KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY

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ASSESSING THE EFFECTIVENESS OF FDA REGULATION OF ENERGY DRINKS

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DECLARATION

I hereby declare that this submission is my own work towards the Degree of Master of Science in Food Quality Management (MSc. Food Quality Management) and that, to the best of my knowledge, it contains no material previously published by another person nor material which has been accepted for the award of any other degree of the University, except where due acknowledgement has been made in the text.

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ABSTRACT

Energy drinks which contain stimulant drugs chiefly caffeine and are marketed as providing mental and physical stimulation are fast becoming the most popular drink worldwide targeted at the youth. There is a growing concern about its impact on the health of young people due to some adverse effects linked to it. It is therefore no surprise that many countries are calling for tighter control and regulation of energy drinks. Some countries have issued limits for caffeine in such drinks, introduced special tax on them, demanded for the display of caution statements on product labels and restricted its sale. This study was therefore conducted to assess the effectiveness of the Food and Drugs Authority (FDA) regulation of energy drinks. A mixed methods approach was adopted which includes survey, interviews, sampling and testing using HPLC to determine knowledge, perception, effects and actual level of caffeine in some energy drinks on the local market. Results indicated relatively poor regulation of energy drinks in the country. Some products in trade were not registered and the country has no limits set for caffeine. Majority of billboards (87.5%) have not been approved by the FDA. Most consumers of the product had exceeded the maximum daily intake and others were mixing these drinks with alcohol, tramadol and codeine containing cough syrups. The way forward is for better and tighter control and regulation of energy drinks by the Food and Drugs Authority and the education of the public on the adverse effects of excessive consumption of the product and the dangers in mixing it with alcohol, tramadol etc.

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We did it!

DEDICATION

This work is dedicated to my family, friends, colleagues and to all citizens (and not spectators) who wish to change the narrative of Ghana!

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CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Energy drinks is a term used to describe various beverages which usually contain caffeine, sugar, taurine, guarana, taurine, herbal supplements, vitamins and other ingredients, according to Seifert, et al (2011). Manufacturers of these drinks usually promote them as energy improving beverages. These popular drinks date back to the 1960s where they were known in the European and Asian markets but eventually found its way to North America only after 1996 (Heckman, et al, 2010; Johnson, 2006; Reissig, et al 2009). Energy drinks have become one of the fast-growing products on the market in recent times due to their ability to boost the energy of consumers (Heckman et al., 2010). More often than not, advertisements portray the products as enhancing performance, boosting the immune system and also giving users an "extra kick" or a "high" when consumed. While consumers sometimes tend to mix them with alcoholic beverages, some of these drinks are already premixed, i.e. infused with alcohol. Over the past few years, several reports in the media have somewhat raised awareness about energy drink consumption especially among the youth, hence adolescents are no strangers to these drinks. A fruit flavored energy drink, infused with alcohol, hence termed a caffeinated alcoholic drink, was the cause of the hospitalization of nine students of Washington State University in 2010, where one of them almost died. Prior to that, some 23 college students in New Jersey, after becoming intoxicated with this same fruit flavored alcohol infused caffeinated drink, were again hospitalized. Hence, after a yearlong review of such cases, the Food and Drugs Administration in November 2010 issued a warning to some manufacturers of seven alcohol-infused energy drinks to either reformulate or recall their products in trade, stating that, per the legal standard GRAS, the Food and Drugs Administration did not

consider the inclusion of caffeine to alcoholic drinks as belonging to the designation, Generally Recognized as Safe, and that the products which combined these substances posed health risks to its consumers (www.cdc.gov/alcohol/fact-sheets/caffeine-and-alcohol.htm).

Nevertheless, the product market of these drinks has multiplied rapidly in recent times, which almost doubled between the years 2006 and 2012 globally (Meier et al 2012) and generated an annual sale of over $110 million only in Canada It seems that the major target demographic for the marketing of energy drinks are the youth aged between 18 and 34 (Heckman et al., 2010). As a result of the high levels of substances such as caffeine and sugar, and relatively high levels of the other ingredients in this drink; herbal ingredients, guarana, taurine and vitamins, there are some growing concerns about the potentially detrimental effects and risks on the health of the consumer, essentially the youth, with regards to the consumption of energy drinks (Harris and Munsell, 2015; Pomeranz et al., 2013). Some regulatory agencies and poison control centers have in recent times recorded a number of common adverse effects, quite serious in some instances, which include neurological, gastrointestinal and cardiac symptoms experienced by patients after consuming these drinks (Ali et al., 2015; Sepkowitz, (2013); Gunja and Brown, 2012; Seifert et al., 2011).

To add to the preceding point, the consumption of high caffeine-containing energy drinks may lead to adverse effects like jitteriness, anxiety disorders, sleep disturbances, gastrointestinal and cardiac symptoms and in some rare instances may lead to seizures and even death (Bigard, 2010; Harris and Munsell, 2015; Seifert et al., 2011). Other studies have also linked the consumption of energy drinks with some rather risky behaviors often exhibited by adolescents and young adults such as violence, the use of drugs and alcohol, smoking and sexual risk-taking (Azagba et al., 2014; Larson et al., 2015; Miller, 2008; Terry-McElrath et al., 2014).

According to Health Canada, the caffeine intake for a healthy adult and an adolescent not younger than 13 years of age with a body weight not exceeding 2.5mg/kg, must be limited to 400 mg per day (Health Canada, 2013). A single serving can or bottle of an energy drink in this jurisdiction, dependent on the size, normally contains between 80 and 180 mg of caffeine. Health Canada permits 200–400 ppm (mg/L) caffeine content with a maximum of 180 mg per serving/container (Health Canada, 2013). Hence, some statements are required to be displayed on labels of energy drinks including the quantitative declaration of caffeine content and "high caffeine content" which is a qualitative declaration on such product labels, in addition to the following caution statements: "Do not consume more than (X) container(s)/serving(s) daily" or "Usage: (X) container(s)/serving(s) maximum daily." (Health Canada, 2013), where X is 1 or 2, depending on the product's vitamin and mineral content. Although incidences of young adults exceeding the Daily Maximum Intake of caffeine from the consumption of energy drinks have not been recorded in Canada, results from Europe suggest otherwise, indicating that the practice is common (Zucconi et al., 2013).

Even though, adverse effects resulting from the consumption of excess caffeine have been reported (Seifert et al., 2011), Health Canada recognizes that for regulatory requirements to be developed for energy drinks, some information gaps which are outstanding should be resolved first. An example being how useful labeling displayed must be in order to alleviate risks and ascertaining the consumption patterns of these drinks with regards to one's diet. However, in the interim, marketing authorization was found to be most appropriate in terms of regulation, which entailed permitting the sale of energy drinks under some specific conditions, until enough evidence or data is collected and reviewed. These conditions include qualitative declaration of caffeine, quantitative declaration of the amount of caffeine and other ingredients such as minerals and vitamins, caution

statements and restrictions on the advertisements of energy drinks to children (Health Canada, 2013). Future regulation of caffeinated energy drinks (CEDs) may be dependent on useful information gathered on the consumption patterns of young people.

Mordor Intelligence projects that the product market for such beverages in Africa is bound to grow at a CAGR (compound annual growth rate) of about 2% in the forecasted period of 2018-2023 and this can be attributed to the gradually changing lifestyle of the 21st century African and the rising demand for convenience drinks like energy drinks (www.mordorintelligence.com). Hence the major drivers are as a result of the expanding middle-class market which has led to local manufacturers building capacity in the production of these drinks to also bring about growth in the product market. Here in Africa, caffeinated energy beverages hold the major market share and its packaging has a lot to do with the product's performance in the market with cans being the major market shareholder. Availability to consumers of the drink can be attributed to supermarkets, mass-market retailers, and convenience stores which are the major distribution channels of CEDs. In the continent, South Africa is the leading market for the promotion and sale of international and local brands from companies such as Red Bull, Monster Beverage Corporation, Mofaya Energy Drinks and Coca-Cola.

According to a research report published by Canadian, Mahajan, (2011), the continent registered a total amount of 51,559 million liters (13,473 million gallons) of non-alcoholic drinks consumed in 2013. Therefore, the total value of the non-alcoholic beverage industry in Africa was estimated at $54.6 billion USD with an average price of $1.06 per liter (the on and off trade sales values), after the application of a multiplier to the volume of consumption. The Euro Monitor International Report recorded global sales of non-alcoholic drinks as $835 billion USD. According to the African Development Bank, the continent has a population of exactly 1.2 billion people with a

rapidly increasing middle class (in the region of 350 million or 34% of the population in 2010 as per the report of the African Development Bank and 128 million by the year 2020 according to McKinsey there is a clear indications that the 21st century working class of Africans have enough disposable income to spend on non-essential products. The potential size of CEDs market is therefore immensely huge given the undersized $54.6 billion USD valuation of the African non-alcoholic beverage market.

1.2 Problem Statement

Energy drinks sales have surged rapidly in Ghana and many people now depend on all kinds of energy drinks as "the default thirst quencher and a pick-me-up". Some pregnant women are noted to be abusing these energy drinks (www.modernghana.com). Available public health literature indicates that some ingredients in energy drinks like caffeine, glucuronolactone, milk thistle etc. are considered potentially harmful (babyMed, 2017). Oblivious to the effects of these drinks, some people serve them at gatherings such as parties, funerals and church events as soft drinks to adults and children alike. Others even break their fast with these "purported energy drinks" while a section of the working class, particularly the young male adults, mix hard liquor with energy drinks at various pubs to unwind especially over the weekends. A study conducted by the World Health Organization (WHO, 2017) posited that energy drinks may cause health problems. The study maintained that the primary risk of high dependence on these drinks was from high levels of caffeine, which can result in problems such as rapid, strong, or irregular heartbeat known as palpitations, hypertensions, and in some instances, congestive heart failure (CHF) which may lead to death. Some deaths reported in advanced countries have been associated with the excessive intake of energy drinks. The Washington Post in May 2017 reported the death of a 16-year-old

boy in South Carolina, who ingested highly caffeinated drinks in a very short period of time. Some governments because of incidents like these have introduced restrictions on their sale and importation. For example, countries like Norway, Turkey, France, Uruguay, Iceland and Denmark banned Red Bull Energy Drink altogether from their markets because it contained both caffeine in high levels and taurine. France had banned these drinks for 12 years. However, all these European countries only permitted its sale in 2008 after they were forced by EU regulations to legalize the drink on the basis that a health risk could not be proven. Countries such as Sweden have banned the sale of these caffeinated energy drinks to children. As mentioned earlier, countries such as Canada permit the sale of these drinks under some regulatory requirements including warning labels clearly cautioning against their use by children or pregnant women, not to be consumed in large quantities or with alcohol. However, in developing countries such as Ghana, there is a sudden and a rather aggressive approach to marketing these drinks due to the absence of proper regulations to control the sale and promotion to the youth particularly. Therefore this research seeks to assess the effectiveness of Food and Drugs Authority's regulations on energy drinks on the local market.

1.3 Objectives of the study

The ultimate objective of the study is to assess the effectiveness of FDA regulations on energy drinks in Ghana.

Specifically, the study seeks to;

1.To assess the level of use, knowledge and perception of energy drinks.

2.To determine actual levels of caffeine in some energy drinks on the market.

3.To determine the level of compliance of energy drink manufacturers and importers to Food and Drugs Authority regulations.

