommended for those under the age of 18. It would be helpful for consumers if all energy drinks contained precautionary statements that were consistent across all products.

<u>FINDING#4:</u> Energy drink companies make a range of advertising claims related to the functional benefits of their products that are not generally evaluated or substantiated by the FDA. Some of these claims appear to be targeted to young audiences or student athletes.

The FDA and the Federal Trade Commission (FTC) share jurisdiction over health- and nutrient-related claims made by food and supplement manufacturers. FDA oversees labeling requirements that prohibit, among other things, food labeling that is false or misleading. FTC oversees federal consumer protection requirements that prohibit, among other things, deceptive acts or practices in advertising, including food advertising. Under a longstanding memorandum of understanding, the two agencies agreed that FDA has primary responsibility for labeling of food, including dietary supplements and beverages, while the FTC has primary responsibility over the advertising of these products. FTC has recently emphasized in the context of energy drinks that advertising directed to youth, particularly advertising that raises safety concerns, is a priority for the Commission.[29]

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[26] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm234109.htm
[27] http://www.monsterenergy.com/us/en/products/monster-energy/#!/products%3Acuba-lima
[28] Monster website see http://www.monsterenergy.com/us/en/products/monster-energy/#!/products%3Aubermonster and http://www.monsterenergy.com/us/en/products/nitrous-2/#!/products%3Ablack-ice
[29] Letter from Chairman Jon Leibowitz to Congressman Edward J. Markey (January 2, 2013). See: http://markey.house.gov/press-release/markey-asks-ftc-investigate-advertising-claims-energy-drinks

The FDA categorizes health- and nutrient-related claims as follows:

- *Health claims* characterize the relationship of any substance to a disease or health-related condition (e.g., diets low in sodium may reduce the risk of high blood pressure).
- *Structure/function claims* describe the role of, or characterize the mechanism by which, a nutrient affects a body structure or function (e.g., calcium helps build strong bones).
- *Nutrient content claims* characterize the level of a nutrient in a food (e.g., good source of vitamin C).

The survey of energy drink manufacturers found that these companies routinely use structure/function claims to convey the health benefits of their products (See Table 5). Of the 14 companies surveyed, 10 (71%) responded to the question that asked them to identify the types of claims their product makes. Out of these ten respondents, eight (80%) indicated that their product makes structure/function claims. An additional two products, AMP energy and 5-hour energy, did not answer the question regarding claim type, but do make claims both on the product label and in advertising that would be categorized as structure-function claims.

The way in which structure/function claims are validated and governed depends on whether the product is represented as a dietary supplement or beverage. If a dietary supplement includes a structure/function claim, it must have a disclaimer on its label stating, "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."[30] In addition, dietary supplements making a structure/function claim must notify the FDA within 30 days of first making such a claim. As a dietary supplement these claims have limitations and must also be substantiated with data.[31] However, the FDA has limited resources for oversight of dietary supplements and generally has limited information on the number and location of dietary supplement firms, the types of products currently available in the marketplace, and information about moderate and mild adverse events reported to industry.[32] As a result, many of the functional claims made about dietary supplements are not evaluated by the FDA to ensure they perform as advertised.

The limitations, disclaimers and other requirements that apply to structure/function claims made by dietary supplements do not apply to products that are classified as beverages. Instead, the structure/function claims made by beverages are subject to FDA's overall requirement that labeling *not* be false or misleading. However, as indicated by a report released by the Government Accountability Office[33], the FDA has not provided guidance on the scientific support needed to prevent false or misleading information for a structure/function claim for food or beverages. The FDA also has not given its inspectors instructions for identifying potentially false or misleading information in such claims. Furthermore, unlike dietary supplements, the

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[30] The Dietary Supplement Health and Education Act of 1994

[31] Dietary supplement structure function claims must also either: 1) claim a benefit related to a classical nutrient deficiency disease and disclose the prevalence of such disease in the United States, (2) describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, (3) characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or (4) describe general well-being from consumption of a nutrient or dietary ingredient

[32] FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims GAO-11-102, Jan 14, 2011

[33] Ibid

FDA cannot compel food and beverage companies to turn over the data and information used to substantiate product claims. As a result, the claims made by these energy products have never been evaluated or substantiated by the FDA, or any publically accountable body.