1.4 Research Questions

The following questions were addressed in the study:

1. What are energy drinks?
2. What are the contents of energy drinks and their adverse effects and safe concerns?
3. Who are high consumers of energy drinks?
4. What are the perceptions on the use of energy drinks?
5. What are the drivers of energy drinks consumption?
6. What are the roles of Ghana Food and Drugs Authority (FDA) in regulating energy drinks on the local markets?

1.5 Justification for the study

Research and review work on energy drinks consumption, or the consumption patterns of CEDs, in Ghana is almost non-existent in spite of the sudden increase of various brands of energy drinks on the local market. It has been posited that the consumption of energy drinks, particularly among the youth, aged between 18 and 25, is of great concern (Miller, 2008). The World Health Organization (WHO, 2017) opined that high consumption of energy drinks could cause public health problems. It has been noted that as a result of the increasing varieties in brands of CEDs on the market, which are readily accessible, the practice of consuming energy drinks is very common among student-athletes (Buxton and Hagan, 2012). However, many of the energy drinks companies do not state the quantities of their products' constituents or other ingredients, thereby withholding actual amounts of these ingredients by using the term "proprietary blend" which is accepted for products registered as supplements. The absence of proper regulatory actions has resulted in the aggressive advertising of energy drinks, which aim to attract young male adults, as a stimulant drug that enhances mental performance. The Food and Drugs Authority (FDA) as

mandated by law through the Public Health Act 2012 (Act 851) is to ensure that all energy drinks imported into the country or locally manufactured, which falls under the category of food, are safe for consumption before market authorization is given.

1.6 Scope of the Study

The study focuses on exploring the use of energy drinks among the youth especially students from (JSH, SHS and University), the young working adults and assessing the effectiveness of FDA regulations on energy drinks.

1.7 Organization of the Study

The study was organised into five chapters.

A brief background to the research was presented in Chapter 1, including discussion on the research problem, and reason and justification for the research. Chapter 2 reviewed previous work done on CEDs; energy drinks consumption, perceptions on the use of energy drinks and the regulation of these drinks. Chapter 3 discussed the methodology adopted for the research. The chapter sought to describe the type of methods used to conduct the research including the description and measurement of the variables, the research sample and also the techniques for data collection. Both sample size of the study and the detailed sampling method were indicated in the chapter. The results of the study were presented and discussed in Chapter four. Here, statistical tools were used to collect and analyse the data. Chapter 5 which is the last chapter summarised the key findings of the study in the conclusion based on which recommendations were then given.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Introduction

Seifert e t al (2011) define energy drinks as soft drinks that are believed to enhance disposition and mental performance, improve physical performance and prevent or reduce tiredness. Some countries such as New Zealand, Australia, India and Canada, insist that the term "energy drink" is a misnomer as the drink contains stimulants which typically only improve mental alertness or mental performance and does not necessarily provide any increased form of energy compared with an average soft drink. Hence, these drinks are also termed as caffeinated drinks in such jurisdictions (Bagwath Persad ,2011). These beverages termed as energy drinks contain high levels of caffeine and are different from regular drinks like juice because they contain other ingredients included in their formulation which are not present in the regular drinks (Heckman et al., 2010). Harris et al. (2011) claim that energy drinks are categorized into two product types; energy drinks which are often sold in 8-32oz. cans and those normally available in 2-2.5 oz PET bottles known as energy shots. These days however, some manufacturers have produced these energy products in the form of drink powders and effervescent tablets.

There are many of these energy drinks from different manufacturers readily available on the market with some indicating the amounts of ingredients on the labels of the products and others not disclosing the actual amounts. Labeling is a major problem as posited by Harris et al., (2011) and Pomeranz et al., (2013) since some of the companies are inconsistent with serving sizes, or fail to list ingredients such as caffeine or other ingredients that have been associated with some side effects on human health. In considering the different types of energy drinks, some contain caffeine mixed with one or several of the following ingredients: Antioxidants, Artificial Sweeteners,

Creatine, Ginseng, Ginkgo biloba, Glucuronolactone, Guarana, B Vitamins, L-Carnitine, Milk thistle, Sugars, Taurine and Yerba mate (Caffeine informer, 2017; Ishak et al., 2013).

2.2 Composition of Energy drinks

2.2.1 Caffeine.

Caffeine is the primary ingredient in energy drinks that distinguishes this type of drink from the regular soft drink. As previously discussed, some non-alcoholic drinks contain an amount of caffeine in levels below 150mg/l or in some cases or jurisdictions, 200mg/l for use as flavors. However, any amount exceeding this level ceases to become a flavoring enhancer; instead, it serves a function as a psychoactive substance. This naturally occurring alkaloid is found in over 60 plants including cacao beans, kola nuts, coffee beans, tea leaves, yerba mate and even in the berries of guarana (another ingredient of energy drinks). The world's major sources of dietary caffeine are the tea leaves (*Camilia sinniensis*) and roasted coffee beans (*Coffea Arabica* and *Coffea robusta*). A study revealed that approximately 80% of the world's population consumes caffeine in some form and 90% of North American adults take in caffeine daily (Ogawa and Ueki, 2007).

This psychoactive substance is responsible for the "boost" consumers experience after drinking energy drinks. Since caffeine is a central nervous system (CNS) stimulant in humans, it works by blocking the effects of the brain chemical known as adenosine which is responsible for sleep. This almost instantly restores alertness by temporarily warding off fatigue and drowsiness.

According to Julien, et al (2011), 99% of caffeine administered orally will, in 45-90 minutes, be absorbed totally by the gastrointestinal tract. Studies also show that caffeine is metabolized in the liver after which the kidney excretes it with urine (Julien, et al 2011). The diuretic effect of high levels of caffeine could lead to dehydration in athletes who do not drink enough fluids to replace

it since caffeine causes the kidneys to remove extra fluids. Caffeine is well-known for its ergogenic properties, which has very broad spectrum of hormonal, metabolic and psychological effects (Higgins et al., 2010; Heckman et al., 2010). Ergogenic are chemical substances that tend to enhance body performance (Freedictionary.com, 2017). A study showed that ergogenic effect begins by mobilizing fat stores through metabolism and then causes fat to be depleted by muscles during a workout session hence increases workout time since glycogen is saved for use later (Higgins et al., 2010). Caffeine was banned by the International Olympic Committee (IOC) for its ergogenic effects in 1962, but the ban was lifted some ten years later. According to Graham, 2001, 6mg of caffeine per kg body weight administered in vitro could greatly enhance physical performance during workout and this effect could last anywhere from a minute to an hour and twenty minutes. Although the ban was lifted in 1972, the IOC considered it as a restricted drug in 1998 (Hawley, 1998). Caffeine consumption has been linked with fetal growth retardation, decreased birth weight, premature births and miscarriages. School-going caffeine-consuming children have been reported to have experienced withdrawal symptoms after taking in as little as 120 to 145 mg per day (three to five sodas or one to two cups of coffee) over a period of two weeks (Bernstein et al 1998). Heavy caffeine use can result in cardiovascular effects that can be a significant cause of morbidity in athletes. Hypertension and palpitations in the adolescent athlete often lead to vast medical conditions.

2.2.2 Sugar.

Sugar is the second most common ingredient after caffeine in caffeinated energy drinks, and is a major source of energy for the body which is obtained through oxidation and may be used by the muscles (Higgins et al., 2010). Energy drinks mainly contain added sugars and some names commonly used on labels of food products to refer to added sugars are high-fructose corn syrup,

corn syrup, fructose, glucose, sucrose, dextrose etc. One of the effects of ingesting sugar or any of its derivatives is the enhancement of physical and mental performance in the human body (Caffeine informer, 2017; Giles et al., 2012; Higgins et al., 2010). According to Giles et al. (2012) glucose works synergistically with taurine and caffeine to improve concentration and memory, by decreasing the reaction time and sparking the brain activities during fatigue when the brain is inactive. NASA conducted a study which showed that glucose affects various activities and not just memory improvement. For example, it also enhances reading, speaking, communication abilities and decision-making abilities (Elias, et al.,1997). Pomeranz et al. (2013) state that most energy drinks contain high levels of sugar, which is equivalent to high calories, and over 96% of these drinks were found to contain only artificial sweeteners as substitutes to sugar or used in addition to sugar, but more than 50% percent of the energy drinks did not declare sweeteners as part of their ingredients. The American Heart Association recommends that sugar intake for male adults is limited to 9 teaspoons which is equivalent to 37.5g of sugar while female adults and children should consume 6 teaspoons or 25g of sugar daily for a healthy diet (www.heart.org). Some energy drinks on the market contain as much as 55g of sugar which is the equivalent of over 13 teaspoons of sugar. The World Health Organization (WHO), as a result of the effects of over-consumption of sugary drinks, including energy drinks, is calling on governments to take actions in reducing the consumption of sugar. It suggests that taxing such products just as taxing tobacco will help to reduce its use thereby reduce prevalence of obesity, tooth decay and type 2 diabetes.

2.2.3 Ginseng

Also known as “Panax ginseng”, this term is generally used to describe some botanical plants which mostly grow in Vietnam, China, Korea, Japan, some parts of USA and the Himalayan region. For more than two thousand years, Asians have been using this slow growing perennial

plant (Harrison etal.,2013; Heckman et al., 2010). It was first used by ancient people in different ways to help in preventing illnesses, to cure some diseases, to reduce tiredness, or to enhance the quality of life (Babu et al., 2008; Harrison et al., 2013; Heckman et al., 2010). Proponents of ginseng believe that it has numerous benefits including reducing blood sugar, improving brain functions, boosting the immune system, aid in the reduction of certain cancers, help ward off fatigue by increasing energy levels, and the most popular benefit suggested being improving erectile dysfunction and used as an aphrodisiac. That notwithstanding, high levels of ginseng have been linked with adverse effects such as mastalgia, miscarriage, sleep apnea, diarrhea, low blood pressure, vaginal bleeding, euphoria, pruritus, disturbance in body temperature, palpitations, appetite suppression, cholestatic hepatitis, tachycardia and in severe cases even Steven-Jonson Syndrome, and anaphylaxis (Babu et al., 2008; Caffeine informer, 2017; Heckman et al., 2010; Higgins et al., 2010). Some serious side effects ranging from "swallowing problems, euphoria, nervousness, elevated blood pressure, to liver dysfunction and altered ejaculation" have been linked to ingesting products that contain ginseng and one or more of ingredients such as fenugreek, gingko, and/or *Ophiopogon japonicas*, minerals and vitamins (Charrois, et al., 2007).

2.2.4 Taurine.

Taurine or 2-aminoethanesulfonic acid is one of the most abundant amino acids in the human body. It is mostly concentrated in the heart, muscles, brain and the eyes and is one of the most common ingredients in energy drinks. The human body can manufacture taurine on its own from other amino acids, although infants and sick adults must get it from their diet or supplements. Taurine is formed via the metabolizing process of methionine and cysteine (Heckman et al., 2010; Lourenco and Camilo, 2002). It is naturally occurring in animals including birds, fish, mammals and aquatic invertebrates such as oysters hence seafood, dairy and meat which are all great sources

of taurine. Hence, amount of taurine in the body is totally dependent on the diets of a person (Higgins et al., 2010; Lourenco, and Camilo, 2002). The brain and liver are the main producing sites for taurine which means that the production may be inhibited by any medications or diseases in these parts (Lourenco and Camilo, 2002). Excretion of taurine is by two ways: First, it is excreted with urine by the kidneys and secondly, with the bile pigment (Lourenco and Camilo, 2002).

Energy drinks incorporate a synthetic form of taurine through a series of chemical reactions. According to EFSA, the process involves a reaction between ethylene oxide and sodium bisulphite after which liquid ammonia and sulphuric acid are added. The product then has to go through a series of processes including being decolourised, purified, crystallized, centrifuged, etc. until taurine is obtained (European Food Safety Authority, 2012). In this form, it is added to energy drinks. Some of its biological benefits to humans are for antioxidation, osmoregulation, development and functioning of central nervous system, the retina and the skeletal tissues. A study showed it has so many effects on the body including enhancing physical performance, increasing body hormones, and showing some biological effects (Giles et al., 2012; Heckman et al., 2012; Higgins et al., 2010; Lourenco, & Camilo, 2002; Woolsey, 2010). The amount of taurine consumed by the regular intake of energy drinks far exceeds the amount in a normal diet (40–400 mg/day) however there is limited evidence of adverse events from taurine use. Some data from animal models suggest that this amino acid may reduce the effects of alcohol consumption and could, hence will encourage greater alcohol consumption. Some regulatory agencies have indicated that taurine, from studies done so far are safe but there have been more calls to conduct more research to establish side effects or adverse effects of the substance and its effect on other ingredients especially caffeine, in energy drinks.

2.2.5 Guarana.

A plant also known as *Paullinia cupana*, guarana belongs to the family of Sapindaceae and is a native to some tropical rainforests in the Amazon basin in South America. It is a climbing plant which bears red berries. Only one to three seeds are contained in an entire plant and these are the only edible part of the plant (Heckman et al., 2010). Upon maturation, the guarana fruit is about the same size as a coffee bean. The Amazonians for centuries have used it for its therapeutic properties and for many years has been used in Brazil as a tonic for the treatment of certain disorders (Smith N et al., 2010). Large amounts of caffeine are contained in the seeds of guarana and this made it the first source of caffeine in the world (Caffeine informer, 2017; Higgins et al., 2010). Various researches on this prized plant suggest that the guarana seed has an average of 4 times more caffeine than what coffee beans even produce. A research revealed that one (1) gram of guarana could produce 40 milligrams of caffeine (Heckman et al., 2010). Although guarana contains the highest amount of caffeine, it is not considered as caffeine (Caffeine informer, 2017), mainly because there are some additional substances contained in it as well. Tremendous amounts of flavonoids, tannins and saponins, are some examples of other substances in there and because of their antioxidant and bioactivity properties are considered very active compounds (Heckman et al., 2010; Higgins et al., 2010). In addition to these there are also theobromine and theophylline contained in the seed, however amounts in there are less than what is found in caffeine (Babu et al., 2008; Caffeine informer, 2017; Heckman et al., 2010; Higgins et al, 2010). Proponents of guarana insist that the product can fight cancer cell growth and decrease skin aging and the risk of heart disease, reduce fatigue and increase alertness, improve memory, relieve chronic diarrhea and for the treatment of constipation. A study showed that it helps to improve cognitive abilities like concentration, enhances physical performance, alters the mood and is used as a remedy for mental

tiredness (Babu et al., 2008; Caffeine informer, 2017; Heckman et al., 2010; Higgins et al, 2010). Also Meyer and Ball, (2004) state that although guarana improves the cognitive abilities, it also raises the systolic blood pressure. Babu et al., (2008) suggest that because some manufacturers of CEDs do not indicate caffeine from guarana as part of the total caffeine content in the drinks, this inaccurate labeling should be noted because it may lead to serious caffeine overdose issues (Babu et al., 2008).

2.2.6 Vitamins.

Energy drinks also contain essential nutrients which are responsible for maintaining optimal health through specific roles each one plays in various parts of the human body. This group of water-soluble vitamins referred to as the Vitamin B-Complex group are made up of 8 vitamins namely: thiamin (vitamin B1), riboflavin (B2), niacin (B3), pantothenic acid (B5), pyridoxine hydrochloride (B6), biotin (B7), inositol, and cyanocobalamin (B12) (Caffeine informer, 2017; Heckman et al., 2010; Higgins et al., 2010). The functions of these essential nutrients are numerous hence its importance in diets. These include aiding in the nervous system function, digestion, converting food into energy, red blood formation, metabolism of fat, protein and carbohydrate and for the proper function of the immune system. Because of the ability of these vitamins to aid in the production of energy in the body, most manufacturers of CEDs incorporate large amounts of vitamins in their products (Heckman et al., 2010; Higgins et al., 2010).

Some sources of the vitamin B complex group are seafood, eggs, meats, beans, pork, broccoli and mushrooms according to the Food and Drugs Administration Vitamins and Minerals Chart. They can also be found in turkey, potatoes, banana and tuna (Heckman et al., 2010). But even vitamins do have their acceptable daily intake levels hence organizations such as the US FDA, EFSA etc. have recommended daily intakes of these essential nutrients. Some negative effects of consuming

large amounts of these vitamins are the redness of the skin when more than 35mg of niacin is taken, or the burning sensation of the skin caused by nerve problems or even skin diseases when more than 100mg of pyroxidine hydrochloride is ingested (Caffeine informer, 2017).

2.3 Energy Drinks Regulation

The regulation of the sale, advertising and use of caffeinated beverages has always been complicated even in the advanced countries such as USA which illustrates how complex regulating energy drinks actually is. Caffeine-containing non-alcoholic drinks have historically been regulated by the US FDA as foods. Citing concerns with regards to health, the FDA in 1980, recommended eliminating caffeine from soft drinks (Food and Drugs Administration, 1980). However, justification was made by soft drinks manufacturers, for the addition of caffeine to these drinks on the basis that it was a flavoring agent (PepsiCo Inc., 1981), although the scientific basis for that claim has since been challenged (Griffiths and Vernotica, 2000; Keast and Riddell, 2007). Based on their justification, the US FDA approved caffeine for use in cola-type soft drinks but limited the maximum content to 0.02% caffeine, or 71 mg/12 fl. oz. (Food and Drug Administration, 2003). The US FDA might have regulated caffeine as a psychoactive ingredient, as drugs are, if it had not been approved as a flavor enhancer for use in food.

After caffeine was approved by US FDA, manufacturers complied with the regulation by not exceeding the maximum caffeine level; however, since the introduction of energy drinks, the marketplace has changed drastically. About 130 energy drinks now exceed the maximum caffeine content of 0.02% (Caffeine informer, 2017) including one drink that contains as much as 505 mg in a 2oz can (the equivalent of 14 cans of a typical cola or several cups of coffee).

Under the 1994 Dietary Supplement Health and Education Act, products which are derived from natural sources and from herbs may be classified as dietary supplements instead of drugs, hence

many manufacturers are not obliged to adhere to the caffeine limits by claiming their products are dietary supplements (Kapner, 2008). Since there are no standards for energy drinks, the FDA (USA) has been lax in regulating the caffeine content of these drinks and does not require warning labels advising proper use or the declaration of caffeine in the products, as it usually does for over-the-counter (OTC) caffeine-containing drugs. According to the FDA (Food and Drug Administration, 2007), over-the-counter stimulant drug products must contain the following warnings and directions on the product label:

- The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat.
- For occasional use only. Not intended for use as a substitute for sleep. If fatigue or drowsiness persists or continues to recur, consult a (select one of the following: physician or doctor).
- Do not give to children under 12 years of age.
- Directions: Adults and children 12 years of age and over: Oral dosage is 100 to 200 milligrams not more often than every 3 to 4 hours.

It is therefore a striking inconsistency that an OTC drug which contains 100 mg of caffeine per tablet (e.g. NoDoz) should indicate the warnings stated above, but a 500 mg energy drink which has five times more caffeine than is present in the drug can be marketed with no such warnings and no information on amount of caffeine in the product. Two senators by name Durbin and Blumenthal, in 2012, argued for more stringent regulation of energy drinks, including ascertaining

the safety of ingredients and other additives, providing labeling requirements for such drinks and regulating the amount of caffeine permitted in products.

The long-term and widespread use of caffeine-containing beverages such as tea and coffee are part of the reason why regulation of energy drinks has always been fraught with challenges. However, some countries have taken the bold step to regulate the labeling, sale, promotion and distribution of CEDs. European Union (EU) requires energy drinks that have a "high caffeine content" to be labeled as such (European Union, 2007) and Canada requires labels indicating that "CEDs should not be mixed with alcohol, not recommended for children, breastfeeding or pregnant women and persons sensitive to caffeine and that the maximum daily consumption shall not exceed two 8.3 oz. cans" (Health Canada, 2013).

The British Soft Drinks Association also published a Code of Practice on Energy Drinks in 2014 (which has recently been reviewed), which in addition to the mandatory labeling requirements of the EU, require that these drinks indicate the phrase "High Caffeine Content, not recommended for children or pregnant or breast-feeding women". Members of the association are also required to undertake the following voluntary measures for responsible marketing:

1. The labeling should include the statement "Consume moderately" (or in similar words based on consumer thinking)
2. No marketing communication concerning energy drinks will be placed in any media with an audience of which more than 25% is under 16 years of age.
3. No commercial activity of any sort relating to energy drinks by BSDA members will be undertaken in primary or secondary schools.
4. No static or outdoor advertising of energy drinks will be placed within 100m of primary or secondary school main gates.

5. Sampling activity will not deliberately be aimed at or specifically designed to appeal to under 16s.
6. Marketing communications will not promote irresponsible or excessive consumption of energy drinks.
7. Marketing communications will not suggest any association with illegal or anti-social behavior.
8. Manufacturer-produced and controlled marketing communications, including labels, will not make any claims that the consumption of alcohol together with energy drinks counteracts the effects of alcohol.
9. Energy drinks are functional beverages and not sports drinks. Although normal consumption of energy drinks also provides water to the body, energy drinks will not be marketed as sports drinks which deliver a rehydration benefit unless they contain specific ingredients in addition to caffeine to support this claim.

In addition, the Food Standards Australia and New Zealand (FSANZ) regulate these formulated caffeinated beverages (FCBs) under Standard 2.6.4 of the Australia New Zealand Food Standards Code (the Code). According to the Indian regulatory agency known as Food Safety and Standards Authority of India (FSSAI, 2016), the country controls the use and sale of energy drinks by setting a maximum limit for caffeine. Soft drinks containing more than 145mg/l caffeine shall be labeled as "caffeinated beverages" and the amount of caffeine in such drinks must not exceed 300mg/l per regardless of the source of the caffeine and must have an upper limit of 320mg/l. Hence products like Monster, Cloud 9, Red Bull and Tzinga fall under this category and will have to disclose caffeine content on the labels and carbonated beverages which contain less than 145mg/l caffeine, including colas, will not fall in this category. Carbonated beverages manufacturers do not disclose

the caffeine content on the labels but state that the beverage contains caffeine. In addition to declaring caffeine content in the label, other declarations such as recommended daily intake shall also be indicated; "should consume not more than 500ml per day". This is to limit how much of a caffeinated beverage a consumer can have in a day. FSSAI has also placed limits on vitamins such as niacin, cyanocobalamin, thiamine, riboflavin, pyridoxine hydrochloride, which beverages manufacturing companies can add.