TABLE 5: Energy drinks make a range of advertising claims relating to functional benefits

PRODUCT	CLAIM TYPE	EXAMPLES OF CLAIMS
Sambazon	did not answer	Wake up to the energizing powers of the rainforest. Made with all organic and GMO free ingredients sustainably sourced in the Brazilian Amazon, stimulate your body and mind
AMP Energy Boost	did not answer	Caffeine and B-vitamins, Help kick you in high gear, Helps energize and hydrate the body
5-hour Energy	did not answer	Hours of energy, No crash, Helps you feel awake for hours, Power through your day, Stay bright and alert
Jamba	did not answer	All Natural (removed as of November 2012), Natural caffeine for mental alertness, A full serving of fruit per can
Celsius	Health Claims	Reduces body fat, Improves endurance, Increases metabolic rate, Burn calories (based on six clinical studies of product)
Target Archer Farms	Nutrient Content	Sugar free, Low calorie, Energy enhancing properties of ginseng
Venom	Structure/Function	Free agent of energy, Up to the nanosecond performance for MVPs and VIPs, Instant impact
Clif Shot	Structure/Function	Performance enhancing caffeine, Helps with motivation and mental alertness during activity, Clean essential energy and hydration, Fast muscle recovery, Fast acting energy source, Essential electrolytes
Red Bull	Structure/Function	Increases endurance, Increases concentration and reaction speed, Improves performance during stress and strain, Gives you wings, Improves vigilance, Stimulates metabolism, Makes you feel more energetic and improves your overall well-being
Full Throttle Fuze	Structure/Function	Help you get the job done, Feel the energy at work, Easy drinking energy
NOS	Structure/Function	Enhanced mental focus, High performance energy, Get focused, Get 50% more focused, React faster
Rockstar	Structure/Function	Bigger, faster, and stronger that other energy drinks, Provides energy and hydration
Monster Energy	Structure/Function	Rehabilitate with a killer mix, Gives you hydration and energy you need, Quenches thirst, Fires you up and brings you back after a hard night, No 'whip it' but it will whip you good, Delivers a big bad buzz, Unleash the beast, Packs a powerful punch
Arizona	Structure/Function and Nutrient Content	Extreme performance, Loaded with antioxidants, Lasts for hours, Natural energy, Invigorating blend

<u>FINDING #5:</u> In addition to caffeine, energy drinks contain a myriad of specialty ingredients whose combinations and additive impacts are not thoroughly evaluated or well understood. Companies can and often do self-determine that ingredients are safe for use in energy drinks, and there is no requirement for companies to notify the FDA of this determination or the use of the ingredient.

Caffeine and added carbohydrates (usually in the form of natural or synthetic sugars) are the primary ingredients energy drinks rely on to fuel claims of "increased energy". However, these drinks also contain other ingredients for purported health benefits, most commonly high levels of certain B-vitamins, ginseng, guarana, inositol, taurine, and other amino acids (See Table 6). The combined health impacts of these ingredients as well as some less commonly used exotic ingredients, such as methylated xanthines (a stimulant), raise significant concerns for consumers, particularly youth. With the exception of the B-vitamins, the quantities of many of these other ingredients are not required to be disclosed on the label. Similarly to caffeine, some companies[34] choose to voluntarily disclose the amount of some of the more commonly used ingredients, such as guarana and taurine. However, frequently these ingredients are merely labeled without corresponding quantities.