In addition to all this, FSSAI has made it mandatory that a caution statement is prominently displayed that reads: "Not recommended for children, pregnant and lactating women, persons sensitive to caffeine"

According to a study by FSSAI, the US Food and Drug Administration (FDA) regulates caffeine content in soft drinks but does not regulate caffeine content in energy drinks as it is considered safe under the US Code of Federal Regulations. The FSSAI study also stated the European Union does not set an upper limit for caffeine but requires only labeling of caffeine content greater than 150mg a kg with "high caffeine content".

The Codex Alimentarius Commission was set up by WHO and FAO to harmonize all standards, guidelines and codes of practices for food used by various countries to ensure public health and safety and promote fairness in trade and this was established in 1963. In one of such meetings held in the year 2000, some delegations of countries requested that the committee for Nutrition and Foods for Special Dietary Uses considers developing a standard for energy drinks. These products could be classified as soft drinks, and a standard would be required to aid in the regulation of the product. However, a year later during the 23rd session of the committee meeting held in Berlin, members agreed that caffeine in levels above 150mg/l could no longer be classified as a food flavor but as a pharmacologically active substance and hence establishing maximum limits

for such substances in drinks was not within the mandate of the committee. For this reason, no further work was done in that field till date.

In March 2014, upon review of information submitted by the kingdom's Ministry of Interior, the Saudi Arabian cabinet approved the implementation of a number of recommendations made and these include:

An outright ban placed on the advertisement of energy drinks in all forms of media; print, audio or visual. Energy drink companies, as well as their agents and distributors were also banned from sponsoring any sporting, cultural or social event. In addition to these, free distribution of these drinks to all age groups was prohibited. The government also prohibited the sale of energy drinks in educational and health facilities, public and private sports clubs, halls, restaurants and canteens. Lastly, all importers and manufacturers of these drinks were to indicate caution statement on the harmful effects of energy drinks on their products.

Recently in June 2017, the government through the General Authority of Zakat and Tax official website yet again, in an effort to better regulate such products, imposed an excise tax which led to the doubling of prices of cigarettes and energy drinks in the kingdom. This tax, known as the "sin tax" is usually imposed on products which may cause health problems and as such may increase medical bills paid by individuals or the government.

However, in Ghana, the aggressive marketing of energy drinks primarily targeting the youth and advertising products as enhancing mental and physical performance, seems to suggest that regulation may be lax. The Ghana Food and Drugs Authority has not defined any limit of caffeine in energy drinks and has only set specific requirements for energy drinks advertisements.

2.4 Advertising of Energy drinks

There are a number of ways of making energy drinks enticing to consumers. Adverts via TV, radio and print media such as newspapers, point of sale posters or billboards can be used as well through social media, websites of companies and even sponsorships of rallies and sporting events (Pomeranz et al., 2013). Researchers suggest that advertising campaigns have proven to be useful tools for selling CEDs as products that work to ameliorate the overall body activity and to improve the cognitive abilities of an individual. In fact, to support that, there has been a sharp increase in energy drink consumption among the youth (Woolsey, 2010).

Secondly, images of well-known sportsmen or women in commercials, is a highly effective way to entice young people to purchase the drinks through the attractive marketing gimmicks. These kinds of adverts usually focus on a lifestyle based on adventure, sport and fun. Also, customizing the cans of CEDs to bear the images of famous athletes so as to entice mainly young adults is a good marketing tool (Miller, 2008). Specific periods such as examination periods for university students, creates an opportunity for companies to test products before they are launched, by marketing them as effective for fighting stress, improving mental performance and reducing tiredness (Woolsey, 2010). Also, asking consumers to share positive reviews about their experience, for e.g. consumers sharing how amazing they felt taking the products is another way to attract people (Caffeine informer, 2017). An example is the marketing campaign for Rock Star Energy Drink, which places emphasis on kids barely 18 years old, who try to prove that the products help them through their stressful lives as students, doing so in style (Burke et al ,2009). These advertising campaigns endorse the use of these products as enhancing cognitive abilities, physical activity with the added benefits of the various ingredients it contains hence glorifying their use. However, most of these claims have not been substantiated. One study even disputes

this claim and indicates that caffeine consumption rather decreases performance as a result of reduced alertness (Bonnet et al., 2005). In Africa, caffeinated energy drinks hold a major market share and its packaging is a contributory factor to its success on the market. The sales and distribution channels such as supermarkets, mass merchandisers and convenience stores play a significant role in the accessibility of the products.

In its attempt to regulate energy drinks consumption, the Ghana Food and Drugs Authority has outlined some specific requirements for energy drinks advertising on its website for manufacturers and importers of the drink.

These include;

1.All energy drink advertisements shall include the following;

a) Excessive drinking can be detrimental to health
b) Not Recommended for persons under 18 years, Lactating Mothers, Pregnant Women and People Sensitive to Caffeine
c) Any other Health Warnings as prescribed by the Authority

2.Advertisement on energy drinks shall not contain statements or illustrations that have the potential to lead to the abuse or excessive consumption of the product.

3.Energy drinks shall not be advertised as substitute for rest, remedy for fatigue, sexual non-performance or any other physical non-performance.

2.5 Side Effects of Energy Drinks

Energy drinks have always been promoted as boosting consumers' energy levels. However, it is only recently that studies have been conducted in a bid to establish the negative effects of these

products as well. Hence, most consumers especially the youth are unaware of its side effects. According to Reissig et al., (2009) one may develop a tolerance for the drink which will only lead to craving more of it with time. Hence it is very easy for one to abuse these drinks which may lead to risky behavior or worse, severe health problems which include physiological effects, depression and anxiety, mental problems, insomnia, digestive issues and cardiovascular problems.

Although energy drinks when consumed in moderation enhance mood and memory activities (Heckman et al., 2010; Higgins et al., 2010; Ishak, et al., 2013), quite a number of research works have proven that one experiences negative effects such as sleep deprivation, irritability, agitation, insomnia, headache, dizziness and nervousness when high levels of caffeine are consumed (Caffeine informer, 2017; Ishak, et al., 2013; Heneman, & Zidenberg-Cherr, 2007).

A statement released by the American Heart Association after examining facts that linked energy drinks to some health issues, a few years ago, indicated that blood pressure might be affected by CEDs and this could cause arrhythmias (American Heart Association, 2013). It was suggested that levels of caffeine in these drinks can seriously affect the heart's functionality, affect the blood vessels and even cause death (American Heart Association, 2013; Babu et al. 2008; Higgins et al., 2010; Seifert, et al.,2011). The death of a woman was reported after an autopsy report revealed that she died from myocardial infarction which was linked to the consumption of energy drinks as (Babu et al., 2008).

Since 90% of caffeine is absorbed by the digestive system, the consumption of excessive amounts of it can very well affect the gastrointestinal tract (Rath, 2012). Therefore, caffeine can result in a hyper-stimulation of this system which in addition can cause anorexia, pain, vomiting, diarrhea and gastroesophageal reflux due to esophageal lower sphincter losing its ability to contract (Rath, 2012). All of these effects could lead to eating disorders among the youth (Seifert et al., 2011).

Also, since energy drinks contain large amounts of sugar, this may slow down the rate of absorption of fluids into the intestines and reduces the fluids in the blood as well causing dehydration (Bonci, 2002). Although energy drinks in moderation is noted to improve mental performance including alertness, overindulgence in energy drinks with high caffeine content could affect one's decision making ability and may lead to risky behavior including sexual risky behavior and substance abuse (Heckman et al., 2010; Ishak et al., 2013; Miller, 2008; Reissig et al., 2009; Velazquez et al., 2012; Woolsey, 2010). Miller (2008) states that the consumption of CEDs is strongly related to substance abuse like "Marijuana". In 2011, ER cases recorded by the Substance Abuse and Mental Health Services Administration (2013) due to the consumption of energy drinks exceeded 20,500. It also indicated that 58% of these cases were linked to the consumption of only energy drinks, while the rest were related to energy drinks mixed with other substances. The major concern of mixing a depressant- alcohol with a stimulant- energy drink is the fact the it will lead to a decrease in the intoxication symptoms thereby masking the effects of alcohol and lessening a person's feelings of being intoxicated and causing one to drink more (Heckman et al., 2010).

CHAPTER THREE

3.0 MATERIALS AND METHODS

3. 1 Materials

All materials used were initially checked for expiry date and source. Reagents were in good condition and had not expired. The reagents tetrahydrofuran and acetonitrile were acquired from Merck Life Science and Fisher Scientific UK respectively. The anhydrous sodium acetate used was sourced from SureChem Products Limited and glacial acetic acid from Radchem Laboratory Supplies. All these reagents were of HPLC grade. The caffeine reference standard used was from the United States Pharmacopoeia with a purity of 99%.

3.2 Design of Experiment

3.2.1 Design of Experiment for Survey

For the survey, the opinions of respondents were collated on the assertion of knowledge on energy drink, usage, and perception about it at a 95% confidence level. The questionnaires for the survey were essentially tailored towards assessing the knowledge, usage and perception, effect of consuming energy drinks and probing the effectiveness of Food and Drugs Authority's regulations on energy drinks on the local markets. The respondents included consumers from Junior High School, Senior High School, University and working-class group (driver, traders and bankers) from the Accra Metropolitan Assembly.

3.2.2 Sampling Method for Survey

The sampling method employed in the survey was a combination of probability and non-probability techniques in selecting relevant respondents of the sample frame. The probability method used is random sampling whiles the non-probability sampling techniques included convenience and quota sampling (Kothari, 2004).

3.2.3 Questionnaire Administration

i. Pre-testing

Pre-testing of the questionnaires was carried out on KNUST Accra campus to fine-tune the format, wording, length and objectives of the questionnaires using 30 of the draft questionnaires. They were analyzed and the necessary modifications effected prior to its use.

ii. Sample Size and Questionnaire Editing

The total sum of two hundred and fifty (250) of the final questionnaires was issued by hand to respondents drawn from the four sampling units. The StatCalc of the epi info software was used in attaining the sample size. The population size was 700 based on the number of JHS students in some selected classes of the school, SHS students in a particular class, university students in one selected hostel and workers were selected based on some bank branches, bus and taxi stations and markets. Expected frequency was set at 50%, with a 5% acceptable margin of error and both design effect and clusters were set at 1. A total number of 248 was generated but the figure was rounded off to 250. The non-probability approach to selecting relevant respondents (convenience and quota sampling) was used to select 50 respondents each of JHS, SHS and University whereas 100 respondents were selected for the rest of the working class of the sample frame. These units were Dandinas Primary & Junior High School, Nungua Senior High School, University of Ghana and working class (bankers, traders and commercial drivers). Hence, a total sample size (N) is 250.

The questionnaires recovered were edited with checks for omissions, incomplete or otherwise unusable responses, illegibility and inconsistencies.

3.2.4 Sources of Data

Data was obtained from both primary and secondary data sources using varied techniques.

i. Primary Data

Questionnaires and interviews were used in obtaining the primary data. Information from respondents was obtained using diverse interview techniques. Both closed and open-ended questions were employed in this research. To give an objective basis for comparative analysis by restricting interviewees' answers, the closed ended questions were used. Clear instructions for the closed ended questions were given to respondents as well as several alternatives to make analysis easier. In order not to restrict interviewees too much to some questions asked, thus giving them the freedom to share their own opinions, open-ended questions were provided as well. There were two sections for questioning– Sections "A" and "B". The "A" Section was for obtaining personal data of respondents and section "B" provided questions for the research.

ii. Secondary Data

The term Secondary data usually refers to existing data obtained by other researchers and even institutions, for different studies or purposes (Bryman, 2016). Secondary data usually broadens the researcher's appreciation of the study but primarily it enables the researcher put their study into perspective by comparing it with existing literature (Bryman, 2016). Hence articles, journals, guidelines, manuals and other relevant publications on the regulation of energy drinks in various jurisdictions were consulted.

3.3 Laboratory assessment of caffeine levels

3.3.1 Sampling

A convenience sampling technique was used. Samples were acquired from the open markets; Makola, Nungua, Madina, Texpo and Agbogbloshie markets, supermarkets and malls, fuel stations, pubs, gyms and bus and taxi stations. Two of each brand of the 39 samples of commercially available products was purchased from locations listed above between the months of September and November, 2017. The list of products purchased was then compared with products in the database of the Food & Drugs Authority. This was to ascertain registration status of products sampled. Products were observed to be packed in either PET bottles or cans. All samples purchased were in good condition at the time of sampling and testing thus, had not expired per their best before/expiry dates indicated on the labels. Information recorded were product name (coded), source (local/imported), volume, amount of caffeine declared and caution statement. The registration status of product per the FDA database was also recorded.

3.3.2 Physicochemical Analysis

The HPLC method used in the determination of caffeine content for the 39 products was from the United States Pharmacopoeia, the 2017 edition. The retention times of the caffeine peaks for standard solution and sample solution prepared at the same concentration were compared and calculated to give percent of caffeine in products. Analysis was done between the months of November 2017 and January 2018.

i. Procedure

Mobile phase was prepared using acetonitrile, tetrahydrofuran and a sodium acetate buffer in the ratio 25:20:955. This solution was then adjusted to a pH of 4.5 with glacial acaetic acid (GAA). The buffer solution was prepared by weighing 0.82g of anhydrous sodium acetate and dissolving

to 1L with distilled water. The standard solution was then prepared by weighing 5mg of the Caffeine Reference Standard and dissolving with the mobile phase to 25ml resulting in a concentration of 0.2mg/ml. The sample solution was then prepared using the equation:

$C^1 \times V^1 = C^2 \times V^2$

Where V^1 (Initial Volume) = $\frac{\text{Final concentration (std solution 0.2mg/ml)} \times \text{Final Volume (25ml)}}{\text{Initial Concentration (As declared on label in mg/ml)}}$

The volume obtained from the above calculation was then pipetted from the sample and diluted to 25ml in a volumetric flask with the mobile phase and both standard and samples injected via the auto sampler with the following chromatographic system: A detector of UV 275nm, Column (C18) of 4.6mm X 15cm of L1 packing, a flow rate of 1ml/min and an injection volume of 10µl.

The result was calculated per this formula =

$$\frac{\text{Peak area of spl} \times \text{Concentration of std} \times \text{Potency of std} \times 100}{\text{Peak area of std} \quad \text{Concn. Of spl} \quad 100}$$

3.4 Enforcement by FDA

3.4.1 Personal Interview

Personal interviews were conducted with Client Service officers and the Standards Department personnel of both the Food and Drugs Authority (Food Evaluation and Registration and Food Enforcement Departments) and the Ghana Standards Authority (GSA) respectively using semi-structured questions. This was done to help understand the process of registering and advertising energy drinks and how the FDA ensures product compliance with the specified standard from GSA during evaluation.

3.4.2 Advertisement Monitoring

Pictures of eight (8) billboards advertising various energy drinks were taken in the study area to evaluate as per the Guidelines for Advertisements of Food Products. This was done to verify if they met the requirements thereby assessing the effectiveness of monitoring and regulation of advertisements by the FDA.

3.5 Data Analysis Method

Both Qualitative and Quantitative techniques were employed to make deductions from the various data obtained. Mathematical inferences and data in the form of words are the primary focus of data analysis as suggested by Evans (2005). Also, Likert scale was used to measure either positive or negative responses to certain statement in the questionnaire. Responses obtained from the questionnaires were first coded and then evaluated, and from the questionnaires administered, variables were generated. The coded data from the survey was then corroborated and cleaned up, inputted and then analyzed using statistical tool, SPSS® 21 version. All responses were followed by interpretations and comments. For easy interpretation tables and charts were employed in the presentation of the results for the study.

CHAPTER FOUR

4.0 RESULTS AND DISCUSSION

This chapter examines and analyzes data gathered from questionnaires administered, personal interviews conducted, testing and evaluation done on products sampled in trade and evaluation of advertisements (billboards) spotted. Analysis of data are presented and discussed in this chapter. The chapter has been arranged in 5 parts in order to keep the discussion focused and the findings in the right context, due to the considerable amount of data generated. The first part delivers the results and discussion on the knowledge of energy drinks while the second part presents the results and discussion of the perception and usage of energy drinks. The third part presents the discussion of the effects of energy drinks. The fourth part presents the results and discussion of actual amounts of caffeine in 39 sampled products, their FDA registration status and evaluation of labels with regards to caffeine declaration and display of caution statements on labels. The last part presents discussion of regulatory enforcement of the FDA through the evaluation of some eight (8) billboards captured during the study.

A total of two hundred and fifty (250) questionnaires were administered to the target population in the studies. All questionnaires were successfully retrieved and data analyzed using Statistical Package for Social Sciences (SPSS® 21version) at 95% significant level. Interpretation of data was done using tables and charts, which were the main form of descriptive statistics techniques used to give a pictorial representation of the research findings

4.1 Demographic Data of Respondents

Table1: Demographic characteristics of sample (n=250)

Characteristics	SAMPLE SIZE			
	Workers(n=100)	Univ. (n=50)	SHS (n=50)	JSH (n=50)
Gender				
Male	61(61.0%)	40(80.0%)	33(66.0%)	34(68.0%)
Female	39(39.0%)	10(20.0%)	17(34.0%)	16(32.0%)
Age				
Below 13	0(0.0%)	0(0.0%)	0(0.0%)	33(66.0%)
14-17	23(23.0%)	0(0.0%)	34(68.0%)	15(30.0%)
18-20	24(24.0%)	15(30.0%)	16(32.0%)	0(0.0%)
21-30	29(29.0%)	29(58.0%)	0(0.0%)	0(0.0%)
31-40	19(19.0%)	5(10.0%)	0(0.0%)	2(4.0%)
41-50	3(3.0%)	1(2.0%)	0(0.0%)	0(0.0%)
51 and Above	2(2.0%)	0(0.0)	0(0.0%)	0(0.0%)
Marital status				
Single	68(68.0%)	46(92.0%)	50(100.0%)	50(100%)
Married	32(32.0%)	4(8.0%)	0(0.0%)	0(0.0%)

The Demographic data cover the Gender (Sex), Age, Marital status, Category of respondents' distribution profile.

4.2 Knowledge on Energy drinks

The study revealed from the table below that 56.0% of the respondents always read labels on energy drinks before drinking while 44.0% did not. A section of the respondents who disagreed admitted they were illiterates; others had no reason for not reading. A whopping 80.4% of the respondents had no knowledge of caution statements on the labels of energy drinks. This percentage, sadly, included some pregnant women, nursing mothers and adults with heart problems who consume these products. A reason attributed to this was labels of most locally manufactured energy drinks which were more patronized by majority of respondents did not indicate caution statements as part of their labeling. Some respondents also admitted that they only looked out for

brand and date markings which were the most relevant information on labels to them. Only 19.6% of the people were aware of the caution statements.

Table 2: I always read label on energy drinks before drinking

Response	Frequency	Percentage (%)
Strongly agree	38	15.2
Agree	52	20.8
Fairly agree	50	20.0
Strongly disagree	60	24.0
Disagree	50	20.0
Total	2 50	100

From table 3 below, although majority of the respondents (57.6%) suggested they knew the constituents of energy drinks while 8.8% of them disagreed and 33.6% of the respondents had no knowledge about the constituents of energy drinks, out of the 57.6% respondents, 26% of them indicated that they were aware of about three constituents of the drinks being: caffeine, sugar and vitamins. An overwhelming 33.6% of the respondents did not know the difference between energy drinks and soft drinks and hence admitted to not knowing what energy drinks constituted.

Table 3: Energy drinks contain caffeine and other constituents (taurine, guarana, etc.)

Response	Frequency	Percentage (%)
Strongly agree	33	13.2
Agree	46	18.4
Fairly agree	65	26.0
Strongly disagree	11	4.4
Disagree	11	4.4
Don't Know	84	33.6
Total	250	100

From table 4 below, 68.0% of the respondents said energy drinks might contain high level of caffeine while 4.8% of them opposed it and 27.2% of the respondents have no idea.

Table 4: Energy drinks might contain high level of caffeine

Response	Frequency	Percentage (%)
Strongly agree	57	22.8
Agree	41	16.4
Fairly agree	72	28.8
Strongly disagree	11	4.4
Disagree	1	0.4
Don't Know	68	27.2
Total	250	100

A majority of the respondents (78.4%) acknowledged that energy drinks help to reduce or prevent fatigue while 9.6% disagreed and 12.0% of them had no knowledge on the "benefits" of energy drinks as shown in (Table 5). Some reasons given by those who used the product were to ward off sleep and tiredness thus enabling them drive long distances, students acknowledged they take it to help stay awake to study deep into the night and some traders including the elderly (aged 50 and above) take it to keep them active during working hours.

Table 5: Energy drinks help to reduce or prevent fatigue

Response	Frequency	Percentage (%)
Strongly agree	79	31.6
Agree	92	36.8
Fairly agree	25	10.0
Strongly disagree	15	6.0
Disagree	9	3.6
Don't Know	30	12.0
Total	250	100

From the study, when respondents were asked if they knew that drinking energy drinks have some negative effects such as headache, sleep disturbances etc. it was noted that majority of them being

46.0% answered in the affirmative but were not aware of majority of the side effects while 11.2% of them disagreed with such claims and 42.8% of them had no knowledge about the effects of energy drinks from (Table 6). Most respondents who claimed to have experienced negative effects also included not feeling hungry hence some revealed that they could go a whole day without food till they got home after work.

Table 6: Energy drinks have negative effects such as headache high blood pressure, etc.

Response	Frequency	Percentage (%)
Strongly agree	45	18
Agree	45	18
Fairly agree	25	10.0
Strongly disagree	25	10.0
Disagree	3	1.2
Don't Know	107	42.8
Total	250	100

Some 46.8% of the respondents claimed that they consume energy drinks regularly while 37.6% of them drink energy drinks occasionally (sometimes mixed with substances). And 12.4% of the respondents do not drink at all. It was further observed that most workers aged between 13-24 years preferred to mix energy drinks with tramadol, a prescriptive opioid and cough syrups containing codeine. Adults above 25 years however preferred to mix with alcoholic drinks.