From a regulatory perspective, ingredients that are used in energy drinks are treated differently dependent on whether the energy product is represented as a dietary supplement or a beverage. If a dietary supplement manufacturer opts to use a "new dietary ingredient"—an ingredient that was not marketed in the United States before October 15, 1994—the company may be required to notify the FDA before marketing the product, depending on the history of use of the ingredient. For the most part, FDA relies on post-market surveillance efforts—such as monitoring adverse event reports it receives from companies, health care practitioners, and individuals, as well as reviewing consumer complaints and conducting facility inspections—to identify potential safety concerns related to dietary supplements. Even once a safety concern is identified, FDA must demonstrate that the dietary supplement presents a significant or unreasonable risk under its specified conditions of use—a high threshold to meet—before it can remove the product from the market.[35]

For energy drinks classified as beverages, the FDA handles the oversight of ingredients differently. Generally, an ingredient added in a food product must either be generally recognized as safe (GRAS) or go through FDA's review and approval process as a food additive.[36] In order for an ingredient to be considered GRAS there must be a "reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."[37] However, the burden to determine whether an ingredient is GRAS is typically left to the manufacturer and a manufacturer can make this determination on its own, and use the ingredient in a product, without informing the FDA. As a result not only would the FDA potentially not know when a company has made an unsupported or incorrect determination about whether an ingredient is GRAS, the FDA would have no knowledge whether an ingredient was even being

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[34] See for example the label of AMP energy.

[35] FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims GAO-11-102, Jan 14, 2011

[36] Substances that were in use prior to 1958 can be determined GRAS based on its common use in food.

[37] 21 C.F.R 170.3(i)

used or the frequency of its use. In the event that FDA was aware that an unapproved additive was being used in a product and the ingredient was not GRAS for its intended use, the FDA would consider this product to be adulterated, making marketing or selling of the product illegal.

TABLE 6: Ingredients commonly used in energy drink products

BRAND NAME	INGREDIENTS RELATED TO FUNCTIONAL CLAIMS MADE* (not including natural or synthetic sugars)
Arizona	Caffeine, guarana extract, L-carnitine, ginseng extract, eleuthero root, schisandara, green tea extract, B-vitamins
Venom	Caffeine, taurine, guarana, L-carnitine, ginseng extract, inositol, maltodextrin, B-vitamins (niacinamide, B6, riboflavin, B12)
Clif Shot	Caffeine, green tea extract, guarana, maltodextrin
Red Bull	Caffeine, taurine, glucuronolactone, inositol, B-vitamins (niacinamide, B-12, pantothenic acid, pyridoxine)
Full Throttle Fuze	Caffeine, B-vitamins (niacinamide pantothenic acid, pyridoxine)
NOS	Caffeine, guarana, taurine, L-theanine, B-vitamins (B6, B12)
Jamba	Caffeine, green tea extract
Sambazon	Caffeine, yerba matte, green tea extract, guarana
Target Archer Farms	Caffeine, panax ginseng root, guarana, taurine, vitamin B6 and B12
AMP Energy	Caffeine, choline, theanine, maltodextrin, panax ginseng root extract, L-carnitine, guarana, taurine, B-vitamins (riboflavin, pantothenic acid, niacinamide)
Rockstar	Caffeine, guarana, B-vitamin niacin B-12, pantothenic acid, B6) taurine, yerba mate, green tea extract, L-carnitine, inositol
5-hour Energy	Caffeine, citicoline, L-tyrosine, L-phenylalanine, malic acid, glucuronolactone, taurine, B-vitamins (Niacinamide, pyridoxine,B12, folic acid), methylated xanthines
Celsius	Caffeine, guarana, taurine, green tea extract, glucuronolactone, ginger extract, B-vitamins (riboflavin, niacin, B6, B12, pantothenic acid)
Monster Energy	Caffeine, taurine, L-carnitine, glucuronolactone, guarana, panax ginseng extract, inositol, maltodextrin