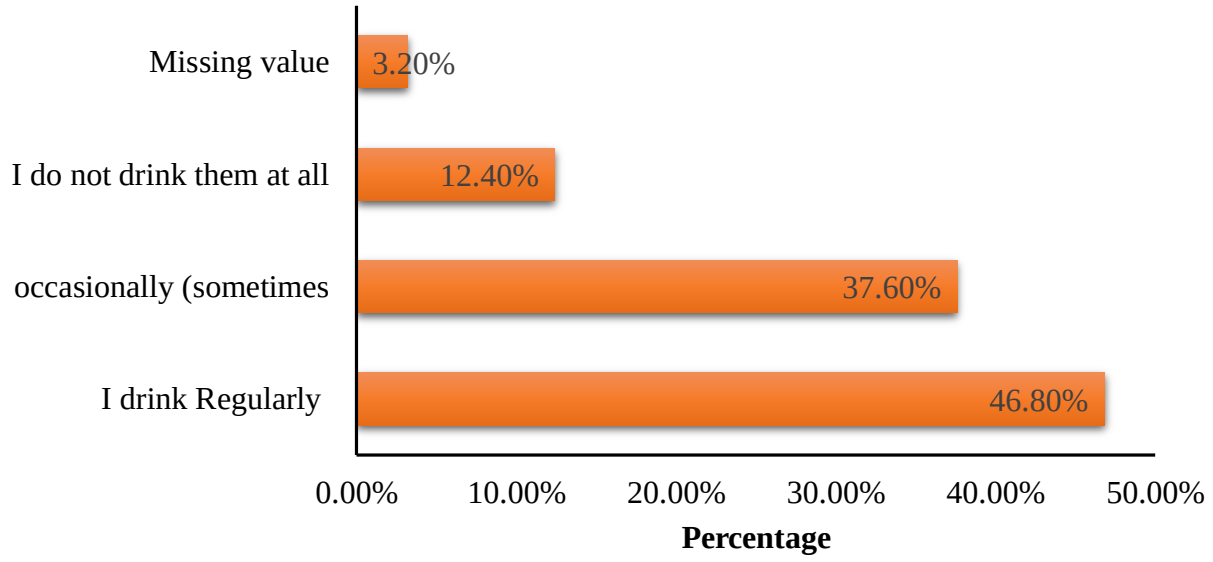

Figure 1: How often energy drinks are consumed by respondents.

It was also noted that majority of the respondents (55%) started taking energy drinks from the ages of 5-17years, 18-35years were 35%, 36-45years were 5% and 46-55years were also 5%.

Interestingly those in the 5-17years (55%) category admitted to either being given these drinks by an older person such as a parent or being served these drinks at events or gatherings such as birthday parties, funerals or church programs just like any other soft drink was served. They could not tell the difference between an energy drink and the average soft drink because their packaging was similar; especially those in the PET bottles and had the same bright colors just as the soft drinks do. One 14-year-old food vendor claimed her mother served her a bottle of energy drink as part of her breakfast to keep her active and energized during the day.

Approximately, 40% of the respondents consumed 2 cans/bottles per day, 8 per week, 32 per month while 50% consumed 3 cans/bottles per day, 12 per week, 48 per month and 10% of the respondents do not remember the number of cans/bottles consumed. Exceeding two in a day was

more prevalent among older respondents. Majority of this group admitted that they could not function properly in a day without the drink and were addicted to it, a disorder described as the Caffeine Dependence Syndrome by WHO, 2013 in The International Statistical Classification of Diseases and Related Health Problems (10th Revision; ICD-10). Some female food vendors admitted taking it at specific times of the day to keep them active the entire day; one just before the start of work, another just before lunch and the third a few hours after lunch Some drivers and their mates corroborated the statement above, that because they did not have the luxury of time to have a proper meal, they would purchase some pastries e.g. bread, and energy drinks in traffic to sustain them. Most of these respondents had exceeded the maximum daily intake, potentially increasing the risk of experiencing adverse effect.

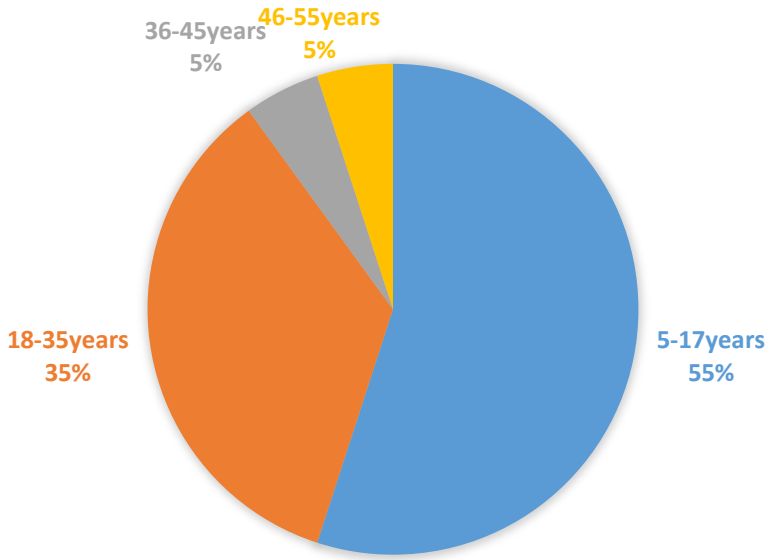

Figure 2: Age at which respondents first had energy drink.

4.3 Perceptions of Energy drinks

From the study, it was noted that a substantial majority of the respondents (96.4%) stated that energy drinks are easy to access on the Ghanaian markets while 3.6% of them disagreed. Most of them also expressed the view that energy drinks were usually more affordable than fruit juices and malt drinks hence was easy on the pocket for consumers; children and adults alike.

From table 7, majority of the respondents 60.0% claimed they drink energy drinks during physical activities while 36.8% of them do not, and 3.2% have no idea. The greater number acknowledged using them during a workout; male adults used them in the gyms while some male JHS students took them during games or Physical Education (PE) activities. Interestingly, most gyms and all provision shops in the vicinity of schools stocked these drinks.

Again, 61.6% of the respondents claimed that they like trying new products, new things, and they are adventurous, that is why they drink energy drinks while 31.2% debunked such claims, and 7.2% of them have no idea.

Furthermore, 54.8% of the respondents claimed energy drinks mean youth and strength, hence it gives them the zeal to drink while 45.2% disagreed.

Table 7: I drink energy drinks during physical activities

Response	Frequency	Percentage (%)
Strongly agree	112	44.8
Agree	25	10.0
Fairly agree	13	5.2
Strongly disagree	38	15.2
Disagree	54	21.6
Don't Know	8	3.2
Total	250	100

There is a notion that commercials say: “Energy drinks boost my energy so; I drink them”. From table 8, 68.4% of the respondents supported the notion while 31.6% debunked it. This conformed to the study by Pomeranz et al., 2013 which states that “advertising campaigns on TV, radio and print media (such as billboards, newspapers or point of sale posters), as well as sponsoring games or rallies, social media ads and even company websites” influence the consumption of energy drinks.

Table 8: Commercials say “Energy drinks boost energy” so I drink them

Response	Frequency	Percentage (%)
Strongly agree	104	41.6
Agree	55	22.0
Fairly agree	12	4.8
Strongly disagree	35	14.0
Disagree	44	17.6
Total	250	100

In addition, the study indicated that 68.8% of respondents drink energy drinks because everybody around them - their friends and parents- drink energy drinks while 31.2% of them disagreed. (Table 9).

Finally, 64.4% of the respondents said energy drinks make them feel awake and alert while 17.2% disagreed and 18.4% of them have no idea.

Table 9: It seems that everybody around me- my friends and my parents- drink energy drinks

Response	Frequency	Percentage (%)
Strongly agree	87	35.2
Agree	59	23.6
Fairly agree	25	10.0
Strongly disagree	22	8.8
Disagree	56	22.4
Total	250	100

From the study, respondents were asked to list their reasons for taking energy drinks. 95% stated their reasons which are shown below in (Figure 3). Out of the 95%, 45% of them admitted using these drinks to energize them, keep them awake and alert. Some of the respondents (25%) used them for aphrodisiac purposes, especially after mixing these CEDs with alcohol or tramadol. 15% used it to "party longer", thus, to ward off the effects of alcohol so they could consume more, stay out late and also drive home safely. About 10% of respondents had other reasons such as "love the taste", "it makes me courageous", "because parents drink it too", "when I'm hungry" etc. and the remaining 5% indicated that they consumed them like they did any other soft drink and had no specific reasons.

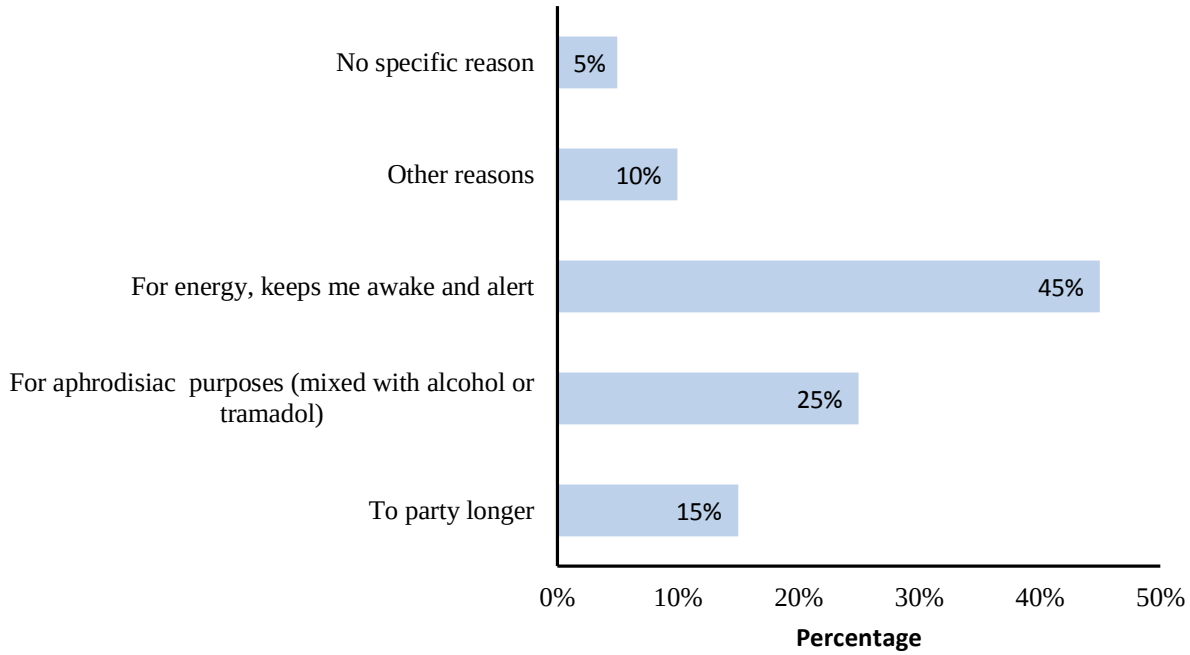

Figure 3: Reasons why respondents take in energy drinks

4.4 Effect of Energy drinks

Energy drinks are targeted at the youth with claims to boosting their energy; but most often than not, consumers are not aware of the side effects of these drinks. Often the consumption of large amounts of energy drink can lead to a myriad of health problems and some risky behaviour.

From the study, according to 85.0% of the respondents, they experience sleep disturbances, restlessness and have headaches when they take in energy drinks. And 15% of them have no ideas about the side effects of energy drinks.

This conformed to the study by Ishak, et al., (2013) that agitation, irritability, insomnia, anxiety, dizziness, headaches etc. were some negative side effects of CEDs. Moreover, mixing energy drinks with tramadol and alcohol can cause mental issues.

4.5 Actual amount of caffeine in some energy drinks on the Ghanaian markets

The table 10 below indicates the actual amount of caffeine in some energy drinks on the Ghanaian markets. Laboratory analysis was conducted by the use of HPLC to detect the actual amounts of caffeine in the energy drinks.

Table 10: Actual amount of caffeine in some energy drinks on the Ghanaian markets

NO	PRODUCT NAME	LOCAL/ IMPORTED	VOL/ Ml	CAFFEINE DECLARED	ACTUAL CAFFEINE	CAUTION STATEMENTS	*REGISTRATION STATUS
1.	EDL1	Local	350 ml	Not declared	29 mg/100ml	18^{+}drink responsibly Not suitable for pregnant woman, lactating mothers or persons sensitive to caffeine	Registered
2.	EDL2	Local	350 ml (PET) 330ml (CAN)	Not declared	33mg/100ml	Not stated	Registered
3.	EDL3	Local	500 ml	Not declared	30mg/100ml	Not stated	Registered
4.	EDI1	Imported	250 ml	32 mg/100g 80 mg/250 ml	30mg/100ml	High caffeine content Not recommended for children under 12 years of age, pregnant and lactating women and persons sensitive to caffeine	Not Registered
5.	EDI2	Imported	500 ml	31.5 mg/100 g 78.8 mg/250 ml	33mg/100ml	High caffeine content	Registered

						Not recommend for children under 12 years of age; pregnant or lactating women, persons sensitive to caffeine	April 2020
6.	EDI3	Imported	250 ml	21mg/100 ml	21mg/100ml	High Caffeine Content Not recommended for children or pregnant or breastfeeding women	Registered July 2020
7.	EDI4	Imported	250 ml	31.5mg/100ml	30mg/100ml	Not stated	Not Registered
8.	EDI5	Imported	250 ml	31.5 mg/100 ml	32mg/100ml	Increased caffeine content Not recommended for children, pregnant women, persons sensitive to caffeine and diabetics	Registered
9.	EDI6	Imported	250 ml	32mg/100 ml	31mg/100ml	Not recommended for children or pregnant or breastfeeding women. Do not mix with alcohol	Not Registered
10.	EDI7	Imported	250 ml	32mg/100 ml	29mg/100ml	High caffeine content Not recommended for children or pregnant or breastfeeding women.	Registered

						Not recommended for people sensitive to caffeine and diabetics	
11.	EDI8	Imported	250 ml	32 mg/100ml	32mg/100ml	Not recommended for children, pregnant and lactating women and individuals sensitive to caffeine	Expired in 2014
12.	EDI9	Imported	250 ml	32mg/100 ml	33mg/100ml	Not stated	Not Registered
13.	EDI10	Imported	250 ml	31.5 mg/100 ml	30mg/100ml	Not recommended for children, diabetes, pregnant or breast feeding women and persons sensitive to caffeine	Registered
14.	EDI11	Imported	250 ml	30 mg/100ml	29mg/100ml	Not recommended for children, pregnant women, lactating mothers, diabetics and people sensitive to caffeine	Registered June 2018
15.	EDI12	Imported	250 ml	32 mg/100ml	30mg/100ml	Not recommended for children or pregnant or breast feeding women	Registered April 2018
16.	EDI13	Imported	250 ml	32 mg/100ml	31mg/100ml	Not recommended for children or pregnant	Registered

						women and persons sensitive to caffeine	April 2019
17.	EDI14	Imported	330 ml	*32 mg/100ml *106 mg/330 ml	32mg/100ml	Not recommended for children under 12 years of age, pregnant or lactating women and persons sensitive to caffeine	Not Registered
18.	EDI15	Imported	250 ml	32mg/100 ml	29mg/100ml	Not recommended for children under 16, pregnant or breast feeding women. Not recommended for people suffering from hypertension, cardiac patients or people sensitive to caffeine Combining with alcohol is not recommended	Registered Aug 2020
19.	EDI16	Imported	500 ml	32 mg/100 ml	29mg/100ml	Not recommended for children or pregnant or breast feeding mothers	Registered Sept 2020
20.	EDI17	Imported	500 ml	30 mg/100ml	31mg/100ml	High caffeine content Not recommended for children or pregnant or lactating women	Not Valid May 2017

21.	EDI18	Imported	440 ml	*20 mg/100ml * 88 mg/serving	19mg/100ml	High caffeine content Not recommended for children under 12 years of age; pregnant or lactating women; persons sensitive to caffeine	Registered Aug 2020
22.	EDI19	Imported	330 ml	32 mg/100 ml	30mg/100ml	Not suitable for children, pregnant women and people sensitive to caffeine	Registered Oct 2020
23.	EDI20	Imported	250 ml	32 mg/100 ml	30mg/100ml	Not recommended for children or pregnant or lactating women. Drink in moderation	Registered
24.	EDI21	Imported	325 ml	32 mg/100 ml	33mg/100ml	High caffeine content Not recommended for children or pregnant or lactating women	Registered
25.	EDI22	Imported	250 ml	32 mg/100 ml	31mg/100ml	High caffeine content Not recommended for children or pregnant or lactating women	Not Registered
26.	EDL4	Local	250 ml	Not declared	30mg/100ml	Not stated	Registered

27.	EDI23	Imported	250ml	32mg/100ml	32mg/100ml	High caffeine content. Not recommended for children or pregnant women or breast-feeding woman. Consume in moderate (office) amounts.	Registered July 2020
28.	EDI24	Imported	250ml	30mg/100ml	29mg/100ml	High caffeine content. Not recommended for children or pregnant or breast-feeding women. Consume in moderation as part of a varied and balanced diet and healthy lifestyle.	Registered July 2019
29.	EDI25	Imported	250ml	32mg/ml	30mg/100ml	Consume with moderation. Not suitable for children, pregnant women and lactating mothers.	Registered Oct 2020
30.	EDI26	Imported	250ml	30mg/100ml	27mg/100ml	High caffeine content. Not recommended for children or pregnant or breastfeeding women.	Registered
31.	EDI27	Imported	59ml	As much caffeine as a 12oz. cup of coffee	32mg/100ml	For maximum energy, drink entire contents all at once. For moderate energy: Drink half the contents or less or sip throughout the day.	Registered July 2018

						Persons sensitive to caffeine should take with caution. Consult your healthcare provider if you have an existing medical condition or take medication. Do not consume if pregnant or lactating.	
32.	EDI28	Imported	250ml	32mg/100ml	31mg/100ml	High caffeine content. Not recommended for children or pregnant or breastfeeding women.	Registered
33.	EDI29	Imported	60ml	32mg/100ml	33mg/100ml	Not allowed for women during pregnancies and lactation, children below the age of 16, persons allergic to caffeine, heart and arterial disease patients, athletes during sporting activities. Reduces ability to sleep in case of excessive consumption because it has high levels of stimulants. HIGH CAFFEINE CONTENT.	Registered

						Permitted daily intake shall not exceed 120ml or 2 cans.	
34.	EDI30	Imported	355ml	32mg/100ml	32mg/100ml	Not allowed for pregnant or lactating women, persons under the age of 16years, persons with sensitivity to caffeine, and those who suffer from certain diseases may effect on their health conditions especially heart, arterial patients, as well as athletes during exercise. It reduces the ability to sleep in excessive quantity because they contain high levels of stimulants. HIGH CAFFEINE CONTENT. Permitted daily intake shall not exceed 120ml or 2 cans.	Registered Feb 2020
35.	EDL5	Local	500ml PET 330ml CAN	32mg/100ml	29mg/100ml	Not recommended for persons under 18 (PET) NO CAUTION STATEMENTS FOR CAN	Registered

36.	EDL6	Local	350ml	31mg/100ml	27mg/100ml	18+, Not recommended for pregnant or breastfeeding women	Registered Sept 2019
37.	EDI31	Imported	250ml	32mg/100ml	30mg/100ml	High caffeine content. Not recommended for children, pregnant and breastfeeding women. Not recommended for people sensitive to caffeine.	Not Registered
38.	EDI32	Imported	500ml 250ml	32mg/100ml	 29mg/100ml	High caffeine content. Not recommended for children, pregnant and breastfeeding women. No English labelling	Not Registered
39.	EDI33	Imported	57ml	230mg	241mg	Take one half (1/2) bottle for moderate energy. Take one whole bottle for maximum energy. Do not exceed two bottles daily, consumed several hours apart. Contains caffeine comparable to 12 ounces of the leading premium coffee. Limit caffeine products to avoid nervousness,	Registered

						sleeplessness and occasional rapid heartbeat. You may experience a niacin flush (hot feeling, skin redness) that lasts a few minutes. This is caused by increased blood flow near the skin. Do not take if you are pregnant or nursing. Not recommended for children. If you are taking medication or have a medical condition, consult your doctor before use.	

***Food and Drugs Authority Registration Records, 2018**

Out of thirty-nine (39) products sampled from the open markets; Makola, Nungua, Madina, Texpo and Agbogbloshie markets, supermarkets and malls, fuel stations, pubs, gyms and bus and taxi stations, 33 (84.6%) were imported and 6 (15.4%) were locally manufactured. Again, from the 39 products crosschecked with the FDA database, 30 products (76.9%) were registered while 7 products (18.0%) were not registered or had never been registered by the Authority and 2 products (5.1%) had been registered before but had expired licenses and had failed to renew their licenses. The license of EDI17 had expired in May 2017, however that for EDI8 had expired in 2014 hence its importer had been operating without a license for over 3years. One unregistered product did not bear English labeling contrary to the LI 1541. From the study it was also noted that all 6 locally manufactured energy drinks were at the time of the research, registered and had valid licenses however the 7 products which were not registered by FDA but had found its way into trade and the 2 products with expired licenses were imported. This may be due to the fact that the Food Enforcement Department which is responsible for local facility inspections renews the manufacturer's facility license yearly through their scheduled inspections. A valid facility license is a pre-requisite for the acquisition of a registration certificate for local manufacturers. Another challenge with regulating imported products is that most come through unapproved routes making it difficult to trace the importer; however local manufacturers can be easily located. Also, all imported products sampled; registered or not did not bear the unique FDA registration numbers but the local products bore their FDA numbers hence easy to verify if products had at least been checked by the Authority.

Four (4) products, all local, had not declared caffeine content on labels being 10.3% of total samples yet contained caffeine, and there were no caution statements on 15.4% (6 drinks) of the products sampled. Two packaging types of one of these products (EDL5) were observed in trade-

can and bottle; the bottle bore the caution statement "Not recommended for persons under 18, however the can bore no caution statement. Both products were however, registered.

Also, 6 of the samples representing 17.1% have caffeine contents exceeding the amounts stated on the labels while 22 samples (62.9%) have caffeine contents below the stated amount on the labels. 20% of samples (7 products) declared content corresponded to actual caffeine after testing.

4.6 Enforcement of regulatory standards

4.6.1 Market Authorization

The interview with the Clients Service officers at the FDA revealed that before a manufacturer or an importer of energy drinks obtains market authorization from the FDA to sell or advertise their drinks, the products will first have to be registered. The process involves the submission of an application, a model label, certificate of analysis based on the product specific test parameters provided by the Authority, samples based on volume of products and an amount charged depending on whether the applicant is a local manufacturer or an importer. The Food Evaluation and Registration Department (FERD) then sends some of the samples to the Laboratory Services Department for physicochemical and microbiological analysis using parameters based on the Ghana Standard for that particular product type. The label is evaluated by FERD per the requirements of the legislative instrument 1541 (L.I 1541) to ensure it conforms to the standard. The manufacturer's production facility or the importer's warehouse is the inspected by the Food Enforcement Department to ensure their activities comply with the current codes of Good Manufacturing (GMP) or Good Warehouse Practices (GWP) respectively. When applicants are successful with analysis, label evaluation and facility licensing, then the product is registered and given a unique FDA number which is valid for three (3) years. However, the license for the warehouse or manufacturing facility is valid for a year only.