*ingredients may vary dependent on product

The FDA has raised concerns that some ingredients that have been present in the food supply for many years are now being added to energy drinks at levels in excess of how they are traditionally used.[38] This trend raises questions regarding whether these higher levels and other new conditions of use are safe. For example, guarana is a FDA approved additive for flavor, but is commonly and intentionally added to energy drinks as an extra source of caffeine stimulant, sometimes at higher levels than what would be used if guarana was only being added for flavor. Taurine, an amino acid, is another frequently added ingredient in energy drinks. It has never been affirmed as GRAS by the FDA, nor has it been approved as a food additive. However, taurine is considered GRAS by the Flavor and Extract Manufacturers Association of the United States for flavor use. The European Commission (EC), assessed the use of taurine in energy drinks and couldn't conclude taurine concentrations used in energy drinks are safe.[39] Furthermore, caffeine is universally added to energy drinks at levels that are far beyond what has been affirmed as GRAS by the FDA for use in cola-type beverages (approximately 71 mg per 12 ounces).[40]

Recently, the City Attorney of San Francisco wrote a letter to FDA Commissioner Margaret Hamburg, challenging the GRAS determination energy drink companies have made to use levels of caffeine beyond what is typically found in cola-type beverages. According to the city attorney's letter, which was supported by 18 independent scientific experts, the addition of caffeine in the amounts used in energy drinks is not safe based on scientific evidence, and as such, the FDA should enforce limits in energy drinks that are comparable to what is commonly found in cola-type beverages. Historically, the FDA has not challenged the use of caffeine in other beverages at levels that are comparable to the GRAS level for cola beverages. However, the use of caffeine in energy drinks far surpasses that which is found in common sodas. The FDA should use its current authority to evaluate whether the levels of caffeine and other ingredients commonly used in energy drinks is in fact GRAS and revise its regulations accordingly. The FDA should also set limits for the use of these ingredients for single serve containers.

[38] FDA Draft Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods. (December 2009)
[39] http://ec.europa.eu/food/fs/sc/scf/out22_en.html
[40] 21 CFR 182.1180

Conclusions and Recommendations

Energy drinks are a relatively new product category that is rapidly growing in the marketplace and may serve as an emerging public health risk, particularly for adolescents. Energy drinks universally contain high levels of intentionally added caffeine, sugar and other novelty ingredients that are often advertised and marketed toward young people or presented in youth-oriented media and venues. The use of these ingredients and their combinations have largely not been assessed for safety by the FDA, but recent indications of adverse events and increased hospitalizations that may be associated with consumption of energy drinks call into question both the safety and the claims made by these companies.

The inconsistency in the way these products are represented to consumers, marketed, and labeled poses unique challenges to federal regulation and oversight. Furthermore, because of the way energy drinks are regulated, ingredients are often not presented on the label in a manner that enables consumers to make an informed decision about quantities of caffeine and other ingredients they purchase and consume. The lack of transparency in the labeling practices of energy drinks combined with the inconsistent way in which they are presented in the market and the advertising claims and marketing practices of these companies have the capability of eroding consumer confidence in the safety of all FDA-regulated products.

We call on all manufacturers of energy drink products, whether they are marketed as dietary supplements or conventional foods (beverages) to take the following steps to improve transparency and representation of its products and ensure that children and teens are adequately protected from deceptive advertising practices:

1. **Label products with a clear description of the total amount of caffeine (in milligrams) added to the product from all sources. For products that are packaged in non-resealable containers (such as pop-top cans), the label should include the amount of caffeine from all sources in the entire container, not just one serving.**

2. **For products that contain caffeine that has been intentionally added to the product at levels above 200 parts per million (approximately 71 milligrams per 12 fluid ounces), the level affirmed as GRAS by the FDA, display a prominent precautionary statement that at a minimum says, "This product is not intended for individuals under 18 years of age, pregnant or nursing women or for those sensitive to caffeine. Consult with your doctor before use if you are taking medication and/or have a medical condition."**

3. **Cease marketing of energy drink products to children and teens under the age of 18. Marketing includes use of both traditional media and social media as well as the sponsorship of events, activities and individuals that are intended for an audience comprised primarily of children or teens.**

4. **Report to the FDA the receipt of any serious adverse events associated with energy drink use. Serious adverse events are defined by the FDA, but reporting is currently only required by the FDA for products that are represented as dietary supplements.**