The interview also revealed that the FDA currently uses the Ghana Standard for Soft Drinks (GS 176-1999 NON-ALCOHOLIC BEVERAGES - SPECIFICATION FOR SOFT DRINK), to evaluate energy drinks since there is no Standard for Energy Drinks. This was confirmed by the Ghana Standards Authority which indicated that a standard was yet to be developed for the product.

4.6.2 Advertisement of Energy Drinks

If a manufacturer or importer wishes to advertise the energy drink in print media, on TV or radio, then an application for advertising is submitted comprising the application form, a copy of the FDA registration certificate for the product, the advertisement script and an amount of GH¢ 600 for regular application or GH¢ 1800 for expedited service. The script is then evaluated and vetted by a committee to ensure it conforms to the Guidelines for the Advertisements of Foods (FDA/FID/GL-AD/2016/01) taking into account Section 3.3 Specific Requirements for Energy Drinks which states:

1. All energy drink advertisements shall include the following;

d) Excessive drinking can be detrimental to health

e) Not Recommended for persons under 18 years, Lactating Mothers, Pregnant Women and People Sensitive to Caffeine

f) Any other Health Warnings as prescribed by the Authority

2. Advertisement on energy drinks shall not contain statements or illustrations that have the potential to lead to the abuse or excessive consumption of the product.

3. Energy drinks shall not be advertised as substitute for rest, remedy for fatigue, sexual non-performance or any other physical non-performance.

The applicant is then asked to submit the actual video or audio once the script is approved to be compared to the approved script to ascertain if any changes have been made before a unique FDA number is assigned to that particular advert which is to be displayed in the print media or mentioned on air for easy monitoring. The advert is valid for a period of one (1) year.

Any company found advertising unapproved adverts is sanctioned by the FDA which normally includes a fine not less than GH¢ 25,000 and in addition to that the radio or TV adverts taken off air or billboards pulled down at the cost of the company, while they are a given a timeline to regularize their activities, that is, put in an application for the approval of their advertisement.

4.6.3 Monitoring of Advertisements

The following billboards were observed in the months of the study.

Figure 4: Advertisement of Boss Energy Drink

Figure 5: Advertisement of Burn Energy Drink

Figure 6: Advertisement of Mamba Energy Drink

Figure 7: Advertisement of Storm Energy Drink

Figure 8: Advertisement of Blue Jeans Energy Drink

Figure 9: Advertisement of Rush Energy Drink

Figure 10: Advertisement of Carabao Energy Drink

Figure 11: Advertisement of Blue Jeans Energy Drink

Out of the eight billboards spotted, only one complied with the Section 3.3 of the Guidelines for Advertising Food, i.e. 12.5% of outdoor advertisements observed, bore the caution statements as required by the Food and Drugs Authority. And a staggering 87.5% did not have the caution statements. It can therefore be deduced from the above that the majority of these advertisements have not been approved by the FDA because of the absence of the caution statements.

Also, four (4) of these billboards (50%) were found to contravene Section 3.3.3 of the Guidelines for the Advertisements of Food which states that "*Energy drinks shall not be advertised as substitute for rest, remedy for fatigue, sexual non-performance or any other physical non-performance".* It is no surprise, therefore, that majority of the workers among the respondents, including drivers, admitted using them to ward off fatigue and keep them alert and awake while driving long distances or for long hours. This also encourages the use of energy drinks for physical activities which has become a common practice here in Ghana, where such products are sold in the gyms as a substitute for sports drinks. Most male JHS students between the ages of 13-17 also admitted using these products during games at school, e.g. in a game of football, because the advertisements depict energy drinks as good for sportsmen.

It is therefore important to note that though such outdoor advertisements (billboards) clearly violate the FDA regulations they have not been pulled down as stipulated in the Guidelines as one of the regulatory sanctions to be meted out to importers or manufacturers of energy drinks who flout the regulations seeing the effects it has on consumers.

CHAPTER FIVE

5.0 CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

Based on the analyses of the data, the following conclusions were drawn; The Ghana Food and Drugs Authority has not defined any limit for caffeine in energy drinks and currently evaluates these products using the soft drinks standard hence products are sold to the public including children as such. The only form of regulation for energy drinks which exists comes into play during product advertising when the advert must meet the requirements of the FDA's Guidelines for the Advertisement of Food.

Most of the energy drinks companies are currently not complying with the requirements for advertisements specified by FDA. For instance, some advertisements placed at vantage points on highways and between towns encourage the consumption of these drinks by tired drivers, other advertisements do not indicate the caution statements at all.

Majority of respondents had exceeded the maximum daily intake of caffeine, thereby potentially increasing the risk of experiencing adverse effects. In addition to this, others admitted mixing energy drinks with alcohol, tramadol and codeine-containing cough syrups to ward off fatigue, boost their energies, give them a false sense of bravado and for aphrodisiac purposes.

From the research it was observed that children, pregnant women and nursing mothers and individuals with heart conditions were consuming these drinks although these products are not recommended for them. Another observation made was sports drinks were being substituted with energy drinks by athletes or most people engaged in some form of sporting activity.

Indeed, there is the absence of regulatory oversight which has resulted in the aggressive marketing of energy drinks, targeted primarily toward the youth in Ghana. As a result of the rapidly growing popularity of these drinks, most of the local soft drinks manufacturers have introduced energy drinks in their product brands to cater to the demands of the consumers.

5.2 Recommendations

Based on the findings above the following recommendations have been made;

- The Food and Drugs Authority as a regulatory body together with Ghana Standards Authority should develop a standard for energy drinks which should include limits for caffeine in energy drinks and caution statements. This should then be communicated to all stakeholders including manufacturers, importers, advertising agencies and the media.
- Food and Drugs Authority should enforce the laws by intensifying advertisements monitoring and more stringent sanctions should be imposed on those who openly disregard the laws to serve as a deterrent to others. FDA should also enforce the laws by restricting the sale of such products to children below the age of 18.
- It is recommended that the Food and Drugs Authority should intensify public education especially at the markets, bus and taxi stations and schools, to educate the public on the adverse health effects of excessive consumption of energy drinks and the dangers of mixing them with substances such as tramadol, codeine and alcohol.

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APPENDIX

QUESTIONNAIRE

MASTER OF SCIENCE IN FOOD QUALITY MANAGEMENT

This research is for academic purposes only. It is to assess the effectiveness of Food and Drugs Authority regulation on energy drinks on the local market. Respondents are assured that any information given out will be accorded the necessary confidentiality. Thank you.

QUESTIONNAIRE FOR CONSUMERS

SECTION A

DEMOGRAPHIC INFORMATION

Please tick (✓) as appropriate

1. Gender: Male ☐ **Female** ☐

2. Age: below 13 ☐ **14- 17** ☐ **18- 20** ☐ **21-30** ☐ **31-40** ☐

41-50 ☐ **51-60** ☐ **60 and above** ☐

3. Category: Worker ☐ **University** ☐ **SHS** ☐ **JSH** ☐

4. Marital status: Single ☐ **Married** ☐

SECTION B

PART II: KNOWLEDGE ON ENERGY DRINKS

Please indicate by ticking, whether you agree or Disagree to the following statement using the keys below; a Strongly Agree [5] b. Agree [4] c. Fairly Agree [3] d. Disagree [2]

e. Strongly Disagree [1] f. Don't know [0]

	Statement	5	4	3	2	1	0
1	I always read label on energy drinks before drinking.						
2	Energy drinks consist of taurine, guarana, B. vitamins, ginseng, ginkgo biloba, L-carnitine, Sugars, Antioxidants, glucuronolactone, yerba mate, creatine, milk thistle, artificial sweeteners, caffeine etc.						
3	Energy drinks might contain high level of caffeine.						
4	Energy drinks help to reduce or prevent fatigue.						
5	Energy drinks have negative effects such as headache high blood pressure, sleep disturbances etc.						
6	Energy drinks work to increase cognitive activities; e.g thinking, remembering, learning etc.						

7. Which one applies to you?

a-I drink energy drinks regularly ☐

b-I drink energy drinks occasionally (sometimes mixed with substances) ☐

c-I do not drink them at all ☐

8. How old were you when you had energy drinks for the first time? ----------

9. I mix energy drinks with other substances? Yes ☐ **No** ☐

10. If Yes? Why do you mix energy drinks with substances such as alcohol, tramadol etc.?

a-To party longer ☐

b- So I can drive after partying ☐

c-To relieve alcohol effects & fight hangover effects ☐

d- To make alcohol taste better ☐

e-For aphrodisiac purposes ☐

11. Do you read label on energy drinks before drinking? Yes ☐ **No** ☐

12. How often have you drunk energy drink during the last 7 days?.....

13. How often have you had pre-mixed energy drink and alcohol during the last 14 days?.....

14. Approximate number of cans/bottles consumed per week ……...

PART III: PERCEPTIONS ON ENERGY DRINKS IN GHANA

Please indicate by ticking, whether you agree or Disagree to the following statement using the keys below; a Strongly Agree [5] b. Agree [4] c. Fairly Agree [3] d. Disagree [2]

e. Strongly Disagree [1] f. Don't know [0]

	Statement	5	4	3	2	1	0	
15	Energy drinks are easy to access.							
16	I drink energy drinks during physical activities.							
17	My parents are drinking energy drinks, so do I.							
18	I like trying new products, new things, and I am adventurous, that's why I drink energy drinks							
19	I drink them without specific reason							
20	Commercials say: "Energy drinks boost my energy" So, I drink them.							
21	Energy drinks mean youth &strength.							
22	Athletes and celebrities drink them, so do I.							
23	I can't function without energy drinks							
24	It seems that everybody around me- my friends and my parents- drink energy drinks.							
25	Energy drinks prices are cheap.							
26	Energy drinks are advertized, so they must be approved by Food and Drugs Authority?							
27	Energy drinks are tested.							
28	I drink energy drinks because my friends/ roommates recommended them to me.							
29	Energy drinks represent sports, adventure, outdoor, and athletic life style, so I like them.							
30	Energy drinks makes me feel alert and/or awake.							
31	Energy drinks makes me feel healthy.							

32 List 3 reasons why you TAKE OR DO NOT TAKE energy drinks.

……..

……...

……

PART IV: EFFECT OF ENERGY DRINKS

33. When I drink energy drink with alcohol drinks, I feel - (Please select all that applicable to you by putting √)

---

a- Drowsy
b- Restless
c- Insomnia
d- Nausea
e- Agitating
f- Jolt/Crash episode
g- Not hungry
h- My heart beat faster than before
i- I feel that I am not drunk, if I mix them with alcohol
j- Mentally active
k- All of them
l- Others

---

34. When I drink energy drink with alcohol drinks, I feel - (Please select all that applicable to you by putting √)

---

a- I need to drink alcohol more than usual
b- I get more courage to do new things
c- More aware about things around me
d- I can make accurate decisions
e- I party a lot.
f- I want to engage in intimate relation (sex)
g- Others

***if you select others, please specify----------**

35. Which side effects can energy drinks cause? Select all that apply to you by putting (√)

a-I have no idea
b-Itch
c- Headache
d-High blood pressure
e-Sleep disturbances
f-Addiction
g-Restlessness
h-Diarrhea
i-Seizures
k-caffeine related problems

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Thank you